

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA**

MARCO MUNGUIA, Individually and
on Behalf of All Others Similarly
Situated,

Plaintiff,

v.

ATYR PHARMA INC. and SANJAY S.
SHUKLA,

Defendants.

Case No. '25CV2681 WQHSBC

CLASS ACTION

**COMPLAINT FOR VIOLATIONS
OF THE FEDERAL SECURITIES
LAWS**

DEMAND FOR JURY TRIAL

1 Plaintiff Marco Munguia (“Plaintiff”), individually and on behalf of all other
2 persons similarly situated, by their undersigned attorneys, alleges in this Complaint
3 for violations of the federal securities laws (the “Complaint”) the following based
4 upon knowledge with respect to their own acts, and upon facts obtained through an
5 investigation conducted by his counsel, which included, *inter alia*: (a) review and
6 analysis of relevant filings made by aTyr Pharma Inc. (“aTyr” or the “Company”)
7 with the United States Securities and Exchange Commission (the “SEC”); (b)
8 review and analysis of aTyr’s public documents, conference calls, press releases,
9 and stock chart; (c) review and analysis of securities analysts’ reports and advisories
10 concerning the Company; and (d) information readily obtainable on the internet.
11

12 Plaintiff believes that further substantial evidentiary support will exist for the
13 allegations set forth herein after a reasonable opportunity for discovery. Most of the
14 facts supporting the allegations contained herein are known only to the defendants
15 or are exclusively within their control.
16

17 **NATURE OF THE ACTION**

18 1. This is a federal securities class action on behalf of all investors who
19 purchased or otherwise acquired aTyr common stock between January 16, 2025, and
20 September 12, 2025, inclusive (the “Class Period”), seeking to recover damages
21 caused by Defendants’ violations of the federal securities laws (the “Class”).
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23 2. Defendants provided investors with material information concerning
24 aTyr’s Phase 3, randomized, double-blind, placebo-controlled study to evaluate the
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1 safety and efficacy of intravenous Efzofitimod in patients with pulmonary
2 sarcoidosis (EFZO-FIT). Defendants' statements included, among other things,
3 aTyr's top executives' confidence in the forced taper approach of the Company's
4 study design.
5

6 3. Defendants provided these overwhelmingly positive statements to
7 investors while, at the same time, disseminating false and misleading statements
8 and/or concealing material adverse facts concerning the efficacy of Efzofitimod,
9 particularly, the drug's capability to allow a patient to completely taper their steroid
10 usage. This caused Plaintiff and other shareholders to purchase aTyr's securities at
11 artificially inflated prices.
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14 4. The truth emerged on September 15, 2025 (pre-market) when aTyr
15 hosted an investor call announcing that the EFZO-FIT study did not meet its primary
16 endpoint. In pertinent part, Defendants announced that the study did not meet the
17 primary endpoint in change from baseline in mean daily OSC dose at week 48.
18 Additionally, aTyr announced that the Company's next step was to engage with the
19 FDA to determine a path forward, given the disappointing topline results.
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22 5. As a result, investors and analysts reacted immediately to aTyr's
23 revelation. The price of aTyr's common stock declined from a closing market price
24 of \$6.03 per share on September 12, 2025 to \$1.02 per share on September 15, 2025,
25 a decline of 83.2% in the span of just a single day.
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1 6. Investors have sustained significant damages as a result of Defendants'
2 fraudulent statements. Plaintiff seeks to recover those damages by way of this
3 lawsuit.
4

5 **JURISDICTION AND VENUE**

6 7. Plaintiff brings this action, on behalf of himself and other similarly
7 situated investors, to recover losses sustained in connection with Defendants' fraud.
8

9 8. The claims asserted herein arise under and pursuant to §§10(b) and
10 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5
11 promulgated thereunder by the SEC (17 C.F.R. §240.10b-5).
12

13 9. This Court has jurisdiction over the subject matter of this action
14 pursuant to 28 U.S.C. §§1331 and 1337, and Section 27 of the Exchange Act, 15
15 U.S.C. §78aa.
16

17 10. Venue is proper in this District pursuant to §27 of the Exchange Act
18 and 28 U.S.C. §1391(b), as Defendant aTyr is headquartered in this District and a
19 significant portion of its business, actions, and the subsequent damages to Plaintiff
20 and the Class, took place within this District.
21

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

12. 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 transaction(s) in aTyr is attached hereto.

13. 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."

14. Defendant Sanjay S. Shukla ("Shukla") was, at all relevant times, the President, Chief Executive Officer, and Director of aTyr.

15. Defendant Shukla is sometimes referred to herein as the "Individual Defendant." aTyr together with the Individual Defendant are referred to herein as the "Defendants."

16. 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

1 position and access to material non-public information available to him, the
2 Individual Defendant knew that the adverse facts specified herein had not been
3 disclosed to, and were being concealed from, the public, and that the positive
4 representations which were being made were then materially false and/or
5 misleading. The Individual Defendant is liable for the false statements pleaded
6 herein, as those statements were each “group-published” information, the result of
7 the collective actions of the Individual Defendant.
8

9
10 17. aTyr is liable for the acts of the Individual Defendant, and its employees
11 under the doctrine of respondeat superior and common law principles of agency as
12 all the wrongful act complained of herein were carried out within the scope of their
13 employment with authorization.
14

15
16 18. The scienter of the Individual Defendant, and other employees and
17 agents of the Company are similarly imputed to aTyr under respondeat superior and
18 agency principles.
19

20 **SUBSTANTIVE ALLEGATIONS**

21 **A. Company Background**

22 19. aTyr is a clinical stage biotechnology company leveraging evolutionary
23 intelligence to translate tRNA synthetase biology into new therapies for fibrosis and
24 inflammation. The Company’s discovery platform is focused on unlocking hidden
25 therapeutic intervention points by uncovering signaling pathways driven by its
26 proprietary library of domains derived from all 20 tRNA synthetases.
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B. Defendants Materially Misled Investors Concerning the Company's Phase 3 Study of Efzofitimod

January 16, 2025

20. On January 16, 2025, aTyr presented at the 43rd Annual J.P. Morgan Healthcare Conference. As part of the presentation Defendant Shukla provided an update on the Phase 3 study, in pertinent part:

aTyr is a company that has a real major Phase III 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 III in these indications.

* * *

Efzofitimod is our lead asset in Phase III. 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 talked 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 III.

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 finishing our trial are demanding to remain in our

1 trial right now, even though they're blinded and we are blinded to what
2 they're receiving -- the respite from some of the toxic therapies that
3 they've been receiving for some times 5 or 10 years in this trial has been
4 something that they want more of.

5 * * *

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

12 * * *

13 ***Our global Phase III design is fully enrolled, a good timing for all of***
14 ***you. We're finished with enrollment, and now we're just waiting for***
15 ***data. This was now a well-powered and highly powered designed trial,***
16 ***88 patients per arm. We took the 2 efficacious doses in Phase II***
17 ***forward. We finally enrolled 268 patients.***

18 ***Some key things here. In the last trial, we noticed we could knock***
19 ***down steroids pretty well down to 5 milligrams, but we're leaning into***
20 ***that signal a little bit more in this trial, and we're attempting to taper***
21 ***people to 0. And we're already seeing benefit in many of the patients,***
22 ***as I mentioned, who have finished the trial. We're now refusing to go***
back on steroids.

23 So we've had to step up with an expanded access program rather quickly
24 here, working with certain regions that allow it. But this is a patient --
25 this is a trial where we'll look to taper down from an entry dose of 7.5
26 to 25 and then observe patients from week 12 to week 48. ***What we***
27 ***expect to see in the placebo population is flaring exacerbation, and***
28 ***you'll see that prednisone dose jump back up.***

1 We think using our drug, we can keep patients at low or no dose. But
2 that's really what we're trying to basically see with our statistical delta.
3 I'm trying to see a difference in that average daily prednisone dose. And
4 even if we could peel away 1 or 2 milligrams, agencies look at that as
important.

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

9 (Emphasis added).

10
11 21. Also during the conference, Defendant Shukla answered analyst
12 questions pertaining to the Phase 3 study design, in pertinent part:

13
14 <Q: Unknown Attendee> Maybe I'll ask the next question. As it relates
15 to the Phase III, can you explain the steroid taper protocol? How is it
16 similar or different to the Phase II? And how are you thinking about
17 minimizing the PI discretion and subjectivity?

18 <A: Defendant Shukla> Yes, it's a great question because with some of
19 those approved therapies that are out there, there was a lot of
20 contentious debate because there's investigator subjective judgment.
21 And one of the things we work with the agency is, let's have a validated
22 tool that guides taper decisions. And perhaps they even learned from
the TAVNEOS approval.

23 So we have a tool we use the PGA. It's a validated instrument that every
24 2 weeks, we're assaying these patients, how are you doing? How have
25 your last 2 weeks been? And if there's any worsening on that PGA, even
26 a 1 point worsening, there's an automatic edit check that goes out from
27 drug -- from data management even saying we should see a steroid
28 increase.

1 So patients are asked to follow their prednisone dose every day in their
2 trial. If there's a worsening in PGA every 2 weeks, it's being assayed,
3 and that guides some of that judgment. So we're taking a little bit of the
4 keys away of the car from the pulmonologists here because we want to
have that titration based on the PGA.

5 *How is it different? One of the key differences, as I mentioned, we*
6 *knocked everyone down to 5 milligrams and then look to see if they*
7 *flare in the last trial. This trial we're knocking folks down to 0. So*
8 *what we expect is more unmasking of disease in placebo, more steroid*
9 *rescue there. That could then serve as how I said with the area into*
10 *the curve, a delta emerge. So those are some of the key differences on*
11 *how we're minimizing some of that investigator bias, but also*
12 *potentially seeing a greater signal of steroids bearing with EFZO.*

(Emphasis added).

13 March 13, 2025

14 22. On March 13, 2025, aTyr announced fourth quarter financial results and
15 hosted an associated earnings call. CEO Sanjay Shukla provided an update on the
16 Phase 3 study, in relevant part:

17
18 2024 was an important year for aTyr as we completed enrollment in our
19 global pivotal Phase III EFZO-FIT study of efzofitmod in patients with
20 pulmonary sarcoidosis in major form of ILD, which is our lead
indication.

21 This is the largest interventional study ever conducted in pulmonary
22 sarcoidosis, and we look forward to releasing top-line data from this
23 study in the third quarter of this year.

24 EFZO-FIT is a randomized, double-blind, placebo-controlled 52-week
25 study. It consists of 3 parallel cohorts, randomized equally to either 3
26 milligrams per kilogram or 5 milligrams per kilogram of efzofitmod or
27 placebo, dosed intravenously monthly for a total of 12 doses.
28

1 The study enrolled 268 patients at 85 centers in 9 countries. The trial
2 design incorporates a forced steroid taper with steroid reduction as the
3 primary endpoint of the study.

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

8 The EAP was implemented primarily based on feedback from multiple
9 study principal investigators or PIs whose patients requested to
10 continue treatment once they had completed the study. These patients
11 will receive 5 milligrams per kilogram of efzofitmod while in the EAP.

12 ***However, PIs, patients, and the company remain blinded to the***
13 ***EFZO-FIT treatment assignments of these EAP patients.***
14 ***Additionally, we have now held 4 positive Data and Safety Monitoring***
15 ***Board or DSMB reviews for this study, all of which have identified***
16 ***no safety concerns and recommended that the study continue***
17 ***unmodified.***

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

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

26 ***In a poster, we will be able to get a sense of the profile of the patients***
27 ***enrolled, including baseline steroid dose and background***
28 ***immunomodulator use and how the profile matches the inclusion and***
29 ***exclusion criteria for the study.***

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

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

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

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

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

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

17 While we brought you up to date on EFZO-FIT, I want to take a few
18 minutes to provide you with critical insights into the pulmonary
19 sarcoidosis landscape in the US that have emerged from some of our
20 early pre-commercial activities.

21 We believe these findings support a potentially larger market
22 opportunity for efzofitimod in sarcoidosis.

23 (Emphasis added.)

24 23. During a question-and-answer portion of the same earnings call,
25 Defendant Shukla answered questions from analysts in attendance, in relevant part:

26 <Q: Derek Christian Archila -- Wells Fargo Securities – Analyst> And
27 then just a follow-up here. I know you highlighted in the prepared
28 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

1 percentage of the patients who are in the trial rolling over into the
2 expanded access or a new program there.

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

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

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

16 We have committed to helping patients who are performing well in the
17 trial to roll into the EAP, but it's an individual site-by-state site decision
18 because, of course, we are not in a formal open-label type extension. So
19 very pleased with the progress. I think it's a great signal, a great interim
20 biomarker, if you will.

21 And we're going to continue to support those patients to move into that
22 EAP. But again, to get into specific numbers and try to get into the
23 math, it's probably not helpful.

24 ***And just as a reminder, we are blinded. We're blinded to what these
25 patients are on during the trial. So there's always a chance that all of
26 these patients are on placebo and that they have been able to taper
27 more or less off their steroids and it doesn't have anything to do with
28 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.

1 <Q: Yasmeen Rahimi -- Piper Sandler & Co – Analyst> Congrats on
2 all the exciting progress and an exciting year ahead of us. I got 2 quick
3 questions. One is around managing patients with steroid reduction that
4 led to engaging with the agency to make this change from a sort of
clinical perspective.

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

8 And question 2, it's really exciting to see the baseline demographics
9 from the study here upcoming at ATS.

10 Could you maybe help us understand what we should be looking for?
11 Obviously, it's a tremendous study with globally, lots of work that went
12 into it. So just kind of help us framework on what are some of the
13 measures that we should be looking closely to in terms of this patient
population. And I'll jump back in the queue.

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

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

22 So we're very rigorous, and I like to be very rigorous around, hey, let's
23 get everything pre-hoc organized down to the details exactly how do
24 you want us to program and even look at some of this steroid reduction.

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

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

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

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

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

20 The important thing for investors to pay attention to is the average
21 prednisone dose. I'll remind everyone in the last trial, the Phase II trial,
22 we had an average dose somewhere in that 11 to 13 range.

23 This trial, where we're enrolling patients with a slightly lower basement
24 dose of 7.5 milligrams, I expect that prednisone dose may be maybe a
25 little bit lower, but we want to take a look at that. And then that helps
26 with all the investors that want to do the modeling with regards to how
27 much steroid delta you want to see there.

28 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.)

May 7, 2025

24. On May 7, 2025, aTyr announced first quarter 2025 financial results and provided a corporate update. The press release included an update pertaining to aTyr's Phase 3 EFZO-FIT study, in pertinent part:

On track to announce topline data in the third quarter of 2025 from the global pivotal Phase 3 EFZO-FIT™ study to evaluate the efficacy and safety of efzofitimod in patients with pulmonary sarcoidosis. This is a randomized, double-blind, 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.)

August 7, 2025

25. On August 7, 2025, aTyr announced second quarter 2025 financial results and provided a corporate update. The press release included an update pertaining to aTyr's Phase 3 EFZO-FIT study, in relevant part:

Completed the last patient visit in the global pivotal Phase 3 EFZO-FIT™ 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, 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

1 study enrolled 268 patients with pulmonary sarcoidosis across 85
2 centers in nine countries. The trial design incorporates a forced steroid
3 taper. The primary endpoint of the study is steroid reduction measured
4 as the absolute change from baseline to week 48. Secondary endpoints
5 include measures of sarcoidosis symptoms and lung function. Patients
6 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.

7 26. Also as part of the press release, Defendant Shukla issued a statement
8 pertaining to the Phase 3 EFZO-FIT study, in pertinent part:
9

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

15 27. The above statements in Paragraphs 20 to 26 were false and/or
16 materially misleading. Specifically, Defendants created adverse facts concerning
17 aTyr's study design for EFZO-FIT, giving the false impression that Efzofitimod
18 would meet its primary endpoint. In fact, Defendants misled and deceived investors
19 by crafting a narrative that the Phase 3 EFZO-FIT study would provide a way for
20 patients to fully remove steroids from their treatment plans. Defendants failed,
21 however, to disclose that there may be other factors that permit patients to
22 completely remove steroids from their treatment plans, thus, their Phase 3 EFZO-
23 FIT study failed to meet the primary endpoint in change from baseline in mean daily
24 OCS dose at week 48.
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C. The Truth Emerges

September 15, 2025

28. On September 15, 2025 (pre-market), aTyr hosted an investor presentation announcing topline results for Phase 3 EZFO-FIT study of Efzofitmod in pulmonary sarcoidosis. In pertinent part:

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 efzofitmod 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 efzofitmod 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 efzofitmod 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
 - Efzofitmod 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 efzofitmod across multiple clinically relevant efficacy endpoints
 - Company plans to engage with the U.S. FDA to determine the path forward for efzofitmod in pulmonary sarcoidosis

3

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

As the primary endpoint did not achieve statistical significance, p-values for other endpoints should be interpreted as nominal p-values.



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

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29. As part of the investor presentation, Defendant Shukla detailed the topline results, 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 5 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 5 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 5-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 3 and 5-milligram per kilogram 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

1 efzofitimod was associated with a greater amount of steroid reduction,
2 including steroid withdrawal, a clinical improvement and the quality of
3 life for these patients and the maintenance of lung function. This is the
4 first Phase III trial and largest ever interventional study conducted in
5 pulmonary and the data generated from this study is likely to inform
6 treatment practices for all sarcoidosis patients moving forward. Based
7 on these consistent findings, which we believe indicate drug activity for
8 efzofitimod across multiple clinically relevant efficacy endpoints, we
9 plan to engage with the FDA to determine the path forward for
10 efzofitimod in pulmonary sarcoidosis.

11 As a reminder, EFZO-FIT was a global Phase III 52-week randomized,
12 double-blind, placebo-controlled, multicenter study in 268 patients
13 with pulmonary sarcoidosis. It consisted of 3 parallel cohorts,
14 randomized equally to either 3 or 5 milligrams per kilogram of
15 efzofitimod or placebo, dosed intravenously once a month for a total of
16 12 doses. The primary endpoint of the study was steroid reduction at
17 week 48. Additionally, clinical and efficacy assessments included the
18 KSQ lung score or FVC, complete steroid withdrawal all at week 48.

19 In terms of the trial design, the study included a protocol guided steroid
20 taper in the first 12 weeks of the study, followed by continued taper or
21 rescue until week 48. Steroid taper and titration were guided by the
22 Patient Global Assessment, or PGA, which was administered every 2
23 weeks. If there was any clinical worsening the principal investigator of
24 PI was required, to rescue based on this PGA. And if there was
25 improvement, the PI was required to taper.

26 * * *

27 In our modeling, we assumed that patients on efzofitimod would taper
28 from baseline to an average daily prednisone dose between 1 to 4
milligrams, with placebo expected to taper to between 4 to 7. 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.

1 30. The aforementioned investor presentation and statements made by the
2 Individual Defendant was misleading and in direct contrast to statements made in
3 his previous press releases and presentations. In his previous statements, Defendant
4 Shukla reiterated that the EFZO-FIT study was a “real major Phase III catalyst,”
5 particularly pertaining to the capability of Efzofitmod to remove steroid usage from
6 pulmonary sarcoidosis patients’ treatment plans.
7

8
9 31. Analysts expressed surprise and concern at the Company’s primary
10 endpoint miss. In particular, RBC Capital Markets slashed its price target to \$1.50
11 from \$16.00, noting that the miss “creates a challenging path forward for Efzo.”
12

13 32. Similarly, Freedom Broker published a report titled “The EFZO-FIT
14 study’s Phase III concluded without meeting primary objectives” and decreased its
15 price target for aTyr to \$1.00 from \$9.50. In particular, the report noted, in pertinent
16 part:
17

18 The study did not meet its primary endpoints (steroid dose reduction),
19 showing only minor differences from placebo. Nonetheless,
20 statistically significant improvements were recorded in several
21 secondary indicators, such as improved quality of life (KSQ-Lung
22 Score) and a higher rate of complete steroid discontinuation in the
23 efzofitmod 5.0 mg/kg group. Given these results, the company is
24 committed to continuing the program and is preparing for a meeting
25 with the FDA, anticipated in the first half of 2026. This meeting will be
26 critical in shaping the future strategy for efzofitmod therapy.
27 Considering the failure to achieve the primary endpoints in the EFZO-
28 FIT study and the persisting uncertainty in the future development
pathway for the therapy, we have revised the probability of approval
downward. This revision has negatively affected our financial
performance forecast adjusted for the probability of approval.
Consequently, we are decreasing our price target for aTyr shares from

1 \$9.50 to \$1.00 and changing our recommendation from “Buy” to
2 “Hold.” The forthcoming meeting with the FDA will be pivotal in
3 assessing the potential path forward for efzofitmod therapy.

4 33. As a result, investors and analysts reacted immediately to aTyr’s
5 revelation. The price of aTyr’s common stock declined from a closing market price
6 of \$6.03 per share on September 12, 2025 to \$1.02 per share on September 15, 2025,
7 a decline of 83.2% in the span of just a single day.
8

9 **D. Loss Causation and Economic Loss**

10 34. During the Class Period, as detailed herein, aTyr and Defendants made
11 materially false and misleading statements and engaged in a scheme to deceive the
12 market and a course of conduct that artificially inflated the price of aTyr’s common
13 stock and operated as a fraud or deceit on Class Period purchasers of aTyr’s common
14 stock by materially misleading the investing public. Later, when aTyr and
15 Defendants’ prior misrepresentations and fraudulent conduct became apparent to the
16 market, the price of aTyr’s common stock materially declined, as the prior artificial
17 inflation came out of the price over time. As a result of their purchases of aTyr’s
18 common stock during the Class Period, Plaintiff and other members of the Class
19 suffered economic loss, *i.e.*, damages under federal securities laws.
20
21
22
23

24 35. aTyr’s stock price fell in response to the corrective event on September
25 12, 2025, as alleged *supra*. On September 12, 2025, Defendants disclosed
26 information that was directly related to their prior misrepresentations and material
27
28

omissions concerning the efficacy of aTyr's Phase 3 trial intravenous Efzofitimod in patients with pulmonary sarcoidosis.

E. Presumption of Reliance; Fraud-On-The-Market

36. At all relevant times, the market for aTyr's common stock was an efficient market for the following reasons, among others:

(a) aTyr's common stock met the requirements for listing and was listed and actively traded on the NASDAQ during the Class Period, a highly efficient and automated market;

(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;

(c) 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.

37. As a result of the foregoing, the market for aTyr's common stock promptly digested current information regarding the Company from all publicly

1 available sources and reflected such information in aTyr's stock price. Under these
2 circumstances, all purchasers of aTyr's common stock during the Class Period
3 suffered similar injury through their purchase of aTyr's common stock at artificially
4 inflated prices, and a presumption of reliance applies.

5
6 38. Alternatively, reliance need not be proven in this action because the
7 action involves omissions and deficient disclosures. Positive proof of reliance is not
8 a prerequisite to recovery pursuant to ruling of the United States Supreme Court in
9 *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972). All that is
10 necessary is that the facts withheld be material in the sense that a reasonable investor
11 might have considered the omitted information important in deciding whether to buy
12 or sell the subject security.

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14
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16 **F. No Safe Harbor; Inapplicability of Bespeaks Caution Doctrine**

17 39. The statutory safe harbor provided for forward-looking statements
18 under certain circumstances does not apply to any of the material misrepresentations
19 and omissions alleged in this Complaint. As alleged above, Defendants' liability
20 stems from the fact that they provided investors with statements about regulatory
21 developments and prospects while at the same time omitting acute risks undermining
22 the validity of their statements.

23
24
25 40. To the extent certain of the statements alleged to be misleading or
26 inaccurate may be characterized as forward looking, they were not identified as
27 "forward-looking statements" when made and there were no meaningful cautionary
28

1 statements identifying important factors that could cause actual results to differ
2 materially from those in the purportedly forward-looking statements.

3
4 41. Defendants are also liable for any false or misleading “forward-looking
5 statements” pleaded because, at the time each “forward-looking statement” was
6 made, the speaker knew the “forward-looking statement” was false or misleading
7 and the “forward-looking statement” was authorized and/or approved by an
8 executive officer of aTyr who knew that the “forward-looking statement” was false.
9
10 Alternatively, none of the historic or present-tense statements made by Defendants
11 were assumptions underlying or relating to any plan, projection, or statement of
12 future economic performance, as they were not stated to be such assumptions
13 underlying or relating to any projection or statement of future economic performance
14 when made, nor were any of the projections or forecasts made by the Defendants
15 expressly related to or stated to be dependent on those historic or present-tense
16 statements when made.
17
18

19
20 **CLASS ACTION ALLEGATIONS**

21 42. Plaintiff brings this action as a class action pursuant to Federal Rule of
22 Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who
23 purchased or otherwise acquired aTyr’s common stock during the Class Period (the
24 “Class”); and were damaged upon the revelation of the alleged corrective disclosure.
25 Excluded from the Class are Defendants herein, the officers and directors of the
26 Company, at all relevant times, members of their immediate families and their legal
27
28

1 representatives, heirs, successors or assigns and any entity in which Defendants have
2 or had a controlling interest.

3
4 43. The members of the Class are so numerous that joinder of all members
5 is impracticable. Throughout the Class Period, aTyr's common stock were actively
6 traded on the NASDAQ. While the exact number of Class members is unknown to
7 Plaintiff at this time and can be ascertained only through appropriate discovery,
8 Plaintiff believes that there are hundreds or thousands of members in the proposed
9 Class. Record owners and other members of the Class may be identified from records
10 maintained by aTyr or its transfer agent and may be notified of the pendency of this
11 action by mail, using the form of notice similar to that customarily used in securities
12 class actions. As of August 1, 2025, there were 97.99 million shares of the
13 Company's common stock outstanding. Upon information and belief, these shares
14 are held by thousands, if not millions, of individuals located throughout the country
15 and possibly the world. Joinder would be highly impracticable.
16
17
18
19

20 44. Plaintiff's claims are typical of the claims of the members of the Class
21 as all members of the Class are similarly affected by Defendants' wrongful conduct
22 in violation of federal law that is complained of herein.
23

24 45. Plaintiff will fairly and adequately protect the interests of the members
25 of the Class and has retained counsel competent and experienced in class and
26 securities litigation. Plaintiff has no interests antagonistic to or in conflict with those
27 of the Class.
28

1 46. Common questions of law and fact exist as to all members of the Class
2 and predominate over any questions solely affecting individual members of the
3 Class. Among the questions of law and fact common to the Class are:
4

- 5 (a) whether the federal securities laws were violated by Defendants' acts
6 as alleged herein;
7
8 (b) whether statements made by Defendants to the investing public during
9 the Class Period misrepresented material facts about the business,
10 operations and management of aTyr;
11
12 (c) whether the Individual Defendants caused aTyr to issue false and
13 misleading financial statements during the Class Period;
14
15 (d) whether Defendants acted knowingly or recklessly in issuing false and
16 misleading financial statements;
17
18 (e) whether the prices of aTyr's common stock during the Class Period
19 were artificially inflated because of the Defendants' conduct
20 complained of herein; and
21
22 (f) whether the members of the Class have sustained damages and, if so,
23 what is the proper measure of damages.

24 47. A class action is superior to all other available methods for the fair and
25 efficient adjudication of this controversy since joinder of all members is
26 impracticable. Furthermore, as the damages suffered by individual Class members
27 may be relatively small, the expense and burden of individual litigation make it
28

1 impossible for members of the Class to individually redress the wrongs done to them.

2 There will be no difficulty in the management of this action as a class action.

3
4 **COUNT I**

5 ***Against All Defendants for Violations of***
6 ***Section 10(b) and Rule 10b-5 Promulgated Thereunder***

7 48. Plaintiff repeats and realleges each and every allegation contained
8 above as if fully set forth herein.

9
10 49. This Count is asserted against defendants and is based upon Section
11 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated
12 thereunder by the SEC.

13
14 50. During the Class Period, Defendants engaged in a plan, scheme,
15 conspiracy and course of conduct, pursuant to which they knowingly or recklessly
16 engaged in acts, transactions, practices and courses of business which operated as a
17 fraud and deceit upon. Plaintiff and the other members of the Class; made various
18 untrue statements of material facts and omitted to state material facts necessary in
19 order to make the statements made, in light of the circumstances under which they
20 were made, not misleading; and employed devices, schemes and artifices to defraud
21 in connection with the purchase and sale of securities. Such scheme was intended to,
22 and, throughout the Class Period, did: (i) deceive the investing public, including
23 Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and
24 maintain the market price of aTyr common stock; and (iii) cause Plaintiff and other
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1 members of the Class to purchase or otherwise acquire aTyr's securities at artificially
2 inflated prices. In furtherance of this unlawful scheme, plan and course of conduct,
3 Defendants, and each of them, took the actions set forth herein.
4

5 51. Pursuant to the above plan, scheme, conspiracy and course of conduct,
6 each of the Defendants participated directly or indirectly in the preparation and/or
7 issuance of the quarterly and annual reports, SEC filings, press releases and other
8 statements and documents described above, including statements made to securities
9 analysts and the media that were designed to influence the market for aTyr's
10 securities. Such reports, filings, releases and statements were materially false and
11 misleading in that they failed to disclose material adverse information and
12 misrepresented the truth about the Company.
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16 52. By virtue of their positions at the Company, Defendants had actual
17 knowledge of the materially false and misleading statements and material omissions
18 alleged herein and intended thereby to deceive Plaintiff and the other members of
19 the Class, or, in the alternative, Defendants acted with reckless disregard for the truth
20 in that they failed or refused to ascertain and disclose such facts as would reveal the
21 materially false and misleading nature of the statements made, although such facts
22 were readily available to Defendants. Said acts and omissions of Defendants were
23 committed willfully or with reckless disregard for the truth. In addition, each
24 Defendant knew or recklessly disregarded that material facts were being
25 misrepresented or omitted as described above.
26
27
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1 53. Information showing that Defendants acted knowingly or with reckless
2 disregard for the truth is peculiarly within Defendants' knowledge and control. As
3 the senior manager and/or director of the Company, the Individual Defendant had
4 knowledge of the details of aTyr's internal affairs.

6 54. The Individual Defendant is liable both directly and indirectly for the
7 wrongs complained of herein. Because of his position of control and authority, the
8 Individual Defendant was able to and did, directly or indirectly, control the content
9 of the statements of the Company. As officer and/or director of a publicly-held
10 company, the Individual Defendant had a duty to disseminate timely, accurate, and
11 truthful information with respect to aTyr's businesses, operations, future financial
12 condition and future prospects. As a result of the dissemination of the
13 aforementioned false and misleading reports, releases and public statements, the
14 market price of aTyr's common stock was artificially inflated throughout the Class
15 Period. In ignorance of the adverse facts concerning the Company which were
16 concealed by Defendants, Plaintiff and the other members of the Class purchased or
17 otherwise acquired aTyr's common stock at artificially inflated prices and relied
18 upon the price of the common stock, the integrity of the market for the common
19 stock and/or upon statements disseminated by Defendants, and were damaged
20 thereby.

26 55. During the Class Period, aTyr's common stock was traded on an active
27 and efficient market. Plaintiff and the other members of the Class, relying on the
28

1 materially false and misleading statements described herein, which the Defendants
2 made, issued or caused to be disseminated, or relying upon the integrity of the
3 market, purchased or otherwise acquired shares of aTyr's common stock at prices
4 artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the other
5 members of the Class known the truth, they would not have purchased or otherwise
6 acquired said common stock, or would not have purchased or otherwise acquired
7 them at the inflated prices that were paid. At the time of the purchases and/or
8 acquisitions by Plaintiff and the Class, the true value of aTyr's common stock was
9 substantially lower than the prices paid by Plaintiff and the other members of the
10 Class. The market price of aTyr's common stock declined sharply upon public
11 disclosure of the facts alleged herein to the injury of Plaintiff and Class members.
12

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14
15
16 56. By reason of the conduct alleged herein, Defendants knowingly or
17 recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act
18 and Rule 10b-5 promulgated thereunder.
19

20 57. As a direct and proximate result of Defendants' wrongful conduct,
21 Plaintiff and the other members of the Class suffered damages in connection with
22 their respective purchases, acquisitions and sales of the Company's common stock
23 during the Class Period, upon the disclosure that the Company had been
24 disseminating misrepresented financial statements to the investing public.
25
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28

COUNT II

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

58. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

59. During the Class Period, the Individual Defendant participated in the operation and management of the Company, and conducted and participated, directly and 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.

60. As officer and/or 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.

61. Because of his position of control and authority as senior officer, the 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

1 Exchange Act. In this capacity, he participated in the unlawful conduct alleged
2 which artificially inflated the market price of aTyr's common stock.

3
4 62. The Individual Defendant, therefore, acted as a controlling person of
5 the Company. By reason of his senior management position and/or being director of
6 the Company, the Individual Defendant had the power to direct the actions of, and
7 exercised the same to cause, aTyr to engage in the unlawful acts and conduct
8 complained of herein. The Individual Defendant exercised control over the general
9 operations of the Company and possessed the power to control the specific activities
10 which comprise the primary violations about which Plaintiff and the other members
11 of the Class complain.
12
13

14 63. By reason of the above conduct, the Individual Defendant and/or aTyr
15 are liable pursuant to Section 20(a) of the Exchange Act for the violations committed
16 by the Company.
17

18 **PRAYER FOR RELIEF**

19
20 **WHEREFORE**, Plaintiff demand judgment against Defendants as follows:

21 A. Determining that the instant action may be maintained as a class action
22 under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the
23 Class representatives;
24

25 B. Requiring Defendants to pay damages sustained by Plaintiff and the
26 Class by reason of the acts and transactions alleged herein;
27
28

1 C. Awarding Plaintiff and the other members of the Class pre-judgment
2 and post-judgment interest, as well as their reasonable attorneys' fees, expert fees
3 and other costs; and
4

5 D. Awarding such other and further relief as this Court may deem just and
6 proper.
7

8 **DEMAND FOR TRIAL BY JURY**

9 Plaintiff hereby demands a trial by jury.

10 Dated: October 9, 2025
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