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9 **UNITED STATES DISTRICT COURT**
10 **NORTHERN DISTRICT OF CALIFORNIA**

11 SUNG KIM, Individually and on behalf of all
12 others similarly situated,

13 Plaintiff,

14 v.

15 ALLAKOS INC., ROBERT ALEXANDER,
16 LEO REDMOND, HENRIK RASMUSSEN,
17 AND ADAM TOMASI,

18 Defendants.

Case No: 4:20-cv-01720-JSW

**SECOND AMENDED CLASS ACTION
COMPLAINT FOR VIOLATIONS OF THE
FEDERAL SECURITIES LAWS**

JURY TRIAL DEMANDED

19 Lead Plaintiff Sung Kim and Named Plaintiffs Christian Mayo and Allison Skye
20 (“Plaintiffs”), individually and on behalf of all other persons similarly situated, by Plaintiffs’
21 undersigned attorneys, for Plaintiffs’ complaint against Defendants (defined below), alleges the
22 following based upon personal knowledge as to Plaintiffs and Plaintiffs’ own acts, and information
23 and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through
24 Plaintiffs’ attorneys, which included, among other things, a review of the Defendants’ public
25 documents, conference calls and announcements made by Defendants, United States Securities and
26 Exchange Commission (“SEC”) filings, wire and press releases published by and regarding
27 Allakos Inc. (“Allakos” or the “Company”), analysts’ reports and advisories about the Company,
28 and information readily obtainable on the Internet. Plaintiffs believe that substantial evidentiary
support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

1 **NATURE OF THE ACTION**

2 1. This is a federal securities class action on behalf of a class consisting of all persons
3 and entities other than Defendants who purchased the common stock of Allakos between March 14,
4 2019 and December 21, 2021, both dates inclusive (the “Class Period). Plaintiffs seek to recover
5 compensable damages caused by Defendants’ violations of the federal securities laws and to pursue
6 remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the “Exchange
7 Act”) and Rule 10b-5 promulgated thereunder.

8 2. Allakos is a clinical stage biopharmaceutical company that has never generated any
9 revenue. Allakos’ business is focused on a single drug, AK002, which it is developing to treat
10 eosinophil and mast related cell diseases. Accordingly, Allakos’ business is entirely dependent on
11 its ability to continue to raise money from investors until AK002 is approved by the U.S. Food and
12 Drug Administration (the “FDA”) and Allakos can commercialize the drug.

13 3. According to Allakos, the “lead indications” — diseases that AK002 is furthest along
14 in the FDA approval process for — are eosinophilic gastritis (“EG”) and eosinophilic duodenitis
15 (“EoD”). Prior to 2020, Allakos referred to EoD as eosinophilic gastroenteritis (“EGE”). EG and
16 EGE/EoD are inflammatory diseases of the stomach and small intestine. The current standard of
17 care for those diseases is the use of steroids to decrease inflammation.

18 4. During 2018 and the first half of 2019, Allakos conducted a Phase 2 clinical trial that
19 tested AK002 on EG and EGE/EoD patients for safety and effectiveness against those diseases,
20 which the Company refers to as the “ENIGMA” Trial, and is referred to herein as “Phase 2
21 ENIGMA.” Given that EG and EGE/EoD are the lead indications for AK002, Phase 2 ENIGMA
22 was the most important trial in Allakos’ history, at the time it was conducted.

23 5. On August 5, 2019, Defendants announced “positive” results for Phase 2 ENIGMA,
24 and repeatedly emphasized that it was a “randomized, double-blind, placebo-controlled” clinical
25 trial. Defendant Alexander, Allakos’ CEO, told analysts that Phase 2 ENIGMA would be one of the
26 two trials that Allakos intended to submit to the FDA when it tried to gain approval for the use of
27 AK002 in EG and EGE/EoD patients in the future.

28 6. Allakos’ stock shot up after the announcement and Defendants immediately

1 capitalized. Mere hours after announcing the Phase 2 ENIGMA results, Allakos announced that it
2 was conducting a \$200 million secondary offering of common stock, more than its \$134.4 million
3 July 2018 Initial Public Offering (“IPO”). The next day Allakos announced that it was upsizing its
4 offering to \$350 million and the Company ultimately raised \$377.5 million in that secondary
5 offering.

6 7. On December 18, 2019, Seligman Investments (“Seligman”) issued an extensive
7 research report about Phase 2 ENIGMA. Seligman, among other things, interviewed trial
8 investigators who conducted Phase 2 ENIGMA for Allakos and reviewed and reprinted numerous
9 posts that Phase 2 ENIGMA participants and their families made to a private Facebook group.
10 Seligman’s research showed that Defendants had made numerous material misstatements and/or
11 omissions about Phase 2 ENIGMA:

- 12 • Contrary to multiple statements in Allakos’ public filings and how the vast majority
13 of clinical trials are conducted, Allakos did not employ a third-party Contract
14 Research Organization (“CRO”) to conduct Phase 2 ENIGMA. Use of CROs is an
15 important part of ensuring the integrity of clinical trials and Allakos’ own trial
16 investigators believed that the Company’s failure to use one undermined the
17 reliability of Phase 2 ENIGMA.
- 18 • Due to poor controls, including the failure to use a CRO, the blinding of Phase 2
19 ENIGMA was severely compromised for multiple reasons, including: (1) adverse
20 reactions to infusions of AK002 made patients aware of whether they were receiving
21 AK002 or placebo, (2) trial investigators told patients whether they believed they
22 were getting the drug instead of a placebo, (3) patients were able to see their test
23 results during the Trial, (4) patients were told they would qualify for an extension
24 study if they did well in the Trial, encouraging them to report symptom
25 improvement, and (5) Allakos’ executives had improper access to data and the
26 patients during the Trial.
- 27 • The use of steroids was inconsistent and haphazard in Phase 2 ENIGMA and left to
28 the discretion of the trial investigators. This was a significant confounding factor in

1 the Trial since steroids are the current standard of care for EG and EGE/EoD. The
2 administration of steroids may very well have been a cause of the positive results
3 Allakos reported in the trial.

4 8. All of these misstatements and/or omissions were highly material to investors
5 because all of those issues will raise red flags with the FDA, making it less likely that Allakos will
6 be able to use Phase 2 ENIGMA to gain approval of AK002 in the future. These misstatements and
7 omissions also call into question the quality and integrity of the positive results Allakos reported for
8 Phase 2 ENIGMA.

9 9. After Seligman issued its report, Allakos' stock dropped 17% from the closing price
10 on December 17, 2019, over the next two days, harming investors

11 10. Despite the concerns that Seligman raised about Phase 2 ENIGMA, on March 24,
12 2020, Allakos announced that it was conducting a Phase 3 version of Phase 2 ENIGMA, which
13 Allakos intended to be the second trial that it needed for FDA approval of AK002 for use in EG and
14 EGE/EoD patients ("Phase 3 ENIGMA"). When announcing Phase 3 ENIGMA, Allakos
15 emphasized that the patient population would be the same as Phase 2 ENIGMA. Allakos began
16 enrolling patients in Phase 3 ENIGMA in June 2020.

17 11. On October 26, 2020, Allakos released results from a prospective prevalence study
18 (the "Prevalence Study") it had conducted which it said showed EG and EGE/EoD were greatly
19 underdiagnosed in patients with chronic unexplained gastrointestinal symptoms or functional
20 gastrointestinal disorders, such as Irritable Bowel Syndrome ("IBS"). Allakos estimated there could
21 potentially be 6 to 10 million EG and/or EGE/EoD patients to whom Allakos could market AK002
22 in the United States even though published literature put the number of patients with those diseases
23 at 50,000.

24 12. During the presentation announcing the Prevalence Study results, Allakos noted that
25 the characteristics of the patients identified in the Prevalence Study differed significantly from the
26 patients identified for Phase 2 ENIGMA. Unlike in the Prevalence Study, very few Phase 2
27 ENIGMA patients had been diagnosed with IBS and the vast majority of the Phase 2 ENIGMA
28 patients had previously been diagnosed with EG and/or EGE/EoD. Additionally, patients who were

1 identified for Phase 2 ENIGMA had nearly double the eosinophils in their blood as the patients
2 identified in the Prevalence Study. Higher eosinophil counts are an indicator of disease and
3 AK002's mechanism for treating EG and EGE/EoD is depletion of eosinophils.

4 13. Allakos announced that it had completed patient enrollment in Phase 3 ENIGMA on
5 June 7, 2021.

6 14. On September 10, 2021, Defendant Tomasi, the President and COO of Allakos, was
7 publicly interviewed about Phase 3 ENIGMA and the Prevalence Study by a Morgan Stanley
8 analyst at the Morgan Stanley 19th Annual Global Healthcare Conference. During the interview,
9 Defendant Tomasi repeatedly emphasized that it was very important to the expected success of
10 Phase 3 ENIGMA that it have a similar patient population to Phase 2 ENIGMA. He assured
11 investors that the patient populations of the two ENIGMA trials were "identical" and "very similar"
12 and that he could say that because Phase 3 ENIGMA was fully enrolled.

13 15. On December 21, 2021, Allakos announced that Phase 3 ENIGMA had failed
14 because it had not met its patient reported symptomatic co-primary endpoint. Remarkably, the
15 symptoms of the patients in the placebo arm of the trial improved more than the patients who
16 received AK002. Given that EG and EGE/EoD were AK002's lead indication and Allakos' business
17 was entirely based on AK002, Allakos' stock completely collapsed, falling *\$75.84 per share, or*
18 *almost 90%, to close at \$8.55* on December 22, 2021.

19 16. On February 15, 2022, Allakos hosted an Investor Day where its employees
20 discussed the failure of Phase 3 ENIGMA. *Directly contrary to Defendant Tomasi's prior*
21 *statements, Allakos disclosed that the patient population of Phase 3 ENIGMA was significantly*
22 *different from Phase 2 ENIGMA and blamed those differences for the failure of Phase 3*
23 *ENIGMA.*

24 17. The undisclosed differences between the patient populations for Phase 3 and Phase 2
25 ENIGMA were similar to the differences between the patients identified for Phase 2 ENIGMA and
26 the Prevalence Study. The Phase 3 ENIGMA patient population had a much lower percentage of
27 patients who had been previously diagnosed with EG and/or EGE/EoD than Phase 2 and a much
28 higher rate of previous IBS diagnosis. Additionally, the Phase 3 ENIGMA patient population had

1 significantly lower levels of eosinophils in both their blood and tissue than Phase 2.

2 18. The differences between the patient population Allakos identified for Phase 2
3 ENIGMA and the Prevalence Study put Defendant Tomasi on notice that there could be similar
4 differences between the patient population of Phase 2 and Phase 3 ENIGMA given that the
5 Prevalence Study patients met Allakos' EG and/or EGE/EoD criteria despite those differences.
6 Nevertheless, Defendant Tomasi misleadingly told investors that the patient populations were the
7 same. Furthermore, Tomasi, by his own admission, had access to the Phase 3 ENIGMA patient
8 demographics when he made his statements. Additionally, during the February 15, 2022 Investor
9 Day, Allakos' CEO, Defendant Alexander, and its Chief Medical Officer both stated, when
10 discussing another phase 3 clinical trial that Allakos was conducting on only EGE/EoD patients,
11 that Allakos employees had access to patient demographic information from that trial because it was
12 fully enrolled even though the trial was not yet complete.

13 19. Defendant Tomasi had a strong motive not to suggest to investors that differences
14 between the patient population in Phase 2 and Phase 3 ENIGMA had any significance because any
15 such suggestion would have called into question the results of the Prevalence Study and undermined
16 Allakos' claims about AK002's enormous potential market. Accordingly, Allakos did not reveal the
17 differences between the patient population of Phase 3 and Phase 2 ENIGMA until it needed to
18 provide the market an explanation for why Phase 3 ENIGMA failed.

19 20. Additionally, prior to 2021, none of the Defendants sold a single share of Allakos
20 common stock on the open market. However, in 2021, Defendants Tomasi, Alexander, and
21 Rasmussen sold a combined 524,302 shares of Allakos common stock for proceeds of \$56,099,224.
22 Defendants sold their shares for the average price of almost \$107, more than 12 times what the
23 stock was worth after the Company announced the failure of Phase 3 ENIGMA. These
24 unprecedented large scale sales by Defendants show that they lacked confidence in the outcome of
25 Phase 3 ENIGMA.

26 21. As a result of Defendants' knowing and/or reckless false and misleading statements
27 and omissions concerning the Phase 2 and 3 ENIGMA trials, the value of the price of Allakos
28 common stock during the Class Period was artificially inflated. When Seligman's issuance of its

1 report revealed flaws with Phase 2 ENIGMA and when the risk of the different patient populations
2 in Phase 3 ENIGMA and Phase 2 ENIGMA materialized with the failure of Phase 3 ENIGMA,
3 Allakos' share price declined and Plaintiffs and other Class members suffered significant losses and
4 damages.

5 **JURISDICTION AND VENUE**

6 22. The claims asserted herein arise under and pursuant to §§10(b) and 20(a) of the
7 Exchange Act (15 U.S.C. §§78j(b) and §78t(a)) and Rule 10b-5 promulgated thereunder by the SEC
8 (17 C.F.R. §240.10b-5).

9 23. This Court has jurisdiction over the subject matter of this action under 28 U.S.C.
10 §1331 and §27 of the Exchange Act.

11 24. Venue is proper in this Judicial District pursuant to §27 of the Exchange Act (15
12 U.S.C. §78aa) and 28 U.S.C. §1391(b) as Defendants conduct business and the Company is
13 headquartered in this Judicial District.

14 25. In connection with the acts, conduct and other wrongs alleged in this Complaint,
15 Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce,
16 including but not limited to, the United States mail, interstate telephone communications and the
17 facilities of the national securities exchange.

18 **PARTIES**

19 26. Lead Plaintiff, Sung Kim, as set forth in his previously filed certification
20 incorporated by reference herein, purchased Allakos common stock at artificially inflated prices
21 during the Class Period and was damaged upon the revelation of the alleged corrective disclosure.

22 27. Named Plaintiffs Christian Mayo and Allison Skye, as set forth in previously filed
23 certifications, purchased Allakos common stock at artificially inflated prices during the Class Period
24 and were damaged upon the revelation of the alleged corrective disclosure.

25 28. Defendant Allakos is a clinical stage biopharmaceutical company that focuses on
26 developing the drug AK002. The Company is incorporated in Delaware and its principal executive
27 offices are located at 975 Island Drive, Suite 201 Redwood City, California. Allakos common stock
28 are traded on the NASDAQ ("NASDAQ") under the ticker symbol "ALLK."

1 29. Defendant Robert Alexander (“Alexander”) has been the Company’s Chief
2 Executive Officer (“CEO”) since April 2017 and a member of its board of directors since May
3 2017. Defendant Alexander also served as President of the Company from November 29, 2017 until
4 August 2019. Prior to becoming CEO of Allakos, Defendant Alexander served as CEO of another
5 pharmaceutical company, ZS Pharma. He received a Ph.D. with a focus on immunology from the
6 University of North Carolina.

7 30. Defendant Leo Redmond (“Redmond”) served as the Company’s Chief Financial
8 Officer (“CFO”) from August 1, 2019 until February 1, 2021. Prior to joining Allakos, Defendant
9 Redmond served as CFO and President of Presidio Pharmaceuticals.

10 31. Defendant Henrik Rasmussen (“Rasmussen”) served as the Company’s Chief
11 Medical Officer (“CMO”) from June 2017 until June 11, 2021. Defendant Rasmussen previously
12 served as CMO at three other pharmaceutical companies: ZS Pharma, Nabi Biopharmaceuticals,
13 and Genvec. He also had held high level clinical positions at Novo Nordisk, British Biotech, and
14 Pfizer. Defendant Rasmussen has led numerous global drug development programs and regulatory
15 filings worldwide, including New Drug Application submissions to the FDA. He received his Ph.D.
16 and M.D. from the University of Copenhagen in Denmark and is trained in internal medicine and
17 cardiology.

18 32. Defendant Adam Tomasi (“Tomasi”) has served as the Company’s Chief Operating
19 Officer since April 2017, its President since August 2019, and its Secretary since November 2017.
20 He also served as Allakos’ CFO from April 2017 to August 2019 and its acting CFO from February
21 1, 2021 until April 19, 2021. He previously served as Chief Scientific Officer and Head of
22 Corporate Development at ZS Pharma. Defendant Tomasi received a Ph.D in Chemistry from the
23 University of California Irvine and an MBA from the Massachusetts Institute of Technology.

24 33. Defendants Alexander, Redmond, Rasmussen, and Tomasi are sometimes referred to
25 herein as the “Individual Defendants.”

26 34. Each of the Individual Defendants:

27 (a) directly participated in the management of the Company;

28

- 1 (b) was directly involved in the day-to-day operations of the Company at the
2 highest levels;
- 3 (c) was privy to confidential proprietary information concerning the Company
4 and its business and operations;
- 5 (d) was directly or indirectly involved in drafting, producing, reviewing and/or
6 disseminating the false and misleading statements and information alleged
7 herein;
- 8 (e) was directly or indirectly involved in the oversight or implementation of the
9 Company's internal controls;
- 10 (f) was aware of or recklessly disregarded the fact that the false and misleading
11 statements were being issued concerning the Company; and/or
- 12 (g) approved or ratified these statements in violation of the federal securities
13 laws.

14 35. The Company is liable for the acts of the Individual Defendants and its employees
15 under the doctrine of respondeat superior and common law principles of agency because all of the
16 wrongful acts complained of herein were carried out within the scope of their employment.

17 36. The scienter of the Individual Defendants and other employees and agents of the
18 Company is similarly imputed to the Company under respondeat superior and agency principles.

19 37. The Company and the Individual Defendants are referred to herein, collectively, as
20 the "Defendants."

21 **SUBSTANTIVE ALLEGATIONS**

22 **A. Allakos is Small Biotechnology Company Whose Prospects are Entirely Dependent of**
23 **FDA Approval of a Single Drug, AK002.**

24 38. Allakos was founded in March 2012 and became a public company through a July
25 2018 IPO that raised \$134.4 million.

26 39. In the Company's Form 10-K for the fiscal year ended December 31, 2018, filed
27 March 14, 2019 (the "2018 10-K"), Form 10-Q for the quarterly period ended March 31, 2019, filed
28 on May 8, 2019 ("1Q 2019 10-Q"), Form 10-K for the fiscal year ended December 31, 2019, filed

1 February 25, 2020 (the “2019 10-K”), and Form 10-K for the fiscal year ended December 31, 2020,
2 filed March 1, 2021 (the “2020 10-K”), Allakos described itself as entirely focused on the
3 development of a single drug, AK002 (also known as “Lirentelimab” and “Antolimab”), stating
4 “[w]e are a clinical stage biotechnology company developing AK002, our wholly owned
5 monoclonal antibody, for the treatment of various eosinophil and mast cell related diseases. AK002
6 selectively targets both eosinophils and mast cells, white blood cells that are widely distributed in
7 the body and play a central role in the inflammatory response.” The Company further stated in its
8 2018 10-K and 1Q 2019 10-Q that it was “developing AK002 for the treatment of eosinophilic
9 gastritis (‘EG’), eosinophilic gastroenteritis (‘EGE’), and eosinophilic esophagitis (‘EoE’).”

10 40. EG, EGE/EoD, and EoE are eosinophilic inflammatory diseases of the stomach,
11 small intestine, and esophagus, respectively. The current standard of care for those diseases is the
12 use of steroids to decrease the inflammation.

13 41. Although Allakos is also evaluating the use of AK002 in other medical conditions,
14 obtaining FDA approval for the use of AK002 in EG, EGE/EoD, and/or EoE patients would be
15 especially valuable to Allakos because AK002 has received orphan drug designation from the FDA
16 for those diseases. An orphan drug designation is very valuable because it provides seven years of
17 marketing exclusivity upon the approval of a drug intended to treat a rare condition. During that
18 time, the FDA will not approve any other drug for the same indication unless it demonstrates
19 clinical superiority.

20 42. All of Allakos’ product candidates currently under development, other than AK002,
21 are in preclinical development, meaning that they have not reached the state of development where
22 the Company is testing the drug in clinical trials. Allakos previously conducted clinical trials for
23 AK001, a compound similar to AK002, that was also supposed to treat eosinophil and mast cell
24 related diseases, but the Company abandoned research on AK001 due to the drug’s ineffectiveness.

25 43. In its 2018 10-K, 1Q 2019 10-Q, 2019 10-K, and 2020 10-K, Allakos admitted its
26 future prospects were entirely dependent on FDA approval of AK002: “Our future success is
27 dependent on our ability to timely complete clinical trials and obtain marketing approval for, and
28 then successfully commercialize [AK002], our lead compound, for one or more indications...We

1 are not permitted to market or promote [AK002], or any other product candidates, before we receive
2 marketing approval from the U.S. Food and Drug Administration (“FDA”) and comparable foreign
3 regulatory authorities....”

4 44. Despite reaching a market capitalization of more than \$7 Billion during the Class
5 Period, Allakos had a small number of employees throughout the Class Period. As of December 31,
6 2018, Allakos had only 62 full-time employees, 40 of whom were engaged in research and
7 development activities. As of December 31, 2021, Allakos had 192 full-time employees, 132 of
8 whom were engaged in research and development activities.

9 45. Allakos has never generated any revenue. In 2018, 2019, 2020, and 2021, it had net
10 losses of \$43.5 million, \$85.4 million, \$153.5 million, and \$269.9 million, respectively, and as of
11 December 31, 2021 it had accumulated a deficit of \$612.8 million since its founding.

12 **B. Phase 2 ENIGMA, a Purported Phase 2, Double-Blind, Placebo-Controlled Trial of**
13 **AK002 in Patients with EG and/or EGE/EoD.**

14 46. Drugs generally go through three phases of clinical trials prior to their approval by
15 the FDA. In Phase 1 trials, the drug is administered to a small number of patients to test the drug’s
16 safety. If the drug is found to be safe enough, it can be tested in a Phase 2 trial. Phase 2 trials are
17 conducted on larger groups of patients to continue to assess safety and to see if a drug is effective
18 against a particular disease. Phase 3 trials generally enroll an even larger group of patients and focus
19 on the effectiveness of the drug. The FDA generally requires a drug sponsor to demonstrate safety
20 and efficacy in two adequate and well-controlled clinical trials to obtain marketing approval.

21 47. During 2018 and the first half of 2019, Allakos conducted Phase 2 ENIGMA a
22 clinical trial it described in its 2018 10-K as “a randomized, double-blind, placebo-controlled Phase
23 2 trial with AK002 in approximately 60 patients with active, moderate to severe, biopsy-confirmed
24 EG... and/or [EGE/EoD].”¹ Allakos further stated that the primary endpoint in the trial was “the
25 reduction in gastric or duodenal eosinophils post-treatment” based on biopsies conducted on the
26 patients. The secondary endpoint was “changes in EG and [EGE/EoD] patient symptoms, such as
27 abdominal pain, nausea, vomiting and diarrhea, as reported by patients using Allakos’ proprietary

28 _____
¹ 38% of the patients in Phase 2 ENIGMA also had EoE.

1 daily Patient Reported Outcome (“PRO”) questionnaire.”

2 48. A randomized, double-blind, placebo controlled trial is defined as a trial where
3 neither the patients nor the researcher know who is getting the treatment being tested and who is
4 getting the placebo. The purpose of a double-blinded study is to eliminate biased caused by the
5 researchers and patients’ expectations that the treatment will work.

6 49. Defendants Alexander and Rasmussen both discussed Phase 2 ENIGMA in a May 7,
7 2019 conference call with market analysts, both stating that the Company’s “lead indication” for
8 AK002 was EG and EGE/EoD. Accordingly, since Phase 2 ENIGMA was Allakos’ first Phase 2
9 trial testing AK002 on EG and EGE/EoD patients, it was the most important clinical trial in the
10 Company’s history at the time it was conducted.

11 50. In the 2010 10-K and 1Q 2019 10-Q, which the Company issued on March 14, 2019
12 and May 8, 2019, respectively, explained that Allakos, like most small pharmaceutical companies,
13 “do[es] not have the ability to independently conduct [its] clinical trials” and instead “currently
14 rel[ies] on third-parties, such as CROs, clinical data management organizations, medical institutions
15 and clinical investigators, to conduct [its] clinical trials of AK002 and expect to continue to rely
16 upon third-parties to conduct additional clinical trials of AK002 and [its] other product candidates.”
17 The 2010 10-K and 1Q 2019 10-Q further warned that “[i]f we or any of our CROs fail to comply
18 with applicable [Good Clinical Practice] requirements, the clinical data generated in our clinical
19 trials may be deemed unreliable and the FDA...or comparable foreign regulatory authorities may
20 require us to perform additional clinical trials before approving our marketing applications.”

21 51. The use of an independent CRO to conduct clinical trials, such as Phase 2 ENIGMA,
22 is the typical practice for all but the largest pharmaceutical companies because CROs play an
23 important role in making sure that clinical trials are carried out with integrity. Without the
24 independent oversight of a CRO, there are numerous opportunities for a company sponsoring the
25 trial to make changes during the trial and otherwise manipulate results to produce a better outcome
26 for that company’s drug. CROs operate under standard operating procedures which impose rules of
27 Good Clinical Practice, such as Source Document Verification (“SDV”), database lock, and a
28 prospectively defined statistical analysis plan (“SAP”). SDV, which is the comparison of reported

1 trial data with information from primary health records of trial subjects, is an important component
2 of ensuring the integrity of trial data. Database lock is the crucial practice of finalizing the database
3 of trial data to prevent unauthorized or unintentional changes. Database lock is extremely important
4 in randomized blinded trials since the database must be locked before the blind of the doctors and
5 patients is broken to protect the integrity of the trial. Setting up an SAP prior to the trial protects the
6 integrity of a clinical trial because it stops the company conducting the clinical trial from altering
7 the statistical methodology mid-trial to obtain a more favorable result.

8 52. CROs also often have levels of expertise to pressure test the trial's integrity by
9 challenging the study design, filtering out study biases, selecting the endpoints, defining the
10 analysis approaches, and interacting on behalf of the sponsor with FDA. The absence of a CRO
11 would be a red flag to encourage FDA to investigate whether a trial adhered to Good Clinical
12 Practice. If the FDA believes that a trial did not follow Good Clinical Practice, it is less likely that a
13 sponsor can use the trial to gain FDA approval for a drug.

14 **C. On August 5, 2019, Allakos Announces “Positive” Results From Phase 2 ENIGMA on**
15 **the Same Day that it Announces a Secondary Offering of Stock.**

16 53. On August 5, 2019, Allakos issued a Form 8-K signed by Defendant Alexander that
17 attached a press release entitled “Allakos Announces AK002 Met All Prespecified Primary and
18 Secondary Endpoints in Phase 2 Randomized, Double-Blind, Placebo-Controlled Study in Patients
19 with Eosinophilic Gastritis (EG) and/or Eosinophilic Gastroenteritis (EGE),” which touted the
20 “positive results” of the “randomized, double-blind, placebo-controlled” Phase 2 ENIGMA (The
21 “August 5, 2019 ENIGMA Press Release”).

22 54. On August 5, 2019, Allakos also hosted a conference call for analysts discussing the
23 results of Phase 2 ENIGMA (the “August 5, 2019 Conference Call”) and the Company issued a
24 Form 8-K signed by Defendant Alexander on the same date with a presentation entitled “Phase 2
25 Eosinophil Gastritis and Gastroenteritis Study Results.” Defendants Alexander and Rasmussen used
26 that presentation during the August 5, 2019 Conference Call (the “August 5, 2019 Presentation,”
27 attached as Exhibit 1).

28 55. On the August 5, 2019 Conference Call, Defendant Alexander touted the results of

1 Phase 2 ENIGMA and specifically reminded analysts that it was a “randomized, double-blind,
2 placebo-controlled study.” Defendant Alexander further stated that Phase 2 ENIGMA would be one
3 of two trials that Allakos would use to try to gain FDA approval for the use of AK002 in EG and
4 EGE/EoD patients.

5 56. When analysts asked Defendant Alexander about the use of steroids around the
6 dosing of AK002 during Phase 2 ENIGMA on the August 5, 2019 Conference Call, Defendant
7 Alexander stated unequivocally that steroids had no effect on Phase 2 ENIGMA: “In terms of the
8 steroid, I mean, it had absolutely 0 effect on the results, and that was shown in the study. So the idea
9 that steroids are confounding the results is specious.”

10 57. Defendant Rasmussen also stated during the August 5, 2019 Conference Call that
11 “the study design of the ENIGMA study was randomized, double-blind, placebo-controlled study in
12 patients with eosinophilic gastritis and/or gastroenteritis.”

13 58. Mere hours after announcing the results of Phase 2 ENIGMA, Allakos announced a
14 secondary public offering of \$200 million of shares in its common stock and filed a Form S-3
15 registration statement, signed by Defendants Alexander and Redmond, and a preliminary prospectus
16 supplement that continued to tout Phase 2 ENIGMA.

17 59. Allakos also issued its Form 10-Q for the quarterly period ended June 30, 2019, on
18 August 5, 2019 (“2Q 2019 10-Q”). The 2Q 2019 10-Q stated, like the 2010 10-K and 1Q 2019 10-Q
19 did, that Allakos does not have the ability to independently conduct its clinical trials and relies on
20 third-parties, such as CROs, to conduct its clinical trials for AK002.

21 **D. Defendants Capitalize Immediately on their Statements About Phase 2 ENIGMA by**
22 **Almost Doubling the Value of Their Secondary Offering and Granting Stock Options**
23 **to Defendant Redmond that had Already Almost Tripled in Value.**

24 60. Defendants’ statements concerning Phase 2 ENIGMA caused Allakos’ stock to
25 almost triple from its closing price of \$31 on Friday, August 2, 2019 to a closing price of \$87.5 on
26 August 7, 2019.

27 61. On the evening of August 6, 2019, Allakos announced it was upsizing its secondary
28 offering of common stock to \$350 million at an offering price of \$77 per share. The Company filed
its final prospectus supplement for its offering on August 7, 2019. On August 9, 2019, the Company

1 announced it had raised \$377.5 million.

2 62. On August 6, 2019, Allakos also filed a Form 4 stating that it had granted 120,000
3 stock options to Defendant Redmond on August 2, 2019 at a price of \$31. Since Allakos' stock
4 closed at \$79.47 on August 6, 2019, by the time Allakos announced the options grant, Redmond's
5 options were already worth almost \$6 million.

6 **E. On December 18, 2019, Seligman Investments Issues a Detailed Report Showing That**
7 **Defendants Made Numerous Misstatements About Phase 2 ENIGMA.**

8 63. On December 18, 2019, Seligman issued a report entitled "A Suspect Biotech with a
9 Phase 2 Farce, Incredulous Trial Investigators, and Warning Signs of Potential Fraud" (the
10 "Seligman Report," attached as Exhibit 2). Seligman manages long-only and long/short equity
11 strategies and occasionally publishes research reports based on intensive, deep-dive fundamental
12 research.²

13 64. The Seligman Report was the result of extensive research by Seligman into Allakos
14 and Phase 2 ENIGMA. Seligman interviewed four people who served as Trial Investigators for
15 Phase 2 ENIGMA. During a clinical trial, the drug is dispensed under the immediate direction of the
16 Trial Investigators. Accordingly, the Trial Investigators had first-hand knowledge of what occurred
17 during Phase 2 ENIGMA.

18 65. Seligman also reviewed the private Facebook group for EG, which contained
19 hundreds of posts by Phase 2 ENIGMA participants and their families. Seligman believes that most
20 of the 65 participants in Phase 2 ENIGMA are members of the EG Facebook group.

21 1. Contrary to Numerous Statements in its Public Filings, Allakos Did Not Use a CRO
22 When it Conducted Phase 2 ENIGMA.

23 66. Seligman confirmed with four different Phase 2 ENIGMA Trial Investigators that
24 Allakos did not use a CRO to conduct Phase 2 ENIGMA. According to Seligman's research, more
25 than 90% of clinical trials employ a CRO. The trial investigators that Seligman interviewed
26 confirmed that Allakos' failure to use a CRO was highly unusual and said that they had never been
27 involved in another clinical trial that did not use a CRO.

28 ² Seligman is an affiliate of Columbia Threadneedle Investments group, an asset manager
overseeing \$754 billion of client assets.

1 67. The First Trial Investigator that Seligman spoke with initially believed that he was
2 interacting with employees of a CRO during Phase 2 ENIGMA, and was struck by how
3 aggressively they behaved. Because of that, he asked them what company they worked with and
4 they said they were employees of Allakos. He was surprised because he had never seen a biotech
5 company conduct a clinical trial without a CRO before. He said that “[Allakos] was actively
6 involved during the trial” and “aggressive.” He added that “[t]hese guys are businesspeople. They
7 think we made a couple hundred million and this could be one of these.”

8 68. Seligman spoke with a Second Trial Investigator, who also initially assumed that
9 Allakos used a CRO. Seligman asked him to verify that he had been working with a CRO. When
10 the Second Trial Investigator asked his staff and confirmed that he had actually been working with
11 Allakos employees, he was shocked. He stated: “We always deal with a third party CRO that makes
12 sure there’s compliance with internal and external protocols and inclusion/exclusion criteria.” The
13 Second Trial Investigator further explained that “*[i]t should be a third party to prevent bias. I don’t*
14 *know why they didn’t use a third party. I’d say 95% of time it’s a third party. It’s never the*
15 *company. We’ve conducted so many trials. It’s never been the company. It’s one of the biases*
16 *that you definitely want to remove.* Inherent bias from internal review shouldn’t exist in these trials.
17 *This would be a huge red flag in phase three and the FDA wouldn’t like it. They would be stupid*
18 *to have their own people do compliance, assessment, and auditing. It just won’t fly with the*
19 *FDA.”* (emphasis added). The Second Trial Investigator added that he had probably done 20 trials
20 in the past five years and all twenty used a third party CRO because “[t]hat’s standard operating
21 procedure” and its “the right thing to do. I was shocked to see that Allakos served as their own
22 CRO.”

23 69. The Third Trial Investigator that Seligman interviewed, like the first two, had
24 assumed that he was working with a CRO. After he confirmed with his facility’s clinical research
25 coordinator that the person who visited the trial site was an employee of Allakos, not a CRO, he
26 told Seligman: “I believe the site monitors were employees of Allakos. I just asked my clinical
27 research coordinator. *The person who came for site visits is an Allakos employee. My patient*
28

1 *coordinator worked directly with Allakos. If it was an Allakos person and not a CRO I'd be very*
2 *bothered by that. It wouldn't be honest."* (emphasis added).

3 70. Finally, Seligman interviewed a Fourth Trial Investigator, who appeared to know all
4 along that Allakos conducted Phase 2 ENIGMA without a CRO, but he did not know why the
5 Company chose that route. He said that for Allakos to run the Trial properly some employees would
6 need to be blinded and others unblinded. Given the size of Allakos — the Company had only 40
7 employees who were engaged in research and development activities as of the end of 2018 — it
8 would have been very difficult for it to maintain the necessary firewall between employees to
9 maintain the blinding of Phase 2 ENIGMA even if the Company made an honest attempt to do so.
10 Unsurprisingly, as discussed in the next section, the blinding of Phase 2 ENIGMA was severely
11 compromised in numerous ways, including because Defendant Rasmussen had improper contact
12 with a patient and because Allakos had improper access to interim data from the Trial.

13 71. Given that Allakos' failure to use a CRO and aggressive behavior during Phase 2
14 ENIGMA raised troubling questions, Seligman looked into whether the biopsies done for the Trial
15 were sent to the Company or a panel of independent, third party pathologists for analysis, given the
16 well-known issues around bias and subjectivity in biopsy measurements. One of the trial
17 investigators for Phase 2 ENIGMA Trial told Seligman that all the biopsies were sent to one person
18 who had ties to Allakos. Based on reviewing abstracts from the pathology lab, Seligman determined
19 that the reader was either Diane S. Lidke or Tracy I. George. In an article entitled "Variability of
20 PD-LI Expression in Mastocytosis" published in the February 13, 2018 issue of the journal *Blood*
21 *Advances*, Lidke and George both disclosed that they received research funding from Allakos.

22 72. In addition to failing to use a CRO and using a single reader with a conflict of
23 interest for Phase 2 ENIGMA Trial, Allakos' clinical staff is rife with nepotism. Defendant
24 Rasmussen's son, Jacob Rasmussen, and daughter, Camilla Shaw, were VP of Clinical Operations³
25 and a Clinical Program Manager, respectively. According to the Seligman Report, VP of Clinical

26 _____
27 ³ According to Allakos' Proxy Statement filed on April 30, 2019, Jacob Rasmussen's position was
28 Clinical Program Manager, but Seligman stated that based on its research, it believed that Jacob
Rasmussen has either been promoted or the disclosure was wrong. Allakos' Proxy Statement filed
on April 15, 2020, stated that Jacob Rasmussen was Senior Direct of Clinical Project Management.

1 Operations was likely the number two clinical role at Allakos after his father’s role. Shaw held her
2 role even though she is the only Allakos employee located in Utah and she graduated from college
3 in 2012. Defendant Rasmussen and his son also, notably, held their roles even though they are
4 located in Maryland, whereas virtually all other Allakos employees are located in the San Francisco
5 area. As of the issuance of the Seligman Report, Allakos had granted Defendant Rasmussen’s
6 children stock options worth approximately \$13 million.

7 2. Poor Controls Greatly Compromised the Blinding of Phase 2 ENIGMA — Purportedly
8 Randomized and Double-blind — Rendering the Patient Reported Outcome Score
9 Unreliable

10 73. Defendants told investors repeatedly that Phase 2 ENIGMA was a “randomized,
11 double-blind, placebo-controlled” trial, but, unsurprisingly given Allakos’ failure to use a CRO and
12 its admission that it does not have the ability to independently conduct its clinical trials, Phase 2
13 ENIGMA had poor controls that greatly compromised its blinding. According to the Phase 2
14 ENIGMA Trial Investigators and posts on the EG Facebook group, the blinding was compromised
15 because (1) adverse reactions to infusions of AK002 made patients aware of whether they were
16 receiving AK002 or placebo, (2) trial investigators told patients whether they believed they were
17 getting the drug instead of a placebo, (3) patients were able to see their test results during the trial,
18 (4) patients were told they would qualify for an extension study if they did well in the trial,
19 encouraging them to report symptom improvement, and (5) Allakos had improper access to data and
20 the patients during the trial.

21 74. *First*, because AK002 causes a significant reaction in many patients when infused,
22 three of the Phase 2 ENIGMA Trial Investigators that Seligman spoke with expressed concern that
23 the entire Trial was unblinded because reactions to AK002 tipped the patients off about whether
24 they were receiving AK002 or the placebo.

25 75. The EG Facebook group shows that the trial investigators’ fears were warranted —
26 the Seligman Report includes eight Facebook posts in which patients speculated that they were
27 receiving AK002 because they had a reaction to the infusion or that they were not because they did
28 not have a reaction.

76. *Second*, five patients or their family members posted that the *trial investigators*

1 *themselves* told the patients they were likely getting the drug. The posts stated:

- 2 • The symptoms I had: shortness of breath [sic], flushing, chest tightness are
3 very typical generalized transfusion reactions. However with how quickly
4 they happened and that I was able to restart the transfusion without
5 continued reactions the doctors believe it's from the large amount of
6 eosinophils going through lysis so quickly...
- 7 • The doctor is convinced she got the drug and since she has so many
8 [eosinophils], her reaction was due to a large kill off of [eosinophils].
- 9 • My daughter had a severe reaction 2 hours after the start of the first
10 infusion. The doctor thinks she is definitely getting the drug.
- 11 • Since the doctor thinks she was getting the drug all along, it may be no
12 different.
- 13 • Her 1st infusion was a "horrific reaction" and the doctor firmly believes she
14 did get the drug...

15 77. *Third*, remarkably, one patient in Phase 2 ENIGMA posted on Facebook that it was
16 "so great" that he or she was "able to see the test results, biopsies, bloodwork while on the drug."
17 Additionally, seven patients posted that they received endoscopy results during the trial, including
18 one that stated that "clinically and by endoscopy we all should have a clear indication if we are
19 getting the drug or placebo."

20 78. Control problems that tip patients off about whether they are receiving the drug or a
21 placebo are red flags for the FDA that create doubt as to the integrity of the trial and its results. In
22 the FDA's Guidance for Industry on Patient-Reported Outcome Measures: Use in Medical Product
23 Development to Support Labeling Claims, issued in December 2009, the FDA warned that
24 unblinding due to treatment reaction was a serious concern for the FDA when it reviewed Patient
25 Reported Outcomes: "In blinded clinical trials, patients should be blinded to treatment assignment
26 throughout the trial. If the treatment has obvious effects, such as adverse events, the clinical trial
27 may be at risk for unintentional unblinding.... *Suspicion of inadvertent unblinding can be a
28 problematic review consideration for the FDA when assessing PRO endpoints.*" (emphasis
added).

79. *Fourth*, the Patient Reported Outcome scores of patients were also biased by the fact

1 that, according to posts on the EG Facebook group, patients in Phase 2 ENIGMA were informed
2 that if they had success in Phase 2 ENIGMA, they would be accepted into the extension study
3 where they would be guaranteed to receive the drug and avoid placebo. This provided patients with
4 an improper incentive to report improvement in the Patient Reported Outcome surveys.

5 80. *Fifth*, posts to the EG Facebook group also showed that a patient's parent had direct
6 contact with Defendant Rasmussen. Seligman told one of the trial investigators they spoke to about
7 this and the investigator found it very concerning for the integrity of Phase 2 ENIGMA:

8 If Rasmussen talked to a patient's parent, that's what I mean when I say they were
9 heavily involved. That's unusual. It seems a little weird to me. The company
10 should be blinded to the patient's name. It doesn't make any sense. The patient's
11 ID is a private matter. Patients are desperate. Parents sometimes call the company.
12 It's a gray area. Once a patient identifies themselves to the company, it's a
13 HIPAA violation. It's concerning to some degree. He could be influencing them.
14 Randomization should be done by investigational pharmacist at each site. It's
15 unusual and is a little concerning.

16 81. Additionally, two patients or family members of patients posted to the EG Facebook
17 group that they were told that Allakos was discontinuing the lowest (.3mg dose) of AK002 mid-trial
18 because it was ineffective. One of the posts stated that a research coordinator told them that. This
19 shows that Allakos had access to the data during Phase 2 ENIGMA and was, therefore, improperly
20 unblinded. Accordingly, this was a violation of Good Clinical Practices and a red flag for the FDA.

21 3. Defendant Alexander Misrepresented the Effect of Steroids on Phase 2 ENIGMA.

22 82. During the August 5, 2019 Conference Call, Defendant Alexander flatly asserted
23 "[i]n terms of the steroid, I mean, it had absolutely 0 effect on the results, and that was shown in the
24 study. So the idea that steroids are confounding the results is specious."

25 83. According to Seligman's interviews with trial investigators, the administration of
26 steroids during Phase 2 ENIGMA was extremely haphazard. Two of the investigators indicated that
27 it was completely at their discretion whether to put patients on steroids. One of the trial
28 investigators said *he gave all of his patients 20 mg of prednisone (a powerful steroid)* prior to the
first two infusions. Another said he only put some patients on steroids, but said he used *80mg of
prednisone.*

84. The haphazard and inconsistent use of steroids created a significant danger to the

1 reliability of Phase 2 ENIGMA’s results since steroids are the current standard of care for EG and
2 EGE and highly effective against those diseases. For example, the study “Successful Treatment of
3 Eosinophilic Gastroenteritis with Clarithromycin,” which appeared in the December 2012 issue of
4 the *Korean Journal of Internal Medicine*, stated that 90% of EGE/EoD patients respond to steroid
5 therapy and even 5 mg a day could suppress symptoms.

6 85. The FDA’s February 2019 Draft Guidance on EoE, a closely related disease to EG
7 and EGE/EoD,⁴ specifically warned about the importance of steroid controls during clinical trials.
8 Accordingly, widespread steroid use in Phase 2 ENIGMA would be a red flag for the FDA when
9 evaluating the trial. Furthermore, one of Allakos’ own trial investigators told Seligman that he
10 believed steroids could be a confounding factor, stating “[c]ould steroids be a confounding factor
11 here? Of course. With 80mg of prednisone, one shot can give you an acute effect.”

12 86. Notably, accordingly to Facebook posts by family members of participants in the
13 extension study following Phase 2 ENIGMA Trial, Allakos added 80 mg of prednisone to the
14 AK002 infusion protocol along with another steroid, Medrol, that is even stronger. The family
15 members of the patients posted:

- 16 • I am still not sure why it was necessary to be cautious enough today that
17 necessitated her to have 80 mgs [of prednisone] and then also include her
18 medrol during the infusion today. The data that has come in must have shown
19 it is necessary to avoid reaction. After all that is what the trial is for. There
20 must have been reactions as the dose went up without predosing with
21 prednisone. They just told us it was a new protocol to be given 80mgs prior to
22 the infusion. In open label infusions here on.
- 23 • She was predosed with 80 mg of prednisone yesterday that has been a [sic]
24 added protocol to the open label infusions along with getting Medrol during
25 the infusion.

26 If Defendants were certain that only 11 of the 39 patients who received AK002 and completed
27 Phase 2 ENIGMA received steroids and AK002 was effective without steroids, as Defendants
28 claimed, there would have been no reason for Allakos to mandate steroids as part of the protocol for
the extension study. The fact that Allakos did mandate pre-infusion steroids during the extension

⁴ There is no FDA Guidance specifically for EG or EGE/EoD.

1 study strongly suggests that either more than 11 of the 39 AK002 patients in the ENIGMA study
2 received them or that the no steroid group did not perform as well as Defendants contend.

3 87. In an analyst report on Allakos published on March 25, 2020, entitled “Phase 3
4 EGID Program Update Leaves Many Unanswered Questions – Reiterate Underperform,” SMBC
5 Nikko Securities America, Inc. rated Allakos’ common stock as an underperform “[s]ince we still
6 do not know the mean cumulative steroid doses received by [AK002] vs. placebo arms from the
7 [Phase 2] ENIGMA trial, all of the confounding risk remains in [Phase 3].” The analyst report also
8 indicated that Allakos’ Phase 3 trial for EG and EGE/EoD would have a premedication regimen of
9 prednisone before the first dose of AK002 and that investigators would be free to use steroids to
10 manage infusion reactions, which (as with the steroid protocol in the ENIGMA extension study) is
11 inexplicable if Defendants were certain that so few patients in Phase 2 ENIGMA received steroids
12 and patients who did not receive steroids performed as well as Allakos claims. Regarding Allakos’
13 decision to give prednisone, the analyst report stated that “it remains entirely possible that steroids
14 are driving the majority of symptom benefits, which coincidentally occur together with the first
15 dose of [AK002] when steroids are most likely to be given.”

16 88. Accordingly, Defendant Alexander had no basis for stating steroids had no effect on
17 the results of Phase 2 ENIGMA and that steroids were not a confounding factor.

18 **F. The Revelation that Defendants Made Misstatements About Phase 2 ENIGMA Caused**
19 **Allakos’ Stock to Decline by 17% Over Two Days, Harming Investors.**

20 89. After Seligman published its Report on December 18, 2019, Allakos’ common stock
21 fell \$22.73 per share over two days, or more than 17% from the closing price on December 17, 2019
22 to close at \$109.80 on December 19, 2019, damaging investors.

23 **G. Allakos Announces the Initiation of Phase 3 ENIGMA and Tells Investors That the**
24 **Patient Population Would be the Same as Phase 2 ENIGMA.**

25 90. On March 24, 2020, Allakos announced in a press release that it was initiating Phase
26 3 ENIGMA, a “Phase 3 study of antolimab [AK002] for the treatment of eosinophilic gastritis
27 and/or eosinophilic duodenitis (previously referred to as eosinophilic gastroenteritis).” Allakos
28 sometimes referred to Phase 3 ENIGMA as “ENIGMA2,” but, to avoid confusion, this Complaint
replaces those references with “[Phase 3 ENIGMA].” The Defendants intended Phase 3 ENIGMA

1 to be the second of the two studies, along with the original Phase 2 ENIGMA Trial, that Defendants
2 believed Allakos needed for FDA approval for the use of AK002 in EG and EGE/EoD.

3 91. As with Phase 2 ENIGMA, Phase 3 ENIGMA had two endpoints: (1) the reduction
4 in gastric or duodenal eosinophils post-treatment based on biopsies conducted on the patients and
5 (2) the change in patients reported symptoms based on a PRO questionnaire. The symptom based
6 endpoint was considered a co-primary endpoint, however, instead of a secondary endpoint.

7 92. In addition to issuing a press release, the Company hosted a conference call for
8 analysts and investors on March 24, 2020 (the “March 24, 2020 Conference Call”). During the
9 March 24, 2020 Conference Call, Defendant Rasmussen specifically emphasized that Phase 3
10 ENIGMA would have a patient population with the same characteristics as Phase 2 ENIGMA by
11 stating: “[a]nd importantly, the patient population we are going to study [in Phase 3 ENIGMA]
12 are the same as... in the Phase 2 ENIGMA Study.” (emphasis added).

13 93. While speaking during the March 24, 2020 Conference Call, Defendant Rasmussen
14 and other presenting for Allakos used a presentation that was also attached to a Form 8-K that was
15 signed by Defendant Alexander and filed with the SEC on the same date. (Excerpts of the March
16 24, 2020 presentation are attached as Exhibit 3). One of the slides that Defendant Rasmussen used
17 while he spoke during the March 24, 2020 Conference Call described the study design of Phase 3
18 ENIGMA. Across the bottom of that slide, in large lettering and in an individual box, it stated:
19 “Same patient population as Phase 2 ENIGMA study.” (See Exhibit 3 at 16).

20 94. On June 3, 2020, Allakos announced that it had begun recruiting patients for Phase 3
21 ENIGMA.

22 **H. Allakos Announces that its Prevalence Study Showed that EG and EGE/EoD Are** 23 **Greatly Underdiagnosed.**

24 95. On October 26, 2020, Allakos issued a press release entitled “Results from
25 Prospective Prevalence Study Indicate that Eosinophilic Gastritis and Eosinophilic Duodenitis May
26 be Significantly Underdiagnosed” (the “October 26, 2020 Press Release”). The Company attached
27 the October 26, 2020 Press Release to a Form 8-K that was filed with the SEC on the same day and
28 was signed by Defendant Alexander. According to the October 26, 2020 Press Release, the

1 Prevalence Study suggested that based on the measurement of elevated eosinophil and mast cell
2 levels in patients with chronic unexplained gastrointestinal symptoms or functional gastrointestinal
3 disorders, such as IBS, EG and/or EGE/EoD were significantly undiagnosed in those patients.

4 96. The Company also held a conference call for analysts and investors on October 26,
5 2020 (the “October 26, 2020 Conference Call”). During the October 26, 2020 Conference Call,
6 Allakos’ Senior Director of Medical Affairs and Clinical Development, Amol Kamboj, discussed
7 the Prevalence Study. Kamboj explained that Allakos decided to conduct the Prevalence Study
8 because, while the majority of patients evaluated for participation in Phase 2 ENIGMA (62 of 113)
9 entered into the screen for that trial with an established history of EG or EGE/EoD, of 51 patients
10 who entered screening without an established history of those diseases, 26 met the symptom
11 inclusion criteria. Out of those 26 patients, 15 were found to have EG and/or EGE/EoD based on
12 screening endoscopies and biopsies. Out of those 15 patients, 13 were randomized into Phase 2
13 ENIGMA.

14 97. The discovery of those 15 patients led Allakos to believe that EG and EGE/EoD
15 were significantly underdiagnosed. Notably, however, only 13 of 65 participants in Phase 2
16 ENIGMA was from the group of patients that did not have an established history of EG and/or
17 EGE/EoD.

18 98. Later during his presentation, Kamboj highlighted that the patients who were
19 identified as having EG and/or EGE/EoD in the Prevalence Study had peripheral eosinophils
20 “notably lower” than the patients who were identified for Phase 2 ENIGMA. As discussed above,
21 accordingly to Allakos, the mechanism by which AK002 treats EG and EGE/EoD is by depleting
22 eosinophils in blood and tissue.

23 99. During the October 26, 2020 Conference Call, the speakers used a presentation (the
24 “October 26, 2020 Presentation,” excerpts are attached as Exhibit 4), which Allakos attached to a
25 Form 8-K, which was signed by Defendant Alexander and filed with the SEC on the same date.

26 100. Kamboj’s portion of the presentation contained a slide entitled “Baseline
27 Characteristics of Patients in Prevalence Study Compared to ENIGMA,” which compared the
28 characteristics of the 181 patients identified as having EG and/or EGE/EoD in the Prevalence Study

1 to the 72 identified for Phase 2 ENIGMA.⁵ (See Exhibit 4 at 25.) The slide states that the median
2 peripheral blood eosinophils count for patients identified for Phase 2 ENIGMA was almost double
3 that of the Prevalence Study patients: 325 versus 170 per microliter. The slide further states that
4 55% of the Prevalence Study EG and/or EGE/EoD patients had a previous diagnosis of IBS,
5 whereas only 4% of the Phase 2 ENIGMA patients did.

6 101. The results of the Prevalence Study were very important to Allakos because they
7 indicated that the market for AK002 was potentially much bigger than previously believed.
8 According to Allakos' 2020 10-K, "[p]ublished literature reports the prevalence of EG and
9 [EGE/EoD] in the United States to be approximately 50,000 people." In contrast, on Allakos'
10 October 26, 2020 Conference Call, Dr. Nicholas J. Talley, a gastroenterologist at the University of
11 Newcastle in Australia, stated that, based on the Prevalence Study, it would be reasonable to
12 estimate that there were *6 to 10 million* potential EG and/or EGE/EoD patients in the United States.

13 **I. More than Three Months After the Completion of Patient Enrollment in Phase 3**
14 **ENIGMA, Defendant Tomasi States That the Patient Populations of Phase 2 ENIGMA**
15 **and Phase 3 ENIGMA Are "Identical" and "Very Similar."**

16 102. On June 7, 2021, Allakos issued a press release stating that Phase 3 ENIGMA had
17 completed patient enrollment. On the same date, Allakos filed a Form 8-K signed by Defendant
18 Alexander with that press release attached.

19 103. On September 10, 2021, Michael Ulz, an analyst from Morgan Stanley, interviewed
20 Defendant Tomasi at the Morgan Stanley 19th Annual Global Healthcare Conference (the "Morgan
21 Stanley Healthcare Conference"). During the interview, Defendant Tomasi showed great familiarity
22 with the Phase 2 and 3 ENIGMA trials and the Prevalence Study. (A Bloomberg transcript of
23 Defendant Tomasi's remarks at the Morgan Stanley Healthcare Conference is attached as Exhibit
24 5.)⁶

25 104. Ulz asked Defendant Tomasi why Allakos had prioritized Phase 2 and 3 trials for

26 ⁵ The slide considers all 72 patients who were identified as qualified for Phase 2 ENIGMA even
27 though only 65 enrolled.

28 ⁶ The transcript notes that it "may not be 100 percent accurate and may contain misspellings and
other inaccuracies." Plaintiffs' counsel reviewed an audio recording of Tomasi's remarks and made
corrections, which appear in brackets, to the portions of it quoted in this Complaint.

1 AK002's use in EG and EGE/EoD. In response, Tomasi stated that EG and EGE/EoD was Allakos'
2 lead indication and explained that the screening results from Phase 2 ENIGMA showed that the
3 "prevalence of EG and EoD [] proved to be much higher than what was reported in the literature."
4 Tomasi further explained that after getting that information from Phase 2 ENIGMA, Allakos
5 "embarked on a prevalence study to really look at the incidence and prevalence [of] EG and EoD in
6 the basket of people who have what are called functional diseases. These are diseases where
7 patients have symptoms without an identifiable cause. And what we found within that patient
8 population was that we found 45% of people that we biopsied actually met the criteria for EG and
9 EoD and so a really significant finding and pointed to a market of likely millions of patients in the
10 US given the prevalence of these functional diseases."

11 105. When Ulz asked Tomasi to elaborate further about the Prevalence study, Tomasi
12 showed great familiarity with the patient screening for the Phase 2 and 3 ENIGMA trials and the
13 Prevalence study: "what we saw in the prevalence study was [] of the patients who entered
14 screening roughly 33% of those guys ended up meeting the criteria for EG and EoD of the people
15 we biopsied that was a 45% rate. In the Phase 2 study, we saw a 31% from screen to hit rate, so very
16 similar to the 33% that was observed in the prevalence study. And then since then we've obviously
17 enrolled the Phase 3 study and we see a very similar hit rate again. So we've seen reproducibly the
18 same kind of 30 odd percent of patients who go into screening end up meeting the criteria for EG
19 and EoD, so it appears to be [] again a very repeatable result."

20 106. Ulz than asked Tomasi why Allakos had moved into Phase 3 for EG and EGE/EoD.
21 Tomasi responded by citing the strength of the Phase 2 ENIGMA results and emphasized that "***[t]he***
22 ***Phase 3 study is identical with regards to [the] patient population that we're [enrolling].***"
23 (emphasis added).

24 107. Following that, Ulz asked Tomasi whether methodological changes to the symptom
25 score and measurement of the eosinophil depletion that the FDA had asked Allakos to make
26 between the Phase 2 and Phase 3 ENIGMA trials "could impact the outcome of the Phase 3?"
27 Tomasi explained that that these "changes really have a small essentially negligible impact on the
28

1 probability of success.”⁷

2 108. Given that Tomasi did not believe that the Phase 3 methodological changes would
3 make any difference to the results, Ulz followed up by asking: “what’s the risk in your view to the
4 successful Phase 3”? In his response, Tomasi explained that enrolling the same patient population in
5 Phase 3 as Phase 2 was of the utmost importance and assured investors that he knew that the patient
6 populations were “very similar” because Phase 3 ENIGMA was already fully enrolled:

7 *And then probably the most important thing is to make sure that we enrolled the*
8 *same patient population* so that you’re really -- you have the greatest chance to
have to repeat the effect seen [in Phase 2].

9 And so our focus is really making sure that we [had] the same enrollment criteria
10 which we do. *And then as making sure that we have the same type of*
11 *demographics going into the phase 3 study*, making sure that the baseline [Total
Symptom Score] [is] in the same or similar place. And the Phase 3 study as it was
12 in Phase 2 and, *and yeah the study is fully enrolled now*. So I can say that these
13 two things are true. *So we do have a very similar patient population in phase 3*
as we do in phase 2, so I think that was really probably the most thing that, the
most important thing that was in our control.

14 (emphasis added).

15 109. Later in the conversation with Ulz, Tomasi stated that for AK002 to be approved
16 based on Phase 3 ENIGMA, it would need to meet the co-primary endpoints, including symptom
17 improvement.

18 **J. Allakos Announces that Phase 3 ENIGMA Did Not Meet its Symptomatic Co-Primary**
19 **Endpoint, Causing Allakos’ Common Stock to Lose Almost 90% of its Value.**

20 110. On December 21, 2021, Allakos issued a press release (the “December 21, 2021
21 Press Release”) stating that Phase 3 ENIGMA met its histologic eosinophil depletion co-primary
22 endpoint, it did not meet its patient reported symptomatic co-primary endpoint.

23 111. According to the December 21, 2021 Press Release, not only had Phase 3 ENIGMA
24

25 ⁷ Regarding the symptom score, Tomasi explained that the FDA suggested that Allakos no longer
26 consider 2 of the 8 symptoms they measured in Phase 2 (diarrhea and vomiting) since they did not
27 occur with the same frequency as the others. Tomasi explained that he did not expect this to make
28 any difference because the exclusion of those symptoms would not have made any difference in
Phase 2 and, to avoid confounding the results, the Phase 3 PRO was identical to the Phase 2 one
with the diarrhea and vomiting scores excluded after the fact.

1 failed to meet its symptomatic endpoint, *but the patients in the placebo arm of the trial's*
2 *symptoms had actually improved more than the patients who received AK002.*

3 112. Given that EG and EGE/EoD was AK002's lead indication and Allakos' entire
4 business is dependent on AK002, this news caused Allakos' common stock to completely collapse.

5 113. On December 21, 2021, Allakos' stock closed at \$84.39 per share. Allakos released
6 the December 21, 2021 Press Release after the market closed on December 21, 2021. On December
7 22, 2021, *Allakos' stock dropped \$75.84 per share, or almost 90%, to close at \$8.55*, greatly
8 harming shareholders.

9 **K. Allakos Admits, Contrary to Defendant Tomasi's Statements, That the Patient**
10 **Populations of Phase 2 ENIGMA and Phase 3 ENIGMA Were Significantly Different**
11 **and Blamed That for the Failure of Phase 3.**

12 114. On February 15, 2022, Allakos hosted an Investor Day. On the same day, they filed a
13 Form 8-K with the SEC that attached a presentation used during the Investor Day (the "February 15,
14 2022 Presentation," excerpts are attached as Exhibit 6) that was signed by the Company's CFO H.
15 Baird Radford.⁸

16 115. During the February 15, 2022 Investor Day, Allakos admitted that — directly
17 contrary to statements by Defendant Tomasi — the patient populations of Phase 3 and Phase 2
18 ENIGMA were different and blamed those differences for the failure of Phase 3.

19 116. Allakos' CMO Craig A. Paterson⁹ presented on the Phase 3 ENIGMA results during
20 the Investor Day. Paterson presented a slide from the February 15, 2022 Presentation that was
21 entitled "Baseline Demographics & Patient Characteristics: [Phase 2 ENIGMA] and [Phase 3
22 ENIGMA]." (Exhibit 6 at 28.) This slide showed significant differences in both diagnosis history
23 and baseline eosinophil measures between ENIGMA Phase 2 and Phase 3 patients.

24 117. The "Baseline Demographics & Patient Characteristics: [Phase 2 ENIGMA] and
25 [Phase 3 ENIGMA]" slide showed that the patients in Phase 2 and 3 had three significant
26 differences in diagnostic history: (1) 80% of Phase 2 patients had previously been diagnosed with
27 EG or EGE/EoD, whereas only 32% in the AK002 arm of Phase 3 and 29% in the placebo arm of

28 ⁸ Allakos appointed Radford as CFO on April 19, 2021.

⁹ Allakos appointed Paterson CMO after Defendant Rasmussen retired on June 11, 2021.

1 Phase 3 had previously been diagnosed with those diseases; (2) only 3% of Phase 2 patients had
 2 previously been diagnosed with IBS, whereas 40% in the AK002 arm of Phase 3 and 37% in the
 3 placebo arm of Phase 3 had previously been diagnosed with IBS; and (3) 54% of Phase 2 patients
 4 had previously been diagnosed with EoE, whereas only 23% in the AK002 arm of Phase 3 and 24%
 5 in the placebo arm of Phase 3 had previously been diagnosed with EoE. Paterson specifically
 6 discussed the difference in previous EG or EGE/EoD and IBS diagnoses when discussing the slide
 7 and those differences were highlighted on the slide.

8 118. The “Baseline Demographics & Patient Characteristics: [Phase 2 ENIGMA] and
 9 [Phase 3 ENIGMA]” slide also showed the Phase 2 ENIGMA Patients had much higher baseline
 10 eosinophil levels in both their tissue and blood than Phase 3 patients and higher serum
 11 immunoglobulin (“IgE”), which like elevated eosinophil levels, is an indicator of disease: (1) Phase
 12 2 patients had a mean of 84 eosinophils in their tissue per high powered field, whereas patients in
 13 the AK002 arm of Phase 3 had only 65 and patients in the placebo arm of Phase 3 had only 52; (2)
 14 Phase 2 patients had a median of 330 eosinophils per microliter of their blood, whereas patients in
 15 the AK002 arm of Phase 3 had only 200 and patients in the placebo arm of Phase 3 had only 230;
 16 and (3) Phase 2 patients had a median of 141 kilounits of IgE in their blood, whereas patients in the
 17 AK002 arm of Phase 3 had only 59 and patients in the placebo arm of Phase 3 had only 61. Paterson
 18 specifically discussed the difference in tissue eosinophils, blood eosinophils, and IgE levels when
 19 discussing the slide and those differences were highlighted on the slide.

20 119. At the end of his discussion of the Phase 3 ENIGMA, Paterson presented a slide
 21 entitled “Summary of [Phase 3 ENIGMA]” which again indicated that the difference in patient
 22 characteristics explained the difference between the success of Phase 2 ENIGMA and the failure of
 23 Phase 3. (Exhibit 6 at 38.) It stated:

- 24 • [Phase 3 ENIGMA] patients with similar characteristics to those included in Phase 2
 25 reproduced original study results.
- 26 • Key patient characteristics identified include:
 - 27 - Higher tissue [eosinophil] counts
 - 28 - Higher peripheral blood [eosinophil] counts
 - Higher IgE levels

120. Based on the February 15, 2022 Presentation, it is indisputable that — contrary to

1 Defendant Tomasi's statements — there were undisclosed material differences between the patient
2 populations of Phase 3 and Phase 2 ENIGMA.

3 121. Furthermore, the differences between the patients in Phase 2 and 3 of ENIGMA were
4 similar to the differences between the patients in Phase 2 ENIGMA and the Prevalence Study,
5 including the differences in blood eosinophil counts and previous diagnosis of EG and/or EGE/EoD
6 and IBS. Accordingly, Defendant Tomasi and others at Allakos were either aware of or were
7 reckless in not being aware that the Phase 3 ENIGMA patient population could be significantly
8 different than Phase 2 ENIGMA despite meeting the EG and EGE/EoD inclusion criteria. Despite
9 this, Defendant Tomasi unequivocally told investors that the patient populations were the same.

10 122. Allakos was forced to highlight the differences in the Phase 2 and 3 populations
11 during the February 15, 2022 Presentation because they needed an explanation for the failure of
12 Phase 3 ENIGMA that left room for the possibility that the FDA could approved AK002 for use in
13 EG and/or EGE/EoD patients in the future. Prior to that, however, Allakos had a strong incentive to
14 downplay the possibility that the differences discussed during the February 15, 2022 Presentation
15 could be significant. Any suggestion those differences were significant would have cast doubt on
16 whether all the patients identified as having EG and/or EGE/EoD in the Prevalence Study were
17 good candidates for AK002, which would have called into question whether the potential market for
18 AK002 was as large as Allakos portrayed when Allakos released the Prevalence Study.

19 123. During the February 15, 2022 Presentation, Paterson also discussed a Phase 3 trial of
20 only EGE/EoD patients that Allakos was conducting and did not expect results from until the
21 middle of 2022. Paterson stated that since the study was fully enrolled in December 2021, Allakos
22 knew that the population was more like the one in Phase 3 ENIGMA than the one in Phase 2. (*See*
23 *Exhibit 6 at 41.*)

24 124. During the question and answer portion of the Investor Day, Tim Lugo, an analyst at
25 William Blair asked if Allakos could exclude patients from the EoD only Phase 3 Trial for the
26 purpose of creating a patient population that was similar to Phase 2 ENIGMA. Defendant Alexander
27 responded that Allakos had access to the demographic characteristics of the patients and was free to
28 change the criteria up until Allakos broke the blind of the study.

1 125. The fact that Allakos employees had access to patient demographics for the Phase 3
2 Trial for only EoD patients in February 2022 — where that trial was fully enrolled in December
3 2021 and results were not expected until the middle of 2022 — further shows that Defendant
4 Tomasi and other Allakos employees had access to patient demographics for Phase 3 ENIGMA
5 when Defendant Tomasi spoke at the Morgan Stanley Healthcare Conference in September 2021.

6 **MATERIALLY FALSE AND MISLEADING STATEMENTS ISSUED DURING THE**
7 **CLASS PERIOD**

8 **A. Material Misstatements About Using a CRO to Conduct Clinical Trials.**

9 126. On March 14, 2019, Allakos issued the 2018 10-K, which was signed by Defendants
10 Alexander and Tomasi. Additionally, attached to the 2018 10-K were certifications pursuant to the
11 Sarbanes-Oxley Act of 2002 (“SOX”), signed by Defendants Alexander and Tomasi, attesting that
12 “this report does not contain any untrue statement of a material fact or omit to state a material fact
13 necessary to make the statements made, in light of the circumstances under which such statements
14 were made, not misleading with respect to the period covered by this report” and that they have
15 disclosed all fraud.

16 127. On May 8, 2019, Allakos issued its 1Q 2019 10-Q, signed by Defendants Alexander
17 and Tomasi. Additionally, attached to the 1Q 2019 10-Q were certifications pursuant to SOX,
18 signed by Defendants Alexander and Tomasi, attesting that “this report does not contain any untrue
19 statement of a material fact or omit to state a material fact necessary to make the statements made,
20 in light of the circumstances under which such statements were made, not misleading with respect
21 to the period covered by this report” and that they have disclosed all fraud.

22 128. On August 5, 2019, Allakos issued its 2Q 2019 10-Q, which was signed by
23 Defendants Alexander and Redmond. Additionally, attached to the 2Q 2019 10-Q were
24 certifications pursuant to SOX, signed by Defendants Alexander and Redmond, attesting that “this
25 report does not contain any untrue statement of a material fact or omit to state a material fact
26 necessary to make the statements made, in light of the circumstances under which such statements
27 were made, not misleading with respect to the period covered by this report” and that they have
28 disclosed all fraud.

1 129. On August 5, 2019, the Company filed a Form S-3 registration statement, signed by
2 Defendants Alexander and Redmond. That registration statement incorporated the 2018 10-K, 1Q
3 2019 10-Q, and 2Q 2019 10-Q.

4 130. On November 12, 2019, Allakos issued its Quarterly Report on Form 10-Q for the
5 quarter ended September 30, 2019 (the “3Q 2019 10-Q”), which was signed by Defendants
6 Alexander and Redmond. Additionally, attached to the 3Q 2019 10-Q were certifications pursuant
7 to SOX, signed by Defendants Alexander and Redmond, attesting that “this report does not contain
8 any untrue statement of a material fact or omit to state a material fact necessary to make the
9 statements made, in light of the circumstances under which such statements were made, not
10 misleading with respect to the period covered by this report” and that they have disclosed all fraud.

11 131. The 2018 10-K, 1Q 2019 10-Q, 2Q 2019 10-Q, and 3Q 2019 10-Q all contained
12 identical statements that Allakos does not have the ability to independently conduct clinical trials,
13 and therefore it relies on third-parties, such as CROs, to conduct its clinical trials for AK002:

14 *We rely on third-parties to conduct our clinical trials and those third-parties*
15 *may not perform satisfactorily, including failing to meet deadlines for the*
16 *completion of such trials, research and studies.*

17 *We do not have the ability to independently conduct our clinical trials. We*
18 *currently rely on third-parties, such as CROs, clinical data management*
19 *organizations, medical institutions and clinical investigators, to conduct our*
20 *clinical trials of AK002 and expect to continue to rely upon third-parties to*
21 *conduct additional clinical trials of AK002 and our other product candidates.*
22 *Third-parties have a significant role in the conduct of our clinical trials and the*
23 *subsequent collection and analysis of data.* These third-parties are not our
employees, and except for remedies available to us under our agreements, we
have limited ability to control the amount or timing of resources that any such
third-party will devote to our clinical trials. Some of these third-parties may
terminate their engagements with us at any time. If we need to enter into
alternative arrangements, it would delay our drug development activities.

24 (emphasis in first three lines in original; other emphasis added).

25 132. The bold and italicized portion of the foregoing statements was materially false and
26 misleading because Allakos did not use an independent CRO for Phase 2 ENIGMA, which was the
27 most important clinical trial in Allakos’ history at the time it was conducted. Instead, Allakos was
28

1 aggressively and improperly involved in Phase 2 ENIGMA and used a single reader who had
2 financial ties to Allakos to read tissue samples. By misrepresenting and/or failing to disclose these
3 facts, Allakos misled investors about the integrity and quality of the Phase 2 ENIGMA results and
4 about the likelihood that Allakos will be able to use Phase 2 ENIGMA to gain FDA approval of
5 AK002.

6 **B. Misstatements that Phase 2 ENIGMA was a Randomized, Double-blind, Placebo-**
7 **Controlled Trial.**

8 133. Defendants repeatedly told investors that Phase 2 ENIGMA was a “randomized,
9 double-blind, placebo-controlled” trial.

10 134. On March 14, 2019, Allakos issued the 2018 10-K, which was signed by Defendants
11 Alexander and Tomasi. Additionally, attached to the 2018 10-K were certifications pursuant to
12 SOX, signed by Defendants Alexander and Tomasi, attesting that “this report does not contain any
13 untrue statement of a material fact or omit to state a material fact necessary to make the statements
14 made, in light of the circumstances under which such statements were made, not misleading with
15 respect to the period covered by this report” and that they have disclosed all fraud. The 2018 10-K
16 was also incorporated by reference into the Form S-3 registration statement, signed by Defendants
17 Alexander and Redmond, and filed by the Company on August 5, 2019.

18 135. The 2018 10-K referred to Phase 2 ENIGMA as a “randomized, double-blind,
19 placebo controlled” trial: “*We have initiated a randomized, double-blind, placebo-controlled*
20 *Phase 2 trial with AK002* in approximately 60 patients with active, moderate to severe, biopsy-
21 confirmed EG (stomach >30 eosinophils/hpf in 5 hpf) and/or EGE (duodenum >30 eosinophils/hpf
22 in 3 hpf).”

23 136. On August 5, 2019, Allakos issued a Form 8-K signed by Defendant Alexander with
24 the August 5, 2019 ENIGMA Press Release attached. The August 5, 2019 ENIGMA Press Release
25 was also incorporated by reference into the Form S-3 registration statement, signed by Defendants
26 Alexander and Redmond, and filed by the Company on August 5, 2019.

27 137. The August 5, 2019 ENIGMA Press Release stated:
28

1 REDWOOD CITY, Calif., Aug. 05, 2019 (GLOBE NEWSWIRE) -- *Allakos Inc.*
 2 *(the “Company”)* (Nasdaq: *ALLK*) today announced positive results from its
 3 *Phase 2 randomized, double-blind, placebo-controlled trial of AK002 in patients*
 4 *with eosinophilic gastritis and/or eosinophilic gastroenteritis.* All AK002 dose
 5 arms showed clinically meaningful and statistically significant benefits compared
 6 to placebo on all prespecified primary and secondary endpoints, including
 7 gastrointestinal tissue eosinophil counts and patient reported disease symptoms.
 8 Statistically significant differences in patient symptoms between the active and
 9 placebo groups occurred one day following AK002 administration...

7 **Phase 2 ENIGMA Study Design**

8 *This randomized, double-blind, placebo-controlled Phase 2 trial of AK002*
 9 enrolled patients with active, biopsy-confirmed EG and/or EGE. Patients were
 10 required to be moderately to severely symptomatic based on a patient reported
 11 symptom questionnaire and have biopsy confirmed eosinophilia of the stomach
 (≥30 eosinophils/HPF in 5 HPFs) and/or duodenum (≥30 eosinophils/HPF in 3
 HPFs)...

12 (Emphasis in original for “Phase 2 ENIGMA Study Design”; other emphasis added).

13 138. On August 5, 2019, Allakos conducted the August 5, 2019 Conference Call and the
 14 Company issued a Form 8-K signed by Defendant Alexander on the same date with the August 5,
 15 2019 Presentation attached. Defendants Alexander and Rasmussen used the August 5, 2019
 16 Presentation during the August 5, 2019 Conference Call. The Form 8-K with the August 5, 2019
 17 Presentation attached was incorporated by reference into the Form S-3 registration statement,
 18 signed by Defendants Alexander and Redmond, and filed by the Company on August 5, 2019.

19 139. Defendant Alexander stated during the August 5, 2019 Conference call that “[t]he
 20 AK002 met all pre-specified primary and secondary endpoints in our study. And those are in
 21 patients with gastritis, gastroenteritis as well as concomitant EoE. In terms of our primary and 2 key
 22 secondary endpoints, we saw a tremendous effect on all of them. *And a reminder, this was a*
 23 *randomized, double-blind, placebo-controlled study.*” (emphasis added).

24 140. Defendant Rasmussen stated during the August 5, 2019 Conference Call that: “So
 25 basically, the study design of *the ENIGMA study was randomized, double-blind, placebo-*
 26 *controlled study* in patients with eosinophilic gastritis and/or gastroenteritis.” (emphasis added).

27 141. Slides 5, 12, and 40 of the August 5, 2019 Presentation stated that Phase 2 ENIGMA
 28 was a “*Randomized, double-blind, placebo-controlled study.*” (emphasis added).

1 142. Allakos filed a preliminary prospectus supplement on August 5, 2019 and a final
2 prospectus supplement on August 7, 2019, both of which formed part of the Form S-3 registration
3 statement filed by Allakos on August 5, 2019 and signed by Defendants Alexander and Redmond.

4 143. That preliminary prospectus supplement and final prospectus supplement stated:

5
6 ***We recently reported data from a randomized, double-blind, placebo-controlled***
7 ***phase 2 trial of AK002 in patients with active, biopsy-confirmed EG and/or***
8 ***EGE.*** 38% of the patients in the study also had EoE, allowing us to evaluate the
9 effects of AK002 on EoE. All AK002 dose arms showed clinically meaningful
and statistically significant benefit compared to placebo on all prespecified
primary and secondary endpoints, including gastrointestinal tissue eosinophil
counts and patient reported disease symptoms....

10 ***Phase 2 ENIGMA Study Design***

11 ***The randomized, double-blind, placebo-controlled phase 2 trial of AK002***
12 ***enrolled patients*** with active, biopsy-confirmed EG and/or EGE.

13 (Emphasis in original for “Phase 2 ENIGMA Study Design”; other emphasis added).

14 144. The bold and italicized portions of the statements in Paragraphs 135, 137, 139-141,
15 and 143 are false and misleading because Phase 2 ENIGMA was not well controlled and the
16 blinding was compromised. Defendants failed to disclose that Allakos conducted Phase 2 ENIGMA
17 without an independent CRO. Using a CRO to conduct clinical trials is standard industry practice
18 for maintaining proper controls and Good Clinical Practice in clinical trials. Additionally, the
19 blinding of Phase 2 ENIGMA was severely compromised because: (1) infusion reactions made
20 patients aware of whether they were receiving AK002 or the placebo; (2) the trial investigators told
21 patients in the treatment group of the trial that they were likely getting the drug instead of the
22 placebo; (3) patients were able to see their endoscopy results during the Trial; (4) patients in the
23 Trial were told that if they had success in the Trial, they would qualify for an extension study in
24 which they were sure to get the drug and avoid the placebo; and (5) Allakos had improper access to
25 data and the patients during the Trial. By misrepresenting and/or failing to disclose these facts,
26 Allakos misled investors about the reliability of the Patient Reported Outcomes from Phase 2
27 ENIGMA and about the likelihood that Allakos will be able to use Phase 2 ENIGMA to gain FDA
28 approval of AK002.

1 **C. Misstatements Concerning Steroid Use in Phase 2 ENIGMA.**

2 145. On August 5, 2019, Allakos conducted the August 5, 2019 Conference Call and the
3 Company issued a Form 8-K signed by Defendant Alexander on the same date with the August 5,
4 2019 Presentation attached. Defendants Alexander and Rasmussen used the August 5, 2019
5 Presentation during the August 5, 2019 Conference Call. The Form 8-K with the August 5, 2019
6 Presentation attached was incorporated by reference into the Form S-3 registration statement,
7 signed by Defendants Alexander and Redmond, and filed by the Company on August 5, 2019.

8 146. During the August 5, 2019 Conference Call, Defendant Alexander stated that
9 steroids “had absolutely 0 effect on the results” of Phase 2 ENIGMA: *“In terms of the steroid, I*
10 *mean, it had absolutely 0 effect on the results, and that was shown in the study. So the idea that*
11 *steroids are confounding the results is specious.”* (emphasis added).

12 147. The bold and italicized portion of the statement in the foregoing Paragraph was false
13 and misleading because the dosing of the steroids was inconsistent, haphazard, and left to the
14 discretion of the trial investigators. Given that steroids are the current standard of care for EG and
15 EGE/EoD and the poor controls of steroids in Phase 2 ENIGMA, Defendant Alexander lacked a
16 basis to assert that steroids had “absolutely 0 effect on the Results” of Phase 2 ENIGMA. By
17 misrepresenting and/or failing to disclose these facts, Allakos misled investors about the integrity
18 and quality of the Phase 2 ENIGMA results and the likelihood that Allakos will be able to use Phase
19 2 ENIGMA to gain FDA approval of AK002.

20 **D. Misstatements Concerning the Patient Populations of Phase 3 ENIGMA and Phase 2**
21 **ENIGMA.**

22 148. On September 10, 2021, Michael Ulz, a Morgan Stanley analyst, conducted a public
23 interview of Defendant Tomasi at the Morgan Stanley 19th Annual Global Healthcare Conference.

24 149. During the interview, Defendant Tomasi stated that the patient population of Phase 3
25 ENIGMA was identical to Phase 2 ENIGMA:

26 *The Phase 3 study is identical with regards to [the] patient population that we're*
27 *[enrolling].* Chief difference is that we're focusing [on] the high-dose group given
28 greater efficacy that we saw in Phase 2[. T]hat study is 80 patients per arm instead
of being 20 patients per arm, given the strong p-values that we saw in Phase 2, the

1 phase 3 study will power on its end points.

2 (emphasis added).

3 150. Later in the interview Ulz asked Defendant Tomasi “what’s the risk in your view to
4 the successful Phase 3 [ENIGMA]...?” In his response, Defendant Tomasi stated that “we do have a
5 very similar patient population in phase 3 as we do in phase 2”:

6 And then probably the most important thing is to make sure that we enrolled the
7 same patient population so that you're really -- you have the greatest chance to
8 have to repeat the effect seen [in Phase 2].”

9 And so our focus is really making sure that we [had] the same enrollment criteria
10 which we do. And then as making sure that we have the same type of
11 demographics going into the phase 3 study, making sure that the baseline [Total
12 Symptom Score] [is] in the same or similar place. And the Phase 3 study as it was
13 in Phase 2 and, and yeah the stud[y is] fully enrolled now. So I can say that these
14 two things are true. ***So we do have a very similar patient population in phase 3
15 as we do in phase 2, so I think that was really probably the most thing that, the
16 most important thing that was in our control.***

17 (emphasis added).

18 151. The bold and italicized portions of the statements in Paragraphs 149 and 150 were
19 false and misleading because the characteristics of the patient populations in Phase 2 and Phase 3
20 ENIGMA were materially different in both diagnostic history and in baseline eosinophil and IgE
21 levels. Phase 2 and 3 had three significant differences in diagnostic history: (1) 80% of Phase 2
22 patients had previously been diagnosed with EG or EGE/EoD, whereas only 32% in the AK002 arm
23 of Phase 3 and 29% in the placebo arm of Phase 3 had previously been diagnosed with those
24 diseases; (2) only 3% of Phase 2 patients had previously been diagnosed with IBS, whereas 40% in
25 the AK002 arm of Phase 3 and 37% in the placebo arm of Phase 3 had previously been diagnosed
26 with IBS; and (3) 54% of Phase 2 patients had previously been diagnosed with EoE, whereas only
27 23% in the AK002 arm of Phase 3 and 24% in the placebo arm of Phase 3 had previously been
28 diagnosed with EoE. Phase 2 ENIGMA Patients also had much higher baseline eosinophil levels in
both their tissue and blood than Phase 3 patients and higher IgE, which like elevated eosinophil
levels, is an indicator of disease: (1) Phase 2 patients had a mean of 84 eosinophils in their tissue
per high powered field, whereas patients in the AK002 arm of Phase 3 had only 65 and patients in
the placebo arm of Phase 3 had only 52; (2) Phase 2 patients had a median of 330 eosinophils per

1 microliter of their blood, whereas patients in the AK002 arm of Phase 3 had only 200 and patients
2 in the placebo arm of Phase 3 had only 230; and (3) Phase 2 patients had a median of 141 kilounits
3 of IgE in their blood, whereas patients in the AK002 arm of Phase 3 had only 59 and patients in the
4 placebo arm of Phase 3 had only 61. Allakos believed that these differences in patient
5 characteristics between Phase 2 and Phase 3 ENIGMA were so significant that they were the reason
6 that Phase 3 failed.

7 LOSS CAUSATION

8 152. On December 18, 2019, Seligman Investments published the Seligman Report.

9 153. On this news, shares of Allakos fell \$22.73 per share over two days, or more than
10 17% from the closing price on December 17, 2019 to close at \$109.80 on December 19, 2019,
11 damaging investors.

12 154. On December 21, 2021, the risk of the difference in patient population between
13 Phase 3 and Phase 2 ENIGMA materialized when Allakos announced after the close of the markets
14 that Phase 3 ENIGMA failed to meet its patient reported symptomatic co-primary endpoint.

15 155. On that news, Allakos' stock fell \$75.84 per share, or almost 90% from the closing
16 price of \$84.39 per share on December 21, 2021, to close at \$8.55 on December 22, 2021, damaging
17 investors.

18 156. As a result of Defendants' wrongful acts and omissions, Plaintiffs and other Class
19 members have suffered significant losses and damages.

20 ADDITIONAL SCIENTER ALLEGATIONS

21 **A. Defendants Were Motivated to Make False and Misleading Statements Because** 22 **Allakos Could Not Continue its Operations or Drug Development Unless it Raised** 23 **Additional Capital.**

24 157. Allakos admitted in its 2018 10-K, 1Q 2019 10-Q, 2Q 2019 10-Q, 2019 10-K, Form
25 10-Q for the quarterly period ended March 31, 2020 (filed May 11, 2020), and Form 10-Q for the
26 quarterly period ended June 30, 2020 (filed August 10, 2020) that it could not continue its
27 operations if it did not raise additional capital and would have to delay, reduce, or terminate its
28 development efforts: "We will continue to require additional capital to develop our product
candidates and fund operations for the foreseeable future" and "if we are unable to raise additional

1 funds when needed, we may be required to delay, reduce or terminate some or all of our
2 development and commercialization efforts.”

3 158. On August 5, 2019, Allakos announced the results from Phase 2 ENIGMA. Phase 2
4 ENIGMA was the most important trial in Allakos’ history, at that time, since AK002 is the
5 Company’s only clinical stage drug and EG and EGE/EoD are Allakos’ lead indications for AK002.
6 Additionally, Defendant Alexander stated during the August 5, 2019 Conference Call that Allakos
7 intended to use Phase 2 ENIGMA as one of two clinical trials necessary for FDA approval of
8 AK002. As detailed above, Defendants’ announcement of Phase 2 ENIGMA’s results contained
9 numerous material misstatements that misled investors about the integrity and quality of the Phase 2
10 ENIGMA results and the likelihood that Allakos will be able to use Phase 2 ENIGMA to gain FDA
11 approval of AK002.

12 159. Mere hours after announcing the results of Phase 2 ENIGMA, and making numerous
13 material misstatements, Allakos announced a secondary public offering of \$200 million shares of its
14 common stock, the Company’s first public offering of common stock since its IPO. The preliminary
15 prospectus supplement, filed on August 5, 2019 and final prospectus supplement for that offering,
16 filed on August 7, 2019, continued to make material misstatements about Phase 2 ENIGMA.

17 160. After Defendants’ misstatements caused Allakos’ share price to dramatically
18 increase, Allakos announced it was upsizing its secondary offering of common stock to \$350
19 million at an offering price of \$77 per share. On August 9, 2019, the Company announced that it
20 had raised \$377.5 million.

21 161. On October 28, 2020, Allakos announced a public offering of \$250 million of shares
22 of its common stock at \$82 per share two days after announcing the results of the Prevalence Study.
23 Allakos closed the public offering in November 2020 and the net proceeds were \$271.7 million.

24 162. Given that Allakos admitted that it could not continue its operations and would likely
25 have reduce, terminate or delay development of AK002 if it could not raise money, Defendants
26 were highly motivated and had the opportunity to make material misstatements concerning the
27 success of the drug.

28

1 **B. Allakos Purportedly Granted Defendant Redmond 120,000 Stock Options One**
2 **Business Day Prior to Making Misstatements About Phase 2 ENIGMA and Did Not**
3 **Reveal the Options Grant Until it was Worth Almost \$6 Million.**

4 163. Allakos' stock closed at \$31 on Friday, August 2, 2019. After Defendants announced
5 the results of Phase 2 ENIGMA, and made numerous material misstatements, the stock price shot
6 up dramatically and closed at \$79.47 on August 6, 2019.

7 164. On August 6, 2019, Allakos filed a Form 4 that stated it had granted 120,000 stock
8 options to Defendant Redmond *on August 2, 2019 at the price of \$31*. When Allakos announced
9 Defendant Redmond's stock options, they were already worth almost \$6 million.

10 **C. Defendants Behaved Intentionally or Recklessly When They Made Misstatements**
11 **Concerning how Allakos Conducted Phase 2 ENIGMA.**

12 165. Given the importance of Phase 2 ENIGMA to the future of Allakos and the small
13 size of the Company, it is inconceivable that Defendant Alexander, as CEO, would not be aware or
14 have access to information about the aspects of Phase 2 ENIGMA that he made misrepresentations
15 about including, Allakos' failure to use a CRO, the trial's poor blinding controls, and steroid use
16 during the trial. Additionally, because of his Ph.D. in immunology and his previous experience as
17 CEO of another pharmaceutical company, Defendant Alexander well understood the significance of
18 these issues as to Good Clinical Practice and how they affect the reliability, integrity, and quality of
19 the trial results. Furthermore, Defendant Alexander spoke knowledgably about Phase 2 ENIGMA
20 during the August 5, 2019 Conference Call and represented that it would be one of two clinical
21 trials used in Allakos' application to the FDA for approval of AK002 for EG and EGE/EoD
22 patients. Allakos' 2018 10-K, 1Q 2019 10-Q, 2Q 2019 10-Q, and 3Q 2019 10-Q all warn that the
23 Company is "highly dependent" on Defendant Alexander.

24 166. Given the importance of Phase 2 ENIGMA to the future of Allakos and the small
25 size of the Company, it is inconceivable that Defendants Redmond and Tomasi as CFOs during
26 various points during the Class Period, and therefore the principal financial officer of the Company,
27 would not be aware or have access to the information that Allakos failed to use a CRO for Phase 2
28 ENIGMA. Defendants Redmond and Tomasi also would have been aware of or have access to
29 information about the poor blinding controls during Phase 2 ENIGMA and steroid use during the
30 trial. Additionally, because of Defendant Tomasi's Ph.D. in chemistry and his previous experience

1 as Chief Scientific Officer of another pharmaceutical company and Defendant Redmond's
2 experience as President of another pharmaceutical company, Defendants Tomasi and Redmond well
3 understood the significance of these issues as to Good Clinical Practice and how they affect the
4 reliability, integrity, and quality of the trial results. Defendant Tomasi also served as the
5 Company's President and COO during the class period and Allakos' 2018 10-K, 1Q 2019 10-Q, 2Q
6 2019 10-Q, and 3Q 2019 10-Q all warn that the Company is "highly dependent" on Defendant
7 Tomasi.

8 167. Defendants Alexander, Redmond, and Tomasi were provided with copies of
9 Company's SEC filings that they signed that contained misleading statements alleged herein before
10 their issuance and had the ability and opportunity to prevent their issuance or to cause them to be
11 corrected.

12 168. Defendant Alexander was, at minimum, reckless when he authorized the issuance
13 and signed the 2018 10-K, 1Q 2019 10-Q, 2Q 2019 10-Q, 3Q 2019 10-Q, the August 5, 2019 8-Ks
14 with the August 5, 2019 ENIGMA Trial Press Release and the August 5, 2019 Presentation
15 attached, and the August 5, 2019 S-3 registration statement which incorporated the August 5, 2019
16 preliminary prospectus supplement and August 7, 2019 final prospectus supplement. Defendant
17 Alexander was also, at minimum, reckless when he signed the SOX certifications that accompanied
18 the 2018 10-K, 1Q 2019 10-Q, 2Q 2019 10-Q, and 3Q 2019 10-Q. He was also, at minimum,
19 reckless when he made misstatements about Phase 2 ENIGMA on the August 5, 2019 Conference
20 Call.

21 169. Defendant Redmond was, at minimum, reckless when he authorized the issuance and
22 signed the 2Q 2019 10-Q, 3Q 2019 10-Q, and the August 5, 2019 S-3 registration statement. The
23 August 5, 2019 S-3 Registration Statement incorporated the August 5, 2019 preliminary prospectus
24 supplement, the August 7, 2019 final prospectus supplement, the August 5, 2019 8-Ks with the
25 August 5, 2019 ENIGMA Trial Press Release and the August 5, 2019 Presentation attached, the
26 2018 10-K, and the 1Q 2019 10-Q. Defendant Redmond was also, at minimum, reckless when he
27 signed the SOX certifications that accompanied the 2Q 2019 10-Q and 3Q 2019 10-Q.

28 170. Defendant Tomasi was, at minimum, reckless when he signed and authorized the

1 issuance of the 2018 10-K and 1Q 2019 10-Q and when he signed the SOX certificates associated
2 with those filings.

3 171. Given the importance of Phase 2 ENIGMA to the future of Allakos and the small
4 size of the Company, it is inconceivable that Defendant Rasmussen, as CMO would not be aware or
5 have access to information about the aspects of Phase 2 ENIGMA that he made misrepresentations
6 about, including Allakos' failure to use a CRO, the trial's poor blinding controls, and steroid use
7 during the trial. Furthermore, Defendant Rasmussen spoke to investors on the August 5, 2019
8 Conference Call specifically because he was knowledgeable about Phase 2 ENIGMA and he
9 demonstrated his knowledge of Phase 2 ENIGMA on that call. Furthermore, Defendant Rasmussen
10 was knowledgeable about Phase 2 ENIGMA because he is the top clinical officer at Allakos and the
11 Company conducted the Trial without a CRO. He was so intimately involved in the Trial that he
12 improperly spoke to the relative of a patient in the Trial. Additionally, because of his Ph.D. and
13 M.D. and his previous experience in high level clinical positions at other pharmaceutical
14 companies, Defendant Rasmussen well understood the significance of the issues discussed above as
15 to Good Clinical Practice and how they affect the reliability, integrity, and quality of the trial
16 results. Accordingly, Defendant Rasmussen was, at minimum, reckless when he made
17 misstatements on the August 5, 2019 Conference Call and when he authorized the issuance of and
18 used the August 5, 2019 Presentation on that call.

19 **D. Defendant Tomasi Behaved Intentionally or Recklessly When He Made Misstatements**
20 **About the Patient Populations of Phase 3 ENIGMA and Phase 2 ENIGMA.**

21 172. Defendant Tomasi showed great familiarity about Phase 2 and Phase 3 ENIGMA
22 during his remarks at Morgan Stanley Healthcare Conference. Accordingly, he would have known
23 that the patient population of Phase 3 was not "identical" or "very similar" to the patient population
24 of Phase 2. Furthermore, Defendant Tomasi also showed great familiarity with the Prevalence Study
25 during the Morgan Stanley Healthcare Conference. Accordingly, since Allakos' Senior Director of
26 Medical Affairs discussed the differences between the patient populations identified in the
27 Prevalence Study and for Phase 2 ENIGMA during the October 26, 2020 Conference Call,
28 Defendant Tomasi would have been aware of them. This put Defendant Tomasi on notice of the

1 possibility that the Phase 3 ENIGMA patient population could be different from Phase 2 ENIGMA
2 patient population in the similar way that the Prevalence Study patient population study was
3 different. Therefore, Defendant Tomasi was, at minimum, reckless when he assured investors that
4 the patient population of Phase 3 was “identical” or “very similar” to the patient population of
5 Phase 2 even though that was not the case.

6 173. Defendant Tomasi’s statements were also, at minimum, reckless because he had
7 access to information that the Phase 3 ENIGMA patient population was significantly different from
8 Phase 2. Defendant Tomasi indicated this during his remarks at the Morgan Stanley Healthcare
9 Conference when he said that he knew that patient population in Phase 3 was “very similar” to
10 Phase 2 “because [Phase 3 ENIGMA is] fully enrolled now.” Additionally, remarks by Allakos
11 CMO Paterson and Defendant Alexander about the EGE/EoD only Phase 3 study during the
12 February 15, 2022 Investor Day made clear that Allakos employees had access to patient
13 characteristics for trials where enrollment was closed even if the trial was not yet complete.
14 Accordingly, given that Defendant Tomasi is President and COO of the Company and the
15 Company’s public filings, including its 2020 10-K, warn that the Company is “highly dependent”
16 on Defendant Tomasi, Defendant Tomasi would have had access to information about the
17 characteristics of the patient population of Phase 3 ENIGMA when he made his remarks at the
18 Morgan Stanley Healthcare Conference. Defendant Tomasi also could have easily interpreted that
19 data considering that he has a Ph.D. in chemistry and previous experience as Chief Scientific
20 Officer of another pharmaceutical company.

21 174. The specificity of Defendants Tomasi’s statements are also indicative of their
22 recklessness. Defendant Tomasi had no obligation to comment on the characteristics of the patient
23 population for Phase 3 ENIGMA, but once he did, it was, at minimum, reckless of him to
24 unequivocally state that the patient population was “identical” and “very similar” when he had
25 access to contradictory information. Furthermore, given the importance of the patient population to
26 the success of Phase 3 ENIGMA, Defendant Tomasi would have understood that investors would
27 have expected such a specific statement to reflect all the information that Defendant Tomasi had
28 access to.

1 **E. Defendant Tomasi Was Motivated to Downplay the Differences Between Phase 2**
2 **ENIGMA and Phase 3 ENIGMA Because of the Importance of the Prevalence Study to**
3 **Allakos.**

4 175. The Prevalence Study was hugely important to Allakos given that, according to Dr.
5 Talley's comments on Allakos' October 26, 2020 Conference Call, it showed there were potentially
6 6 to 10 million EG and/or EGE/EoD patients in the United States instead of the 50,000 reported in
7 published literature.¹⁰ This enormous increase to AK002's potential market made Allakos a much
8 more attractive investment. The patient population identified as having EG and/or EGE/EoD in the
9 Prevalence Study was significantly different than the patient population in Phase 2 ENIGMA — the
10 patients in the Prevalence study had much lower blood eosinophils counts and a much higher
11 likelihood of a previous diagnosis of IBS. And, of course, unlike the vast majority of patients in
12 Phase 2 ENIGMA, the patients in the prevalence study had not been previously diagnosed with EG
13 and/or EGE/EoD. Accordingly, Defendant Tomasi was strongly motivated not to suggest that
14 differences between the patient population in Phase 2 and Phase 3 ENIGMA could have any
15 significance because any such suggestion would have called into question the results of the
16 Prevalence Study and undermined Allakos' claims about AK002's potential market. Accordingly,
17 Allakos did not reveal the differences between the patient population of Phase 3 and Phase 2
18 ENIGMA until it needed to provide the market with an explanation for why Phase 3 ENIGMA
19 failed.

20 **F. Defendants' Sale of Tens of Millions of Dollar in Allakos Common Stock in 2021**
21 **Showed That They Were Not Confident in the Results of Phase 3 ENIGMA.**

22 176. Prior to 2021, none of Defendants sold a single share of Allakos common stock on
23 the open market. Then in 2021, Defendants Tomasi, Alexander, and Rasmussen sold a combined
24 524,302 shares of Allakos common stock for proceeds of \$56,099,224. Defendants sold their shares
25 for the average price of almost \$107, more than 12 times what the stock was worth after the
26 Company announced the failure of Phase 3 ENIGMA.

27 ¹⁰ During the Morgan Stanley Healthcare Conference, Defendant Tomasi estimated that the
28 undiagnosed market of EGE/EoD was in the neighborhood of 2.5 million, but that could be an
"arguably conservative estimate." Regardless of the precise number of undiagnosed patients,
Allakos touted the Prevalence Study as representing a huge increase in the potential market for
AK002.

1 177. Defendant Tomasi sold 226,318 shares of Allakos common stock for proceeds of
2 \$23,794,432.37.

Date	Shares Sold	Price Per Share	Proceeds
3/3/2021	3,189	\$113.56	\$362,142.84
3/8/2021	20,000	\$122.78	\$2,455,600.00
3/9/2021	20,000	\$121.78	\$2,435,600.00
3/10/2021	20,000	\$121.78	\$2,435,600.00
4/12/2021	20,000	\$104.40	\$2,088,000.00
4/13/2021	20,000	\$103.08	\$2,061,600.00
4/14/2021	20,000	\$107.77	\$2,155,400.00
5/10/2021	20,000	\$96.02	\$1,920,400.00
5/11/2021	20,000	\$97.79	\$1,955,800.00
5/12/2021	20,000	\$99.23	\$1,984,600.00
6/4/2021	642	\$90.26	\$57,946.92
6/7/2021	2,487	\$92.03	\$228,878.61
6/14/2021	20,000	\$91.62	\$1,832,362.00
6/15/2021	20,000	\$91.03	\$1,820,502.00
Total Shares:	226,318	Total Proceeds:	\$23,794,432.37

15 178. Defendant Alexander sold 183,597 shares of Allakos common stock for proceeds of
16 \$19,180,771.53.

Date	Shares Sold	Price Per Share	Proceeds
3/15/2021	20,000	\$122.78	\$2,455,600.00
3/16/2021	20,000	\$121.76	\$2,435,200.00
3/17/2021	20,000	\$121.14	\$2,422,800.00
5/17/2021	14,517	\$99.68	\$1,447,054.56
5/17/2021	5,484	\$99.69	\$546,699.96
5/18/2021	14,517	\$102.32	\$1,485,379.44
5/18/2021	5,484	\$102.29	\$560,958.36
5/19/2021	14,516	\$98.94	\$1,436,213.04
5/19/2021	5,482	\$98.89	\$542,114.98
6/2/2021	14,517	\$94.55	\$1,372,582.35
6/2/2021	5,484	\$94.56	\$518,567.04
6/3/2021	14,517	\$92.14	\$1,337,596.38
6/3/2021	5,484	\$92.09	\$505,021.56
6/4/2021	3,597	\$89.62	\$322,363.14
6/4/2021	14,516	\$89.64	\$1,301,214.24

6/4/2021	5,482	\$89.64	\$491,406.48
Total Shares:	183,597	Total Proceeds:	\$19,180,771.53

179. Defendant Rasmussen sold 114,387 shares of Allakos common stock for proceeds of \$13,124,020.16.

Date	Shares Sold	Price Per Share	Proceeds
3/1/2021	20,000	\$120.66	\$2,413,200.00
3/2/2021	20,000	\$117.32	\$2,346,400.00
3/3/2021	20,000	\$113.00	\$2,260,000.00
3/3/2021	1,952	\$112.83	\$220,244.16
4/1/2021	20,000	\$114.40	\$2,288,000.00
4/5/2021	20,000	\$113.06	\$2,261,200.00
4/6/2021	10,000	\$111.68	\$1,116,800.00
6/4/2021	2,435	\$89.60	\$218,176.00
Total Shares:	114,387	Total Proceeds:	\$13,124,020.16

180. Defendant's sales of tens of millions of dollars of Allakos stock in 2021 after previously not selling any shares shows that they lacked confidence in the outcome in Phase 3 ENIGMA.

G. There is a Strong Inference Allakos Acted With Scienter.

181. Each of the Individual Defendants was a high-ranking management-level employee. The scienter of each of the Individual Defendants and of all other management-level employees of Allakos, including each high-ranking officer or director, is imputable to the Company. The knowledge of each of these individuals should therefore be imputed to Allakos for the purposes of assessing corporate scienter.

182. The facts alleged herein raise a strong inference of corporate scienter as to Allakos as an entity. Corporate scienter may be alleged independent of the finding that any Individual Defendant had scienter where a statement is made or approved by a corporate official sufficiently knowledgeable about the company to know the statement was false or misleading. Given the importance of the Phase 2 and Phase 3 ENIGMA to Allakos, the false and misleading statements alleged in this complaint would necessarily have required the approval of a corporate officer with knowledge that they were false and misleading.

PLAINTIFFS' CLASS ACTION ALLEGATIONS

1
2 183. Plaintiffs bring this action as a class action pursuant to Federal Rule of Civil
3 Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased Allakos
4 common stock during the Class Period, held it until the end of the Class Period, and were damaged
5 upon the revelation of the alleged corrective disclosures (the "Class"). Excluded from the Class are
6 Defendants herein, the officers and directors of the Company, at all relevant times, members of their
7 immediate families and their legal representatives, heirs, successors or assigns and any entity in
8 which Defendants have or had a controlling interest.

9 184. The members of the Class are so numerous that joinder of all members is
10 impracticable. Throughout the Class Period, Allakos common stock were actively traded on the
11 NASDAQ. While the exact number of Class members is unknown to Plaintiffs at this time and can
12 be ascertained only through appropriate discovery, Plaintiffs believe that there are hundreds or
13 thousands of members in the proposed Class. Record owners and other members of the Class may
14 be identified from records maintained by the Company or its transfer agent and may be notified of
15 the pendency of this action by mail, using the form of notice similar to that customarily used in
16 securities class actions.

17 185. Plaintiffs' claims are typical of the claims of the members of the Class as all
18 members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal
19 law that is complained of herein.

20 186. Plaintiffs will fairly and adequately protect the interests of the members of the Class
21 and has retained counsel competent and experienced in class and securities litigation. Plaintiffs have
22 no interests antagonistic to or in conflict with those of the Class.

23 187. Common questions of law and fact exist as to all members of the Class and
24 predominate over any questions solely affecting individual members of the Class. Among the
25 questions of law and fact common to the Class are:

- 26 • whether the federal securities laws were violated by Defendants' acts as alleged
27 herein;

- 1 • whether statements made by Defendants to the investing public during the Class
2 Period misrepresented material facts about the financial condition, business,
3 operations, and management of the Company;
- 4 • whether Defendants' public statements to the investing public during the Class
5 Period omitted material facts necessary to make the statements made, in light of the
6 circumstances under which they were made, not misleading;
- 7 • whether the Individual Defendants caused the Company to issue false and misleading
8 SEC filings and public statements during the Class Period;
- 9 • whether Defendants acted knowingly or recklessly in issuing false and misleading
10 SEC filings and public statements during the Class Period;
- 11 • whether the prices of Allakos common stock during the Class Period were artificially
12 inflated because of the Defendants' conduct complained of herein; and
- 13 • whether the members of the Class have sustained damages and, if so, what is the
14 proper measure of damages.

15 188. A class action is superior to all other available methods for the fair and efficient
16 adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the
17 damages suffered by individual Class members may be relatively small, the expense and burden of
18 individual litigation make it impossible for members of the Class to individually redress the wrongs
19 done to them. There will be no difficulty in the management of this action as a class action.

20 189. Plaintiffs will rely, in part, upon the presumption of reliance established by the fraud-
21 on-the-market doctrine in that:

- 22 • Defendants made public misrepresentations or failed to disclose material facts during
23 the Class Period;
- 24 • the omissions and misrepresentations were material;
- 25 • Allakos common stock are traded in an efficient market;
- 26 • the Company's common stock were liquid and traded with moderate to heavy
27 volume during the Class Period;
- 28 • the Company traded on the NASDAQ, and was covered by multiple analysts;

- 1 • the misrepresentations and omissions alleged would tend to induce a reasonable
- 2 investor to misjudge the value of the Company's common stock; and
- 3 • Plaintiffs and members of the Class purchased and/or sold Allakos common stock
- 4 between the time the Defendants failed to disclose or misrepresented material facts
- 5 and the time the true facts were disclosed, without knowledge of the omitted or
- 6 misrepresented facts.

7 190. Based upon the foregoing, Plaintiffs and the members of the Class are entitled to a
8 presumption of reliance upon the integrity of the market.

9 191. Alternatively, Plaintiffs and the members of the Class are entitled to the presumption
10 of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v.*
11 *United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in
12 their Class Period statements in violation of a duty to disclose such information, as detailed above.

13 **COUNT I**

14 **Violation of Section 10(b) of The Exchange Act and Rule 10b-5**
15 **Against All Defendants**

16 192. Plaintiffs repeat and realleges each and every allegation contained above as if fully
17 set forth herein.

18 193. This Count is asserted against the Company and the Individual Defendants and is
19 based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated
20 thereunder by the SEC.

21 194. During the Class Period, the Company and the Individual Defendants, individually
22 and in concert, directly or indirectly, disseminated or approved the false statements specified above,
23 which they knew or deliberately disregarded were misleading in that they contained
24 misrepresentations and failed to disclose material facts necessary in order to make the statements
25 made, in light of the circumstances under which they were made, not misleading.

26 195. The Company and the Individual Defendants violated §10(b) of the 1934 Act and
27 Rule 10b-5 in that they:

- 28 • employed devices, schemes and artifices to defraud;

- 1 • made untrue statements of material facts or omitted to state material facts necessary
2 in order to make the statements made, in light of the circumstances under which they
3 were made, not misleading; or
- 4 • engaged in acts, practices and a course of business that operated as a fraud or deceit
5 upon Plaintiffs and others similarly situated in connection with their purchases of
6 Allakos common stock during the Class Period.

7 196. The Company and the Individual Defendants acted with scienter in that they knew
8 that the public documents and statements issued or disseminated in the name of the Company were
9 materially false and misleading; knew that such statements or documents would be issued or
10 disseminated to the investing public; and knowingly and substantially participated, or acquiesced in
11 the issuance or dissemination of such statements or documents as primary violations of the
12 securities laws. These Defendants by virtue of their receipt of information reflecting the true facts of
13 the Company, their control over, and/or receipt and/or modification of the Company's allegedly
14 materially misleading statements, and/or their associations with the Company which made them
15 privy to confidential proprietary information concerning the Company, participated in the
16 fraudulent scheme alleged herein.

17 197. Individual Defendants, who are the senior officers and/or directors of the Company,
18 had actual knowledge of the material omissions and/or the falsity of the material statements set forth
19 above, and intended to deceive Plaintiffs and the other members of the Class, or, in the alternative,
20 acted with reckless disregard for the truth when they failed to ascertain and disclose the true facts in
21 the statements made by them or other personnel of the Company to members of the investing
22 public, including Plaintiffs and the Class.

23 198. As a result of the foregoing, the market price of Allakos common stock was
24 artificially inflated during the Class Period. In ignorance of the falsity of the Company's and the
25 Individual Defendants' statements, Plaintiffs and the other members of the Class relied on the
26 statements described above and/or the integrity of the market price of Allakos common stock during
27 the Class Period in purchasing Allakos common stock at prices that were artificially inflated as a
28 result of the Company's and the Individual Defendants' false and misleading statements.

1 199. Had Plaintiffs and the other members of the Class been aware that the market price
2 of Allakos common stock had been artificially and falsely inflated by the Company's and the
3 Individual Defendants' misleading statements and by the material adverse information which the
4 Company's and the Individual Defendants did not disclose, they would not have purchased Allakos
5 common stock at the artificially inflated prices that they did, or at all.

6 200. As a result of the wrongful conduct alleged herein, Plaintiffs and other members of
7 the Class have suffered damages in an amount to be established at trial.

8 201. By reason of the foregoing, the Company and the Individual Defendants have
9 violated Section 10(b) of the 1934 Act and Rule 10b-5 promulgated thereunder and are liable to the
10 Plaintiff and the other members of the Class for substantial damages which they suffered in
11 connection with their purchases of Allakos common stock during the Class Period.

12 **COUNT II**

13 **Violation of Section 20(a) of The Exchange Act**
14 **Against The Individual Defendants**

15 202. Plaintiffs repeats and realleges each and every allegation contained in the foregoing
16 paragraphs as if fully set forth herein.

17 203. During the Class Period, the Individual Defendants participated in the operation and
18 management of the Company, and conducted and participated, directly and indirectly, in the
19 conduct of the Company's business affairs. Because of their senior positions, they knew the adverse
20 non-public information regarding the Company's business practices.

21 204. As officers and/or directors of a publicly owned company, the Individual Defendants
22 had a duty to disseminate accurate and truthful information with respect to the Company's financial
23 condition and results of operations, and to correct promptly any public statements issued by the
24 Company which had become materially false or misleading.

25 205. Because of their positions of control and authority as senior officers, the Individual
26 Defendants were able to, and did, control the contents of the various reports, press releases and
27 public filings which the Company disseminated in the marketplace during the Class Period.
28 Throughout the Class Period, the Individual Defendants exercised their power and authority to

1 cause the Company to engage in the wrongful acts complained of herein. The Individual
2 Defendants, therefore, were “controlling persons” of the Company within the meaning of Section
3 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which
4 artificially inflated the market price of Allakos common stock.

5 206. Each of the Individual Defendants, therefore, acted as a controlling person of the
6 Company. By reason of their senior management positions and/or being directors of the Company,
7 each of the Individual Defendants had the power to direct the actions of, and exercised the same to
8 cause, the Company to engage in the unlawful acts and conduct complained of herein. Each of the
9 Individual Defendants exercised control over the general operations of the Company and possessed
10 the power to control the specific activities which comprise the primary violations about which
11 Plaintiffs and the other members of the Class complain.

12 207. By reason of the above conduct, the Individual Defendants are liable pursuant to
13 Section 20(a) of the Exchange Act for the violations committed by the Company.

14 **PRAYER FOR RELIEF**

15 WHEREFORE, Plaintiffs demand judgment against Defendants as follows:

16 A. Determining that the instant action may be maintained as a class action under Rule
17 23 of the Federal Rules of Civil Procedure, and certifying Plaintiffs as the Class representative;

18 B. Requiring Defendants to pay damages sustained by Plaintiffs and the Class by reason
19 of the acts and transactions alleged herein;

20 C. Awarding Plaintiffs and the other members of the Class prejudgment and post-
21 judgment interest, as well as their reasonable attorneys’ fees, expert fees and other costs; and

22 D. Awarding such other and further relief as this Court may deem just and proper.

23 **DEMAND FOR TRIAL BY JURY**

24 Plaintiffs hereby demand a trial by jury.

25
26 Dated: April 29, 2022

Respectfully submitted,

27 **THE ROSEN LAW FIRM, P.A.**

28 By: /s/ Laurence M. Rosen

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