

Plaintiff John King ("Plaintiff"), individually and on behalf of all other

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- persons similarly situated, by his undersigned attorneys, alleges in this Complaint for violations of the federal securities laws (the "Complaint") the following based upon knowledge with respect to his own acts, and upon facts obtained through an investigation conducted by his counsel, which included, inter alia: (a) review and analysis of relevant filings made by aTyr Pharma Inc. ("aTyr" or the "Company") with the United States Securities and Exchange Commission (the "SEC"); (b) review and analysis of aTyr's public documents, conference calls, press releases, and stock chart; (c) review and analysis of securities analysts' reports and advisories concerning the Company; and (d) information readily obtainable on the internet.
- Plaintiff believes that further substantial evidentiary support will exist 2. for the allegations set forth herein after a reasonable opportunity for discovery. Most of the facts supporting the allegations contained herein are known only to the defendants or are exclusively within their control.

NATURE OF THE ACTION

- 3. This is a federal securities class action on behalf of all investors who purchased or otherwise acquired aTyr common stock, purchased call options on aTyr common stock, and/or sold put options on aTyr common stock, between November 7, 2024, and September 12, 2025, inclusive (the "Class Period"), seeking to recover damages caused by Defendants' violations of the federal securities laws (the "Class").
- aTyr is a clinical-stage biotechnology company engaged in the development of therapies for fibrosis and inflammation. The Company's lead therapy candidate is Efzofitimod, a biologic immunomodulator in clinical development for treating interstitial lung diseases.
- 5. Leading up to the start of the Class Period, aTyr began enrollment for a later phase trial of Efzofitimod. The so called "EFZO-FIT" trial was designed as a global Phase 3 randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of Efzofitimod in patients with pulmonary sarcoidosis. A primary

endpoint of the EFZO-FIT trial was to show the therapy's ability to reduce a patient's steroid usage.

- 6. Throughout the Class Period, the Defendants provided investors with material information concerning the EFZO-FIT trial. This information included, among other things, statements from aTyr's Chief Executive Officer on his confidence in the forced steroid taper approach in the EFZO-FIT's study design.
- 7. Defendants provided these overwhelmingly positive statements to investors while, at the same time, disseminating false and misleading statements and/or concealing material adverse facts concerning the efficacy of Efzofitimod. Principally, Defendants misled investors on the therapy's ability to allow a patient to significantly taper steroid usage. This caused Plaintiff and other shareholders to trade aTyr's securities at artificially inflated prices.
- 8. The truth emerged on September 15, 2025, before market open, when aTyr hosted an investor call. The Company disclosed that the EFZO-FIT trial failed to meet its primary endpoint. Specifically, Efzofitimod usage at 48 weeks did not achieve the hyped steroid dose reduction and results showed only minor differences from placebo. aTyr also announced that the Company's next step was to engage with the FDA to determine a path forward, given the disappointing outcome.
- 9. Investors and analysts reacted immediately to aTyr's disclosures. aTyr's common stock price declined from a market close price of \$6.03 per share on September 12, 2025, to \$1.02 per share on September 15, 2025, an 83.2% price decline over a single trading day.
- 10. Defendants' fraudulent statements have caused investors to sustain significant damages. Accordingly, Plaintiff seeks to recover those damages by way of this securities class action.

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- 11. Plaintiff brings this action, on behalf of himself and other similarly situated investors, to recover losses sustained in connection with Defendants' fraud.
- 12. The claims asserted herein arise under and pursuant to §§10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. §240.10b-5).
- 13. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§1331 and 1337, and Section 27 of the Exchange Act, 15 U.S.C. §78aa.
- 14. Venue is proper in this District pursuant to §27 of the Exchange Act and 28 U.S.C. §1391(b), as Defendant aTyr is headquartered in this District and a significant portion of its business, actions, omissions, and the subsequent damages to Plaintiff and the Class, took place within this District.
- 15. In connection with the acts, conduct and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mail, interstate telephone communications and the facilities of the national securities exchange.

THE PARTIES

- 16. Plaintiff purchased aTyr common stock at artificially inflated prices during the Class Period and was damaged upon the revelation of the Defendants' fraud. Plaintiff's certification evidencing his transactions in aTyr is attached hereto.
- 17. aTyr Pharma, Inc. is a Delaware corporation with its principal executive offices located at 10240 Sorrento Valley Road, Suite 300, San Diego, CA 92121. During the Class Period, the Company's common stock traded on the Nasdaq stock market (the "NASDAQ") under the symbol "ATYR".
- 18. Defendant Sanjay S. Shukla ("Shukla") was, at all relevant times, the President, Chief Executive Officer, and a Director of aTyr.

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- 19. Defendant Shukla is sometimes referred to herein as the "Individual Defendant." aTyr together with the Individual Defendant are referred to herein as the "Defendants."
- 20. The Individual Defendant, because of his position with the Company, possessed the power and authority to control the contents of aTyr's reports to the SEC, press releases, and presentations to securities analysts, money and portfolio managers, and institutional investors, i.e., the market. The Individual Defendant was provided with copies of the Company's reports and press releases alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of his position and access to material non-public information available to them, the Individual Defendant knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations which were being made were then materially false and/or misleading. The Individual Defendant is liable for the false statements pleaded herein, as those statements were each "grouppublished" information, the result of the collective actions of the Individual Defendant.
- 21. aTyr is liable for the acts of the Individual Defendant, and its employees under the doctrine of respondeat superior and common law principles of agency as all the wrongful acts complained of herein were carried out within the scope of their employment with authorization.
- The scienter of the Individual Defendant, and other employees and 22. agents of the Company are similarly imputed to aTyr under respondeat superior and agency principles.

SUBSTANTIVE ALLEGATIONS

Company Background

23. aTyr describes itself as a clinical-stage biotechnology company leveraging evolutionary intelligence to develop novel therapies targeting fibrosis and

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inflammation. The Company focuses on the biology of tRNA synthetases—so called ancient and essential proteins that, beyond their traditional roles, have evolved unique extracellular domains that influence diverse signaling pathways in humans. Through its proprietary discovery platform, aTyr explores these domains across all 20 tRNA synthetases to uncover previously hidden therapeutic targets. The Company's lead candidate, Efzofitimod, is a biologic immunomodulator in clinical development for treating interstitial lung disease, pulmonary sarcoidosis in particular.

- Prior to the start of the Class Period, aTyr conducted a Phase 1b/2a clinical trial of Efzofitimod for patients with pulmonary sarcoidosis (the "Phase 1b/2a Trial"). The main objective of the Phase 1b/2a Trial was to evaluate the safety, tolerability, immunogenicity, and pharmacokinetic profile of multiple doses of Efzofitimod compared to placebo. Secondary objectives included the potential steroid-sparing effects of Efzofitimod, in addition to other exploratory assessments of efficacy.
- On October 2, 2024, aTyr issued a press release announcing the 25. publication of a post hoc analysis of the Phase 1b/2a Trial in the European Respiratory Journal. The publication, entitled, "Therapeutic Doses of Efzofitimod Demonstrate Efficacy in Pulmonary Sarcoidosis" reported that treatment with Efzofitimod at therapeutic doses, as compared with a subtherapeutic dose or placebo, was associated with a lower rate of relapse as oral corticosteroids ("OCS") were tapered. Time-to-first-relapse was defined as the interval from the date of the first successful OCS" taper to the date when "rescue" therapy was first required.
 - 26. Defendant Shukla was quoted in the press release stating:

We continue to publish data from our Phase 1b/2a study that further demonstrate the efficacy of Efzofitimod in pulmonary sarcoidosis patients and positions this first-inclass immunomodulator as a promising new treatment option that can reduce or avoid steroid-related toxicity. We believe we are on the cusp of a paradigm shift in the treatment for sarcoidosis, where patients may have the

opportunity to receive clinically validated therapies that can treat their underlying disease without incurring added harm.

27. On October 8, 2024, aTyr issued a press release announcing that Efzofitimod was being featured in the *Best of CHEST Journals* session at the CHEST 2024 Annual Meeting, taking place October 6 - 9, 2024, in Boston, Massachusetts. Defendant Shukla was quoted in the press release stating:

We are very pleased to have Efzofitimod featured in this year's Best of CHEST session, which speaks to the high quality of the data from the Phase 1b/2a study that was previously published in the journal. We believe the findings from this study, which showed the ability of Efzofitimod to reduce—and in some cases eliminate— steroid use in patients while controlling symptoms, are an important step forward in developing a potential new treatment for sarcoidosis.

28. Before the Class Period, the Company also began enrollment for a subsequent trial phase of Efzofitimod—The EFZO-FIT trial—designed as a global Phase 3 randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of Efzofitimod in patients with pulmonary sarcoidosis. The EFZO-FIT trial was designed as a 52-week study consisting of three parallel cohorts randomized equally to either 3.0 mg/kg or 5.0 mg/kg of Efzofitimod or placebo dosed intravenously once a month for a total of 12 doses. The trial would incorporate a forced steroid taper, with steroid reduction as the primary endpoint of the study. Secondary endpoints would include measures of lung function and sarcoidosis symptoms.

The Defendants' Materially False and Misleading Statements Concerning aTyr's Phase 3 Study of Efzofitimod

The Third Quarter 2024 Financial Report

29. The Class Period begins on November 7, 2024, when aTyr issued a press release announcing its third quarter 2024 financial results and providing a corporate

We achieved a significant milestone this quarter by completing enrollment in our global pivotal Phase 3 EFZO-FIT study in pulmonary sarcoidosis and topline data is expected in the third quarter of 2025. Additionally, our Efzofitimod program was featured in this year's Best of CHEST Journals session at the CHEST 2024 annual meeting and we recently published favorable steroid relapse data for Efzofitimod in the European Respiratory Journal. These events have generated increased interest in Efzofitimod and the potential promise it holds to be a transformative therapy for patients.

(Emphasis added).

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<u>aTyr Announces a Third Positive DSMB</u> <u>Review for Efzofitimod in Phase 3 EFZO-FIT</u>

- 31. On December 10, 2024, aTyr issued a press release announcing a third positive DSMB review for Efzofitimod in the Phase 3 EFZO-FIT study (the "DSMB Review Release"). The DSMB Review Release reported that the DSMB had reviewed all 268 patients enrolled in the study and recommended its continuation without modification.
 - 32. Defendant Shukla was quoted in the DSMB Review Release stating: We are pleased to report yet another positive safety review for Efzofitimod, that have been enrolled in which includes all 268 patients our global pivotal Phase 3 EFZO-FITTM study. *Safety is paramount when looking to provide a*

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disease modifying treatment for a chronic condition such as pulmonary sarcoidosis, where reducing or replacing a toxic standard of care such as oral corticosteroids could be highly meaningful and improve quality of life for patients.

aTyr's Presentation at the 43rd Annual J.P. Morgan Healthcare Conference

33. On January 16, 2025, aTyr provided a presentation at the 43rd Annual J.P. Morgan Healthcare Conference. As part of the event, Defendant Shukla gave an update on the Phase 3 EFZO-FIT study, stating in relevant part:

aTyr is a company that has a real major Phase 3 catalyst later this year in Q3. And much of the presentation is going to center around the opportunity in interstitial lung disease with our therapy Efzofitimod. And it has been a journey to advance what we think is a paradigm shifting therapy in a multibillion-dollar space. So, we're carving out really new territory here, and we're the leading interstitial lung disease company in the world with one of the only programs to ever even make it to Phase 3 in these indications.

* * *

Efzofitimod is our lead asset in Phase 3. It's a first-in-class biologic with an approach to interstitial lung disease that is generating fantastic results thus far. And we'll talk to you about some of that data and why we feel that way. And how we're addressing interstitial lung disease with Efzofitimod.

* * *

And I'm sure you've heard a lot of companies over the last several days talk[] about dose response. We not only saw dose response, but we saw it in all of those end points we measured. So, it gives us a lot of confidence moving here into Phase 3.

Last thing, no known safety issues. We are replacing toxic therapy. So, patients deserve something that is not going to create a new burden of toxicity. This modality offers that opportunity. And it's why patients who are currently

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finishing our trial are demanding to remain in our trial right now, even though they're blinded and we are blinded to what they're receiving -- the respite from some of the toxic therapies that they've been receiving for some time, five or 10 years, in this trial has been something that they want more of.

* * *

So Efzofitimod is positioned as a frontline steroid-sparing and/or reducing agent. We are seeing quite remarkable steroid-sparing effects in our blinded reviews. But the idea here is, can we reduce at a minimum, reduce or maybe even eliminate steroids. And let's avoid some of those toxic effects. And let's also then avoid getting to those third-line agents, which don't work well either and also come with their own toxic baggage. So upwards of 75 percent of the patients, we think here could be targeted with Efzofitimod.

* * *

Our global Phase 3 design is fully enrolled, a good timing for all of you. We're finished with enrollment, and now we're just waiting for data. This was now a well-powered and highly powered designed trial, 88 patients per arm. We took the two efficacious doses in Phase 2 forward. We finally enrolled 268 patients.

Some key things here. In the last trial, we noticed we could knockdown steroids pretty well down to five milligrams, but we're leaning into that signal a little bit more in this trial, and we're attempting to taper people to 0. And we're already seeing benefit in many of the patients, as I mentioned, who have finished the trial. We're now refusing to go back on steroids.

So, we've had to step up with an expanded access program rather quickly here, working with certain regions that allow it. But this is a patient -- this is a trial where we'll look to taper down from an entry dose of 7.5 to 2.5 and then observe patients from week 12 to week 48. What we expect to see in the placebo population is flaring exacerbation, and you'll see that prednisone dose jumps back up.

We think using our drug, we can keep patients at low or no dose. But that's really what we're trying to basically see with our statistical delta. I'm trying to see a difference in that average daily prednisone dose. And even if we could peel away one or two milligrams, agencies look at that as important.

Why? Because it's a cumulative reduction of that burden, 10, 15, 20 less milligrams of prednisone a week, 80, 100 less a month, that adds up to positive benefit for these patients with their quality of life. If we can do that and maintain that immune balance, I think we have something really special here.

(Emphasis added).

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- 34. During the same conference, the Individual Defendant answered questions from analysts. Defendant Shukla had the following relevant exchange with an attendee who asked about the Phase 3 EFZO-FIT study design:
 - <Q: Unidentified Attendee> As it relates to the Phase 3, can you explain the steroid taper protocol? How is it similar or different to the Phase 2? And how are you thinking about minimizing the [principal investigator ("PI")] discretion and subjectivity?
 - <A: Defendant Shukla> Yes, it's a great question because with some of those approved therapies that are out there, there was a lot of contentious debate because there's investigator subjective judgment. And one of the things we work with the agency is, let's have a validated tool that guides taper decisions. And perhaps they even learned from the TAVNEOS approval.

So, we have a tool we use the [Patient Global Assessment ("PGA")]. It's a validated instrument that every two weeks, we're assaying these patients, how are you doing? How have your last two weeks been? And if there's any worsening on that PGA, even a one-point worsening, there's an automatic edit check that goes out from drug—from data management even saying we should see a steroid increase.

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So, patients are asked to follow their prednisone dose every day in their trial. If there's a worsening in PGA every two weeks, it's being assayed, and that guides some of that judgment. So, we're taking a little bit of the keys away of the car from the pulmonologists here because we want to have that titration based on the PGA.

How is it different? One of the key differences, as I mentioned, we knocked everyone down to five milligrams and then look to see if they flare in the last trial. This trial we're knocking folks down to zero. So, what we expect is more unmasking of disease in placebo, more steroid rescue there. That could then serve as how I said with the area into the curve, a delta emerge. So those are some of the key differences on how we're minimizing some of that investigator bias, but also potentially seeing a greater signal of steroids bearing with EFZO.

(Emphasis added).

35. On March 13, 2025, aTyr issued a press release announcing its fourth quarter and full year 2024 financial results and providing a corporate update. On the same day, the Company hosted an analyst conference call to discuss its results. During the call, Defendant Shukla provided an update on the Phase 3 EFZO-FIT study, stating in relevant part:

2024 was an important year for aTyr as we completed enrollment in our global pivotal Phase 3 EFZO-FIT study of Efzofitimod in patients with pulmonary sarcoidosis in major form of ILD, which is our lead indication. This is the largest interventional study ever conducted in pulmonary sarcoidosis, and we look forward to releasing top-line data from this study in the third quarter of this year.

EFZO-FIT is a randomized, double-blind, placebocontrolled 52-week study. It consists of three parallel cohorts, randomized equally to either three milligrams per kilogram or five milligrams per kilogram of Efzofitimod or

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placebo, dosed intravenously monthly for a total of 12 doses.

The study enrolled 268 patients at 85 centers in nine countries. The trial design incorporates a forced steroid taper with steroid reduction as the primary endpoint of the study.

Secondary endpoints include measures of sarcoidosis quality of life and lung function. Patients who complete the study and wish to receive treatment with Efzofitimod outside of the clinical trial are eligible to participate in an individual patient expanded access program, or EAP.

The EAP was implemented primarily based on feedback from multiple study principal investigators or PIs whose patients requested to continue treatment once they had completed the study. These patients will receive five milligrams per kilogram of Efzofitimod while in the EAP.

However, PIs, patients, and the company remain blinded to the EFZO-FIT treatment assignments of these EAP patients. Additionally, we have now held four positive Data and Safety Monitoring Board or DSMB reviews for this study, all of which have identified no safety concerns and recommended that the study continue unmodified.

The most recent preplanned independent review indicates that the study continues to track well from a safety standpoint. We remain confident in the favorable safety profile we have seen for Efzofitimod to date, which we believe is the key value proposition of the drug.

Finally, we'll get our first look at the blinded baseline demographic and disease characteristics of the patients enrolled in the study at the upcoming American Thoracic Society Conference, or ATS, which is scheduled to take place mid-May in San Francisco.

In a poster, we will be able to get a sense of the profile of the patients enrolled, including baseline steroid dose and

background immunomodulator use and how the profile matches the inclusion and exclusion criteria for the study.

As part of our planning for the Phase 3 readout for EFZO-FIT, we recently held a Type C meeting with the US Food and Drug Administration or FDA. The main objective of this meeting was to discuss the statistical analysis plan, or SAP, for the study, including how the primary and secondary endpoints are assessed statistically.

For the primary endpoint, we determined how steroid reduction will be analyzed in the SAP.

As we previously discussed, we initially proposed that we measure steroid reduction based on calculating the average daily steroid dose between week 12 and week 48, which is the protocol-specified post-steroid taper period.

We viewed this as a conservative way of measuring steroid reduction in the study. Based on FDA feedback, we will now measure steroid reduction as the absolute change from baseline to week 48.

We feel this change creates a more simplified assessment to capture the potential steroid delta between groups. The statistical powering for the study remains intact, and we are pleased with the clarification around how we will measure steroid reduction.

With limited clinical studies in sarcoidosis as a benchmark, we are pioneering a path forward to measure how we can potentially improve the lives of these patients.

(Emphasis added.)

- 36. During the same call, the Defendants held a question-and-answer session with financial analysts. Defendant Shukla had the following relevant exchanges with analysts inquiring about the Phase 3 EFZO-FIT study enrollment and design:
 - <Q: Derek Christian Archila, Wells Fargo Securities> I know you highlighted in the prepared comments that there

was investigator and patient enthusiasm for the EAP. So, I just wanted to ask if you have any idea in terms of the percentage of the patients who are in the trial rolling over into the expanded access or a new program there.

<A: Defendant Shukla> Yes, it's a common question I get: how many patients? What's the percent? And I want to start by saying we have seen continued interest, growing interest. But the issue really here is that not all countries and not all centers can participate based on their local regulatory requirements. I've said this before: countries like Japan, for example, do not have a pathway to participate in an EAP-type program.

So, you'd have to subtract out all of those regions that aren't involved and then try to come up with a crude measure of response, which is what I think a lot of investors want to do here.

What I can say is that the interest is still very robust. I was just with about 30 experts recently this past weekend. There continues to be more and more interest in participating in the EAP.

We have committed to helping patients who are performing well in the trial to roll into the EAP, but it's an individual site-by-site decision because, of course, we are not in a formal open-label type extension. So very pleased with the progress. I think it's a great signal, a great interim biomarker, if you will. And we're going to continue to support those patients to move into that EAP. But again, to get into specific numbers and try to get into the math, it's probably not helpful.

And just as a reminder, we are blinded. We're blinded to what these patients are on during the trial. So, there's always a chance that all of these patients are on placebo and that they have been able to taper more or less off their steroids and it doesn't have anything to do with the drug.

So, people know me to be rather conservative in my messaging. I just think it's a great signal to see that

patients who are finishing a trial want to remain in the trial. That, to me, as a former clinician, speaks very powerful to what something is happening during the trial.

<Q: Yasmeen Rahimi, Piper Sandler> Congrats on all the exciting progress and an exciting year ahead of us. I got two quick questions. One is around managing patients with steroid reduction that led to engaging with the agency to make this change from a sort of clinical perspective.

Just maybe if you could kind of shed light on how that meeting came about and why the change makes absolute sense, but maybe the question would be why implement it now and the rationale behind it? That's sort of question one.

And question two, it's really exciting to see the baseline demographics from the study here upcoming at ATS. Could you maybe help us understand what we should be looking for? Obviously, it's a tremendous study with globally, lots of work that went into it. So just kind of help us framework on what are some of the measures that we should be looking closely to in terms of this patient population. And I'll jump back in the queue.

<A: Defendant Shukla> Great questions. I will take the first one and say that the market research is not necessarily really connected to this type of meeting. This is a little inside baseball biostatistics but typically before you lock your database, you have all the rules set up with the Biostats division.

And as a former biostatistician, it's important that we really agree to all the pre-hoc analysis. I think far too many times in biotech, we implement rules, and then after data comes out, we start to do post-hoc analysis and cherry-pick and cut and slice the data. And I wish more biopharmas wouldn't do that.

So we're very rigorous, and I like to be very rigorous around, hey, let's get everything pre-hoc organized down

to the details exactly how do you want us to program and even look at some of this steroid reduction.

But we have proposed something that I viewed as a fairly conservative way of looking at steroids and the average daily steroid dose upon interacting with the FDA here. Their view was this approach would be fine, the suggested approach where we're looking at just a simplified change from baseline.

I'm not going to disagree with that. I'm going to go ahead and implement that approach because, as I said, I think this actually allows us to potentially maximize a signal at the end of the trial.

Remember, there's a forced steroid taper component. Placebo patients will get the benefit of that reduction of the forced steroid taper. But now looking at the end of the trial, the clinical team and I view this as potentially a way to maximize a signal here because as I pointed out, all those peaks and valleys that occur over the course of the trial now should be adequately handled, observed and now we'll have a true measure at the end of the trial.

Your second question was really around the baseline demographics. It's important to put this out. The community is really interested. They want to see data as quickly as possible. Many of our PIs have said, can we take a look at background immunomodulator use. We just want to see the data.

We'd like to see what the average daily steroid doses, duration of disease, and things of that nature. So, these are all important things for us to show to the community, and we already have that data. It's just baseline data. So, why not put it out at a major medical conference?

The important thing for investors to pay attention to is the average prednisone dose. I'll remind everyone in the last trial, the Phase 2 trial, we had an average dose somewhere in that 11 to 13 range. This trial, where we're enrolling patients with a slightly lower basement dose of 7.5

milligrams, I expect that prednisone dose may be maybe a little bit lower, but we want to take a look at that. And then that helps with all the investors that want to do the modeling with regards to how much steroid delta you want to see there.

So it's important to get this baseline data out there, make sure we more or less enrolled per the IE criteria in our trial.

(Emphasis added.)

The First Quarter 2025 Financial Report

37. On May 7, 2025, aTyr issued a press release announcing first quarter 2025 financial results and providing a corporate update (the "1Q25 Press Release"). The 1Q25 Press Release included an update on aTyr's Phase 3 EFZO-FIT study, stating in pertinent part:

On track to announce topline data in the third quarter of 2025 from the global pivotal Phase 3 EFZO-FITTM study to evaluate the efficacy and safety of efzofitimod in patients with pulmonary sarcoidosis. This is a randomized, doubleblind, placebo-controlled, 52-week study consisting of three parallel cohorts randomized equally to either 3.0 mg/kg or 5.0 mg/kg of efzofitimod or placebo administered intravenously monthly for a total of 12 doses. The study enrolled 268 patients with pulmonary sarcoidosis at 85 centers in nine countries. The trial design incorporates a forced steroid taper. The primary endpoint of the study is steroid reduction measured as the absolute change from baseline to week 48. Secondary endpoints include measures of sarcoidosis symptoms and lung function. Patients who complete the study and wish to receive treatment with efzofitimod outside of the clinical trial are eligible to participate in an Individual Patient Expanded Access Program.

(Emphasis added.)

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The Second Quarter 2025 Financial Report

38. On August 7, 2025, aTyr issued a press release announcing second quarter 2025 financial results and providing a corporate update ("2Q25 Press Release"). The 2Q25 Press Release included an update on aTyr's Phase 3 EFZO-FIT study, stating in relevant part:

Completed the last patient visit in the global pivotal Phase 3 EFZOFITTM study to evaluate the efficacy and safety of efzofitimod in patients with pulmonary sarcoidosis. Topline data from the study are expected in mid-September 2025. This is a randomized, double-blind, placebo-controlled, 52week study consisting of three parallel cohorts randomized equally to either 3.0 mg/kg or 5.0 mg/kg of efzofitimod or placebo administered intravenously monthly for a total of 12 doses. The study enrolled 268 patients with pulmonary sarcoidosis across 85 centers in nine countries. The trial design incorporates a forced steroid taper. The primary endpoint of the study is steroid reduction measured as the absolute change from baseline to week 48. Secondary endpoints include measures of sarcoidosis symptoms and lung function. Patients who complete the study and wish to receive treatment with efzofitimod outside of the clinical trial are eligible to participate in an Individual Patient Expanded Access Program.

39. Included in the 2Q25 Press Release was a quote from Defendant Shukla on the Phase 3 EFZO-FIT study, stating in relevant part:

With the recent completion of the last patient visit in our Phase 3 EFZOFIT TM study of efzofitimod in pulmonary sarcoidosis, a major form of interstitial lung disease (ILD), we are on track to report topline data in mid-September. This upcoming readout represents a major inflection point for aTyr, our clinical program for efzofitimod in ILD, and the broader sarcoidosis community, and we look forward to sharing the results.

40. The above statements in Paragraphs 23 to 39 were false and/or materially misleading. Specifically, Defendants misconstrued adverse facts

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concerning aTyr's study design for EFZO-FIT, giving the false impression that Efzofitimod would meet its primary endpoint. Further, Defendants misled investors by creating an impression that the Phase 3 EFZO-FIT study would: (a) reveal the therapy's efficacy when compared with the placebo through the study's forced steroid taper design; and (b) allow patients to effectively remove steroids from their treatment plans. However, Defendants failed to disclose that the design study was not signaling the endpoint objective and there may be other factors that permit patients to effectively remove steroids from their treatment plans. Therefore, the Phase 3 EFZO-FIT study would fail to meet the primary endpoint in change from baseline in mean daily OCS dose at week 48.

The Truth Emerges

aTyr Pharma Announces Topline Results from Phase 3 EFZO-FIT Study

41. On September 15, 2025, before market open, aTyr issued a press release announcing topline results from its Phase 3 EFZO-FIT study. In conjunction with the announcement, aTyr hosted an investor presentation that included the following slides on key findings, takeaways and next steps:

Summary of Key Findings

- Study did not meet primary endpoint in change from baseline in mean daily OCS dose at week 48
- 52.6% of patients treated with 5.0 mg/kg efzofitimod achieved complete steroid withdrawal at week 48 vs 40.2% on placebo (p=0.0919)
- Clinical improvement in KSQ-Lung score at week 48 observed in the 5.0 mg/kg efzofitimod treatment group vs placebo (p=0.0479).
- Greater proportion of patients achieved complete steroid withdrawal at week 48 with a KSQ-Lung score improvement in the 5.0 mg/kg efzofitimod treatment group (29.5%) vs placebo (14.4%) (p=0.0199)
- Lung function as measured by forced vital capacity (FVC) at week 48 was maintained
- Efzofitimod was generally well-tolerated at both the 3.0 mg/kg and 5.0 mg/kg doses, consistent with a previously observed safety profile in all trials conducted to date
- · Findings demonstrate drug activity for efzofitimod across multiple clinically relevant efficacy endpoints
- Company plans to engage with the U.S. FDA to determine the path forward for efzofitimod in pulmonary sarcoidosis

OCS = oral corticosteroids; KSQ = King's Sarcoidosis Questionnaire; FDA = Food and Drug Administration



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Key Takeaways and Next Steps

- Evidence of drug activity observed for 5.0 mg/kg efzofitimod across multiple clinically relevant efficacy endpoints
- Clinical improvement in quality of life as measured by the KSQ-Lung for 5.0 mg/kg efzofitimod vs placebo
- Preservation of lung function with efzofitimod 5.0 mg/kg
- Generally well-tolerated at both the 3.0 mg/kg and 5.0 mg/kg doses, consistent with a previously observed safety profile in all trials conducted to date

Planned Next Steps

- Present EFZO-FIT[™] topline results at the European Respiratory Society Congress on September 30, 2025, at 8:44am CEST in Amsterdam, Netherlands
 - Engage with the U.S. FDA to determine the path forward for efzofitimod in pulmonary sarcoidosis

aTyr

42. Defendant Shukla also detailed the key results of the EFZO-FIT study during the investor presentation, stating in relevant part:

The study, however, did not meet the primary endpoint of change from baseline in mean daily oral corticosteroid or OCS dose at week 48.

Some additional key findings include 52.6% of patients treated with five milligrams per kilogram of Efzofitimod, achieved complete steroid withdrawal at week 48 versus 40.2% on placebo. A clinical improvement in the king sarcoidosis questionnaire or KSQ lung score changed from baseline at week 48 was observed for five milligrams per kilogram of Efzofitimod compared to placebo. And a greater proportion of patients achieved both complete steroid withdrawal at week 48, with KSQ lung score improvement in the five milligram per kilogram Efzofitimod arm compared to placebo. The lung function as measured by [indiscernible] capacity or FVC at week 48 was maintained. And finally, Efzofitimod was well tolerated at both the three and five milligram per kilogram

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doses with a safety profile consistent with that what we've observed in all trials conducted to date.

This study demonstrates that patients with chronic symptomatic sarcoidosis can be managed with substantially lower steroid doses than previously thought without the fear of worsening disease. In spite of a higher-than-anticipated placebo response, we found that treatment with Efzofitimod was associated with a greater amount of steroid reduction, including steroid withdrawal, a clinical improvement and the quality of life for these patients and the maintenance of lung function. This is the first Phase 3 trial and largest ever interventional study conducted in pulmonary and the data generated from this study is likely to inform treatment practices for all sarcoidosis patients moving forward. Based on these consistent findings, which we believe indicate drug activity for Efzofitimod across multiple clinically relevant efficacy endpoints, we plan to engage with the FDA to determine the path forward for Efzofitimod in pulmonary sarcoidosis.

As a reminder, EFZO-FIT was a global Phase 3 52-week randomized, double-blind, placebo-controlled, multicenter study in 268 patients with pulmonary sarcoidosis. It consisted of three parallel cohorts, randomized equally to either three or five milligrams per kilogram of Efzofitimod or placebo, dosed intravenously once a month for a total of 12 doses. The primary endpoint of the study was steroid reduction at week 48. Additionally, clinical and efficacy assessments included the KSQ lung score or FVC, complete steroid withdrawal all at week 48.

In terms of the trial design, the study included a protocol guided steroid taper in the first 12 weeks of the study, followed by continued taper or rescue until week 48. Steroid taper and titration were guided by the Patient Global Assessment, or PGA, which was administered every two weeks. If there was any clinical worsening the principal investigator of PI was required, to rescue based on this PGA. And if there was improvement, the PI was required to taper.

* *

In our modeling, we assumed that patients on Efzofitimod would taper from baseline to an average daily prednisone dose between one to four milligrams, with placebo expected to taper to between four to seven. So, the drug performed accordingly to what we projected. However, we did not achieve statistical significance as the placebo tapering outperformed even our most aggressive modeling. Another important assessment of steroid reduction in the study was patients that achieved complete steroid withdrawal at week 48.

- 43. The above-cited investor presentation and statements made by Defendant Shukla contradicted prior statements made by Defendants in previous press releases and presentations. Importantly, Defendant Shukla had previously reiterated that the EFZO-FIT study was a "real major Phase 3 catalyst," particularly pertaining to the capability of Efzofitimod to remove steroid usage from pulmonary sarcoidosis patients' treatment plans.
- 44. Analysts covering aTyr were surprised by the Company's announcement of missing the trial's primary endpoint. For example, Wells Fargo drastically lowered its price target from \$25 per share to \$1 per share, noting it would "await further clarity before getting constructive." Likewise, RBC Capital Markets substantially lowered its price target from \$16.00 per share to \$1.50 per share, stating that the miss "creates a challenging path forward for Efzo[fitimod]." Similarly, H.C. Wainwright & Co. issued a research note on aTyr's trial results, stating in relevant part:

[aTyr] Management notes that the higher than expected placebo results, which were greater than even the company's most aggressive modeling predicted, were a key driver of this statistically miss. Despite the treatment arm acting as expected, with a 73.6% steroid reduction from baseline at week 48, the placebo arm saw a 63.3% steroid reduction. The company noted this higher than anticipated steroid reduction in the placebo arm could be due to the rigorous study design, which implemented Patients Global

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Assessment (PGA) every two weeks. The frequency of this assessment appears to be higher than current real-world practice, which may be a factor, as well as the impact of background immunosuppression regimens that this very sick patient population were concomitantly on. Both these factors will need to be teased out in further post-hoc analyses.

45. As a result, investors and the market immediately reacted to these revelations. The price of aTyr's common stock declined from a closing price of \$6.03 per share on September 12, 2025, to \$1.02 per share on September 15, 2025, a decline of 83.2% in just a single trading day.

Loss Causation and Economic Loss

- 46. During the Class Period, as detailed herein, Defendants made materially false and misleading statements and engaged in a scheme to deceive the market and a course of conduct that artificially inflated the price of aTyr's common stock and operated as a fraud or deceit on the Class Period purchasers and sellers of aTyr's respective securities by materially misleading the investing public. Later, Defendants' prior misrepresentations and fraudulent conduct became apparent to the market, the price of aTyr's common stock materially declined, as the prior artificial inflation came out of the price over time. As a result of their purchases and/or sales of aTyr's relevant securities during the Class Period, Plaintiff and other members of the Class suffered economic loss, i.e., damages under federal securities laws.
- aTyr's stock price fell in response to the corrective events on September 47. 15, 2025, as alleged herein. On this date, Defendants and analysts disclosed information that was directly related to the Defendants' prior misrepresentations and material omissions concerning the design and endpoints of aTyr's Phase 3 trial of Efzofitimod for patients with pulmonary sarcoidosis.

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Applicability of Presumption of Reliance (Fraud-On-The-Market Doctrine)

- 48. At all relevant times, the market for aTyr's common stock was an efficient market for the following reasons, among others:
- aTyr's common stock met the requirements for listing and was listed and (a) actively traded on the NASDAQ during the Class Period, a highly efficient stock exchange;
- (b) aTyr communicated with public investors via established market communication mechanisms, including disseminations of press releases on the national circuits of major newswire services and other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services;
- aTyr was followed by several securities analysts employed by major brokerage firms who wrote reports that were distributed to the sales force and certain customers of their respective brokerage firms during the Class Period. Each of these reports was publicly available and entered the public marketplace; and
- (d) Unexpected material news about aTyr was reflected in and incorporated into the Company's stock price during the Class Period.
- As a result of the foregoing, the market for aTyr's common stock 49. promptly digested current information regarding the Company from all publicly available sources and reflected such information in aTyr's stock price. Under these circumstances, all purchasers of aTyr's common stock, and purchasers and/or sellers of the relevant options on aTyr's common stock, during the Class Period suffered similar injury through their purchase of, and/or trading relevant options on, aTyr's common stock at artificially inflated prices, and a presumption of reliance applies.
- 50. Alternatively, reliance need not be proven in this action because the action involves omissions and deficient disclosures. Positive proof of reliance is not a prerequisite to recovery pursuant to ruling of the United States Supreme Court in

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Affiliated Ute Citizens of Utah v. United States, 406 U.S. 128 (1972). All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered the omitted information important in deciding whether to buy or sell the subject security.

No Safe Harbor (Inapplicability of Bespeaks Caution Doctrine)

- 51. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the material misrepresentations and omissions alleged in this Complaint. As alleged above, Defendants' liability stems from the fact that they provided investors with statements about business operations and prospects while at the same time omitting material risks that undermined the truthfulness of their statements.
- 52. To the extent certain of the statements alleged to be misleading or inaccurate may be characterized as forward looking, they were not identified as "forward-looking statements" when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements.
- 53. Defendants are also liable for any false or misleading "forward-looking" statements" pleaded because, at the time each "forward-looking statement" was made, the speaker knew the "forward-looking statement" was false or misleading and the "forward-looking statement" was authorized and/or approved by an executive officer of aTyr who knew that the "forward-looking statement" was false. Alternatively, none of the historic or present-tense statements made by Defendants were assumptions underlying or relating to any plan, projection, or statement of future economic performance, as they were not stated to be such assumptions underlying or relating to any projection or statement of future economic performance when made, nor were any of the projections or forecasts made by the defendants

expressly related to or stated to be dependent on those historic or present-tense statements when made.

CLASS ACTION ALLEGATIONS

- 54. Plaintiff brings this action as a class action pursuant to Federal Rules of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired aTyr's common stock, purchased call options on aTyr common stock, and/or sold put options on aTyr common stock, during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosure. Excluded from the Class are defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which defendants have or had a controlling interest.
- 55. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, aTyr's common stock was actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by aTyr or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions. As of August 1, 2025, there were 97,986,634 shares of the Company's common stock outstanding. Upon information and belief, these shares are held by thousands, if not millions, of individuals located throughout the country and possibly the world. Joinder would be highly impracticable.
- 56. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law complained of herein.

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- 57. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.
- 58. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:
- (a) whether the federal securities laws were violated by Defendants' acts as alleged herein;
- (b) whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of aTyr;
- (c) whether the Individual Defendants caused aTyr to issue false and misleading financial statements during the Class Period;
- (d) whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;
- (e) whether the prices of aTyr's common stock during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and
- (f) whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.
- 59. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

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COUNT I

<u>Against All Defendants for Violations of</u> Section 10(b) and Rule 10b-5 Promulgated Thereunder

- 60. Plaintiff repeats, realleges, and reincorporates the allegations contained above in Paragraphs 1-59 as if fully set forth herein.
- 61. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.
- 62. During the Class Period, Defendants: (1) engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class; (2) made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and (3) employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of aTyr common stock; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire or aTyr's securities at artificially inflated prices, and/or to buy or sell options based on an inflated value of aTyr common stock. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.
- 63. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for aTyr's

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- securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about the Company.
- 64. By virtue of his position at the Company, the Individual Defendant had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, the Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to them. Said acts and omissions of the Defendants were committed willfully or with reckless disregard for the truth. In addition, each defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.
- Information showing that Defendants acted knowingly or with reckless 65. disregard for the truth is peculiarly within Defendants' knowledge and control. As a senior manager and director of the Company, the Individual Defendant had knowledge of the details of aTyr's internal affairs.
- 66. The Individual Defendant is liable both directly and indirectly for the wrongs complained of herein. Because of his position of control and authority, the Individual Defendant was able to and did, directly or indirectly, control the content of the statements of the Company. As an officer and director of a publicly-held company, the Individual Defendant had a duty to disseminate timely, accurate, and truthful information with respect to aTyr's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of aTyr's common stock was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning the Company which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise

- 67. During the Class Period, aTyr's common stock was traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of aTyr's common stock at prices artificially inflated by Defendants' wrongful conduct, and/or bought or sold options based on an artificially inflated value of aTyr common stock caused by Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said common stock, and/or traded the relevant options on aTyr common stock. Nor would have Plaintiff and other members of the Class had purchased or otherwise acquired aTyr stock, and/or traded the relevant option on aTyr common stock, at the artificial prices that were paid or sold. At the time of the purchases, acquisitions, and/or option tradings by Plaintiff and the Class, the true value of aTyr's common stock was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of aTyr's common stock declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.
- 68. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.
- 69. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's common stock

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during the Class Period, upon the disclosure that the Company had been

Against the Individual Defendant for Violations of Section 20(a) of the Exchange Act

- 70. Plaintiff repeats, realleges, and reincorporates the allegations contained above in Paragraphs 1-59 as if fully set forth herein.
- During the Class Period, the Individual Defendant participated in the 71. operation and management of the Company, and conducted and participated, directly and/or indirectly, in the conduct of the Company's business affairs. Because of his senior position, he knew the adverse non-public information about aTyr's misstatements.
- 72. As an officer and director of a publicly owned company, the Individual Defendant had a duty to disseminate accurate and truthful information, and to correct promptly any public statements issued by aTyr, which had become materially false or misleading.
- Because of his position of control and authority as a senior officer, the 73. Individual Defendant was able to, and did, control the contents of the various reports, press releases and public filings which aTyr disseminated in the marketplace during the Class Period concerning the misrepresentations. Throughout the Class Period, the Individual Defendant exercised his power and authority to cause aTyr to engage in the wrongful acts complained of herein. The Individual Defendant, therefore, was a "controlling person" of the Company within the meaning of Section 20(a) of the Exchange Act. In this capacity, he participated in the unlawful conduct alleged, which artificially inflated the market price of aTyr's common stock.
- The Individual Defendant, therefore, acted as a controlling person of the 74. Company. By reason of his senior management position and a being director of the Company, the Individual Defendant had the power to direct the actions of, and

by the Company.

PRAYER FOR RELIEF

- WHEREFORE, Plaintiff demands judgment against Defendants as 76. follows:
- A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, certifying Plaintiff as the Class representative;
- B. Requiring Defendants to pay and all damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;
- C. Awarding Plaintiff and the other members of the Class pre-judgment and post judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and
- Awarding such other and further relief as this Court may deem just and D. proper.

DEMAND FOR TRIAL BY JURY

77. Plaintiff hereby demands a trial by jury.

DATED: October 22, 2025 Respectfully Submitted,

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