UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 16, 2022

ATYR PHARMA, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-37378**	**20-3435077**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

3545 John Hopkins Court, Suite #250 **San Diego, CA** **(Address of Principal Executive Offices)**	**92121** **(Zip Code)**

Registrant's telephone number, including area code: (858) 731-8389

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	LIFE	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01 Other Events.

Clinical Trial

On May 16, 2022, aTyr Pharma, Inc. (the "Company"), announced a Phase 3 study evaluating the efficacy and safety of its lead therapeutic candidate, efzofitimod (the non-proprietary name for ATYR1923), in patients with pulmonary sarcoidosis. The study, which will be known as EFZO-FIT™, is expected to initiate in the third quarter of 2022.

The EFZO-FIT™ study is a global Phase 3 randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of efzofitimod in patients with pulmonary sarcoidosis. This will be 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 study intends to enroll 264 subjects with pulmonary sarcoidosis at multiple centers in North America, Europe and Japan. The trial design will incorporate a forced steroid taper. The primary endpoint of the study is steroid reduction. Secondary endpoints include measures of lung function and sarcoidosis symptoms.

Efzofitimod is a first-in-class immunomodulator that downregulates innate and adaptive immune responses in uncontrolled inflammatory diseases states via selective modulation of neuropilin-2. Clinical proof-of-concept was recently established for efzofitimod in a Phase 1b/2a study in patients with pulmonary sarcoidosis, a major form of interstitial lung disease (ILD).

Poster Presentations

On May 17, 2022, the Company announced that clinical data for efzofitimod will be presented in two posters on May 17, 2022 from 11:15AM – 1:15PM PT at the American Thoracic Society (ATS) 2022 International Conference in San Francisco, CA.

Details of the poster presentations are set forth below. The corresponding abstracts are available for review online on the conference website. The posters will be available on the Investor Relations section of the Company's website at www.atyrpharma.com once presented.

Title: Safety and Efficacy ATYR1923, a Novel Immunomodulator for Pulmonary Sarcoidosis: Results of a Phase 1b/2a Randomized Placebo-Controlled Trial
Abstract Number: 3932
Poster Number: P559
Poster Session: Inflammatory Modulation in Sarcoidosis, Lung Transplant, and Other Diseases
Date and Time: Tuesday, May 17, 2022 from 11:15AM – 1:15PM PT
Location: Area G, Hall F (North Building, Exhibition Level), Moscone Center

The poster presents findings from a Phase 1b/2a randomized, double-blind, placebo-controlled study of efzofitimod in patients with pulmonary sarcoidosis. Monthly dosing of efzofitimod was safe and well tolerated. There was a dose-dependent improvement in efficacy parameters, including corticosteroid (CS) taper, percent-predicted forced vital capacity (FVCPP), and patient reported outcomes. All efzofitimod treatment groups had lower (CS) use at week 24 compared to placebo, with the largest difference observed in the 5.0 mg/kg treatment group, where three patients were able to taper off CS completely and maintain that taper through the completion of the study. The two higher doses of efzofitimod, 3.0 mg/kg and 5.0 mg/kg, resulted in improvements in FVCPP and percent-predicted diffusing capacity of the lungs for carbon monoxide ($DL_{CO}PP$) through week 24 compared to placebo. Clinically meaningful and statistically significant improvements at week 24 were observed for key symptom measures in the 5.0 mg/kg treatment group. In small studies such as this, which was not powered for statistical significance, dose dependent improvements are strong evidence for efficacy.

Title: ATYR1923 Treatment Reduces Pro-Inflammatory Serum Biomarkers in Pulmonary Sarcoidosis Patients
Abstract Number: 3933
Poster Number: P560
Poster Session: Inflammatory Modulation in Sarcoidosis, Lung Transplant, and Other Diseases
Date and Time: Tuesday, May 17, 2022 from 11:15AM – 1:15PM PT
Location: Area G, Hall F (North Building, Exhibition Level), Moscone Center

The poster presents clinical biomarker findings from a Phase 1b/2a randomized, double-blind, placebo-controlled study of efzofitimod in patients with pulmonary sarcoidosis. Efzofitimod demonstrated dose dependent control of inflammatory and sarcoidosis disease biomarkers over 24 weeks in the context of a CS taper. The affected inflammatory biomarkers, including IFN-γ, IL-6, IP-10, MCP-1 and TNFa, and key markers of sarcoidosis, including IL-2Ra, SAA, ACE enzyme and ACE protein, are key drivers of sarcoidosis and other ILD and consistent with results from preclinical animal models and a Phase 2 study of efzofitimod in hospitalized COVID-19 pneumonia patients. These results are the first demonstration of efzofitimod's anti-inflammatory mechanism in patients with pulmonary

sarcoidosis. These analyses were exploratory and not adjusted for multiplicity to control for false positive results and will need to be confirmed in a larger study.

A corporate presentation regarding the Phase 3 study design and the Phase 1b/2a clinical study data is attached hereto as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	aTyr Pharma, Inc. Corporate Presentation dated May 16, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ATYR PHARMA, INC.

By: /s/ Jill M. Broadfoot
Jill M. Broadfoot
Chief Financial Officer

Date: May 17, 2022

Exhibit 99.1

A New Path to Medicine

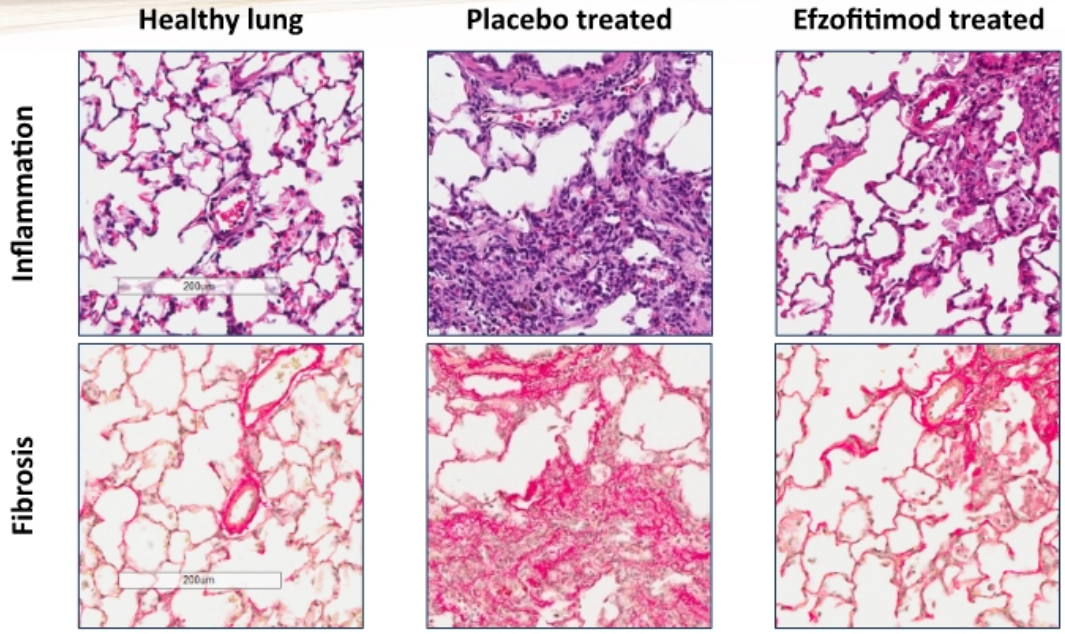
Company Reception

May 16, 2022

Forward Looking Statements

The following slides and any accompanying oral presentation contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. The use of words such as "may," "might," "will," "should," "expect," "plan," "anticipate," "believe," "estimate," "project," "intend," "future," "potential," "opportunity," or "continue," and other similar expressions are intended to identify forward-looking statements. For example, all statements regarding: the potential therapeutic benefits of proteins derived from tRNA synthetase genes and our product candidates, including efzofitimod and ATYR2810, and development programs, including our NRP2 antibody program and our tRNA synthetase program; the ability to successfully advance our product candidates and undertake certain development activities (such as the initiation of clinical trials, clinical trial enrollment, the conduct of clinical trials and announcement of clinical results) and accomplish certain development goals, and the timing of such events; the potential market opportunity for our product candidates; our ability to receive regulatory approvals for, and commercialize, our product candidates; our ability to identify and discover additional product candidates; potential activities and payments under collaboration agreements; and the ability of our intellectual property portfolio to provide protection are forward-looking statements. All forward-looking statements are based on estimates and assumptions by our management that, although we believe to be reasonable, are inherently uncertain. All forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those that we expected. These risks, uncertainties and other factors are more fully described in our filings with the U.S. Securities and Exchange Commission, including our Annual Report on Form 10-K, our Quarterly Reports on Form 10-Q, and in our other filings. The forward-looking statements in this presentation speak only as of the date of this presentation and neither we nor any other person assume responsibility for the accuracy and completeness of any forward-looking statement. We undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise, except as required by law.

Efzofitimod: A Novel Mechanism to Treat Lung Inflammation and Fibrosis



3 Representative histology showing immune cell infiltrate and collagen content in a rat model of bleomycin induced lung fibrosis presented at the ATS annual meeting 2018.

Foundational Science: Novel Functions of Extracellular tRNA Synthetases

tRNA synthetases are secreted extracellularly and occur in novel forms which lose their canonical function

Extracellular tRNA synthetase disruption (genetic/ autoimmune) is associated with disease in humans

Validated synthetase platform is an engine for new protein therapeutics (e.g. efzofitimod) and new target ID (e.g. NRP2)

aTyr

Efzofitimod (ATYR1923, KRP-R120)

A Novel Immunomodulator for Fibrotic Lung Disease

Efzofitimod: First-in-Class Therapy for Fibrotic Lung Disease

MOA	• Targets innate and adaptive immune cells during active inflammation to restore immune balance via selective modulation of NRP2
Pre-Clinical Evidence	• Anti-inflammatory and anti-fibrotic effects demonstrated in translational models of multiple ILDs • Reduces inflammatory cytokines and pro-fibrotic chemokines *in vitro* and *in vivo* • No toxicity observed in GLP toxicology rodents and non-human primates out to 6 months
Clinical Experience	• Safe and well-tolerated in clinical trials to date with exposure to 24 weeks • No immunogenicity observed • Controls inflammation by downregulating cytokines implicated in sarcoidosis and other ILD • Dose-dependent disease control demonstrated in pulmonary sarcoidosis patients

MOA = mechanism of action

Efzofitimod Therapeutic Goal: Restore Immune Balance and Prevent Fibrosis

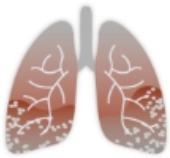
Disease Trigger

Organic; inorganic; infectious; autoimmune

Aberrant Immune Responses

T-cell activation; Pro-inflammatory cytokine/chemokines triggering fibrotic pathways; NRP2 upregulation on immune cells

Lung Inflammation & Fibrosis

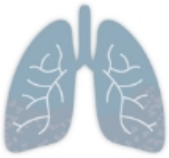


Persistent, unresolved inflammation in the lung can lead to fibrosis; patients experience chronic cough, dyspnea, mortality

Efzofitimod Dampens Immune Responses

Efzofitimod binds to NRP2 and downregulates cytokine and chemokine production and T-cell activation

Stabilized Lung



Reduced inflammation and fibrotic deposition; symptom relief, stabilized lung function*

*aTyr hypothesis

First Efzofitimod Indication: Pulmonary Sarcoidosis

- Multisystem inflammatory disorder of unknown etiology, characterized by the formation of granulomas (clumps of immune cells)
- Lung affected in ~90% of all patients
- ~5x increased mortality in advanced disease
- SOC: corticosteroids; cytotoxic immunosuppressants; anti-TNFs – limited development pipeline
- High unmet need for treatments with improved safety and clinically established efficacy

Large orphan population

50-75% require treatment

Persistent or progressive disease in **30-50%**

10-30% develop fibrosis with **5-10%** mortality

SOC – standard of care; Culver e2019; Baughman 2016; Baughman 2006, Mana 1994; Viskum 1993; Nagai 1999; Judson 1993; Neville 1983; Israel 1986; Wijsenbeek 2019

Efzofitimod (ATYR1923, KRP-R120)

Results from Phase 1b/2a Study in Pulmonary Sarcoidosis

Peter H. S. Sporn, M.D.
Professor of Medicine (Pulmonary and Critical Care); Cell and Developmental Biology; and Medical Education
Northwestern University Feinberg School of Medicine

Phase 1b/2a Trial Design

Design	• Randomized (2:1), double-blind, placebo-controlled, multiple ascending dose • 24 week study: 6 monthly IV doses of efzofitimod tested at 1, 3, and 5 mg/kg • Forced steroid taper to 5 mg by week 8; amendment to allow taper to 0 mg at week 16 in responders
Population	• 37 histologically confirmed pulmonary sarcoidosis patients • ≥10 mg stable oral corticosteroid treatment • Symptomatic/active disease at baseline
Primary Endpoint	• Safety and tolerability of multiple ascending IV efzofitimod doses
Secondary Endpoints	• Steroid-sparing effect • Immunogenicity • Pharmacokinetics (PK) • Exploratory: Lung function (FVC and other PFTs); sarcoidosis symptom scores and quality of life scales; inflammatory and sarcoidosis biomarkers; FDG-PET/CT imaging

FVC = Forced Vital Capacity; PFTs = Pulmonary Function Tests

Phase 1b/2a Inclusion / Exclusion Criteria

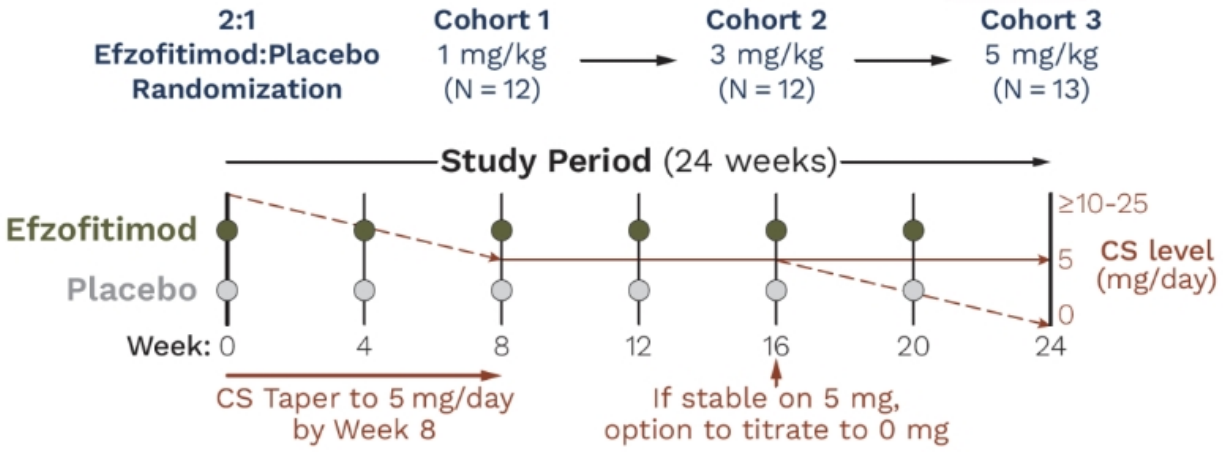
Inclusion

- Histologically proven diagnosis of pulmonary sarcoidosis
- Stable treatment with 10 -25 mg/day oral corticosteroid
  - oral immunomodulator allowed
- Symptomatic/active disease at baseline
  - FVC ≥ 50% percent predicted
  - MRC Dyspnea Scale score (>= 1)

Exclusion

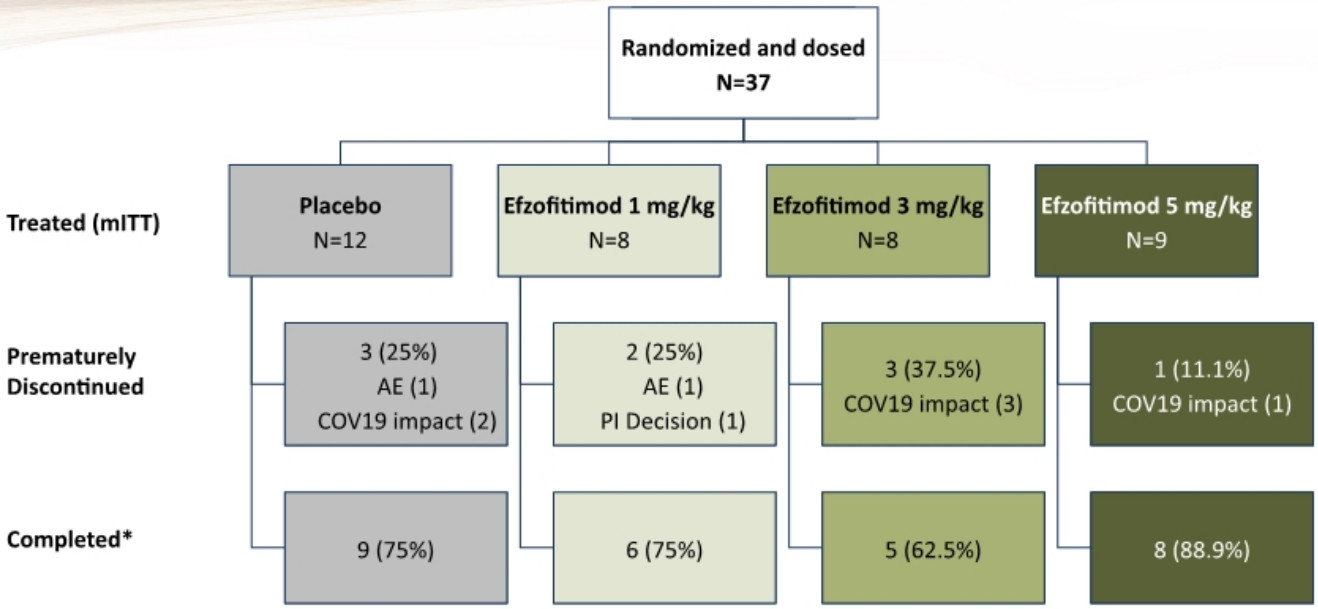
- Disease consistent with Lofgren's syndrome
- Treatment with biological immunomodulator such as tumor necrosis factor-alpha inhibitors
- Clinically significant cardiac, neurological, gastrointestinal, and/or renal sarcoidosis
- PH requiring vasodilator treatment

Phase 1b/2a Study Schema



(1) subtherapeutic dose

Phase 1b/2a Disposition



mITT = randomized and dosed; *Defined as receiving at least 5 doses and having an end of study assessment

Baseline Demographics and Disease Characteristics Generally Balanced

Demographics	Placebo N=12	Efzofitimod 1 mg/kg N=8	Efzofitimod 3 mg/kg N=8	Efzofitimod 5 mg/kg N=9
Age (Years); mean (SD), >=65	52.5 (10.2), 0	54.5 (11.3), 1	51.8 (11.4), 2	50.8 (9.2), 0
Sex (Male); n (%)	5 (42)	4 (50)	4 (50)	4 (44)
Race; White / African American	9 / 3	5 / 3	6 / 2	3 / 6
Disease characteristics Mean (SD)				
FVC (% predicted)	77.3 (11.5)	68.3 (9.7)	83.8 (7.3)	83.8 (16.6)
Duration of disease (Years)	4.2 (3.3)	7.4 (6.1)	5.9 (5.1)	7.7 (9.9)
Baseline Dyspnea Index Score	4.8 (2.0)	4.3 (1.8)	7.6 (3.0)	6.3 (2.5)
Background Therapy				
Steroid dose (mg/day), mean	13.3	11.3	14.4	13.9
Immunomodulator; n (%)	6 (50)	3 (38)	1 (13)	4 (44)

Monthly Dosing of Efzofitimod was Safe and Well-Tolerated

n (%)	Placebo N=12	Efzofitimod 1 mg/kg N=8	Efzofitimod 3 mg/kg N=8	Efzofitimod 5 mg/kg N=9
AEs	10 (83)	8 (100)	7 (88)	8 (89)
Drug-related AEs	4 (33)	3 (38)	1 (13)	3 (33)
Severe AEs (Grade 3 or 4)	4 (33)	2 (25)	0	2 (22)
SAEs	1 (8)	1 (13)	0	0

- No new or unexpected findings with repeat dosing
- No dose-response relationship observed
- Most frequent AEs were consistent with underlying disease: Cough, fatigue, wheezing
- No signal of immunogenicity
- No drug related SAEs
- No deaths

Safety population

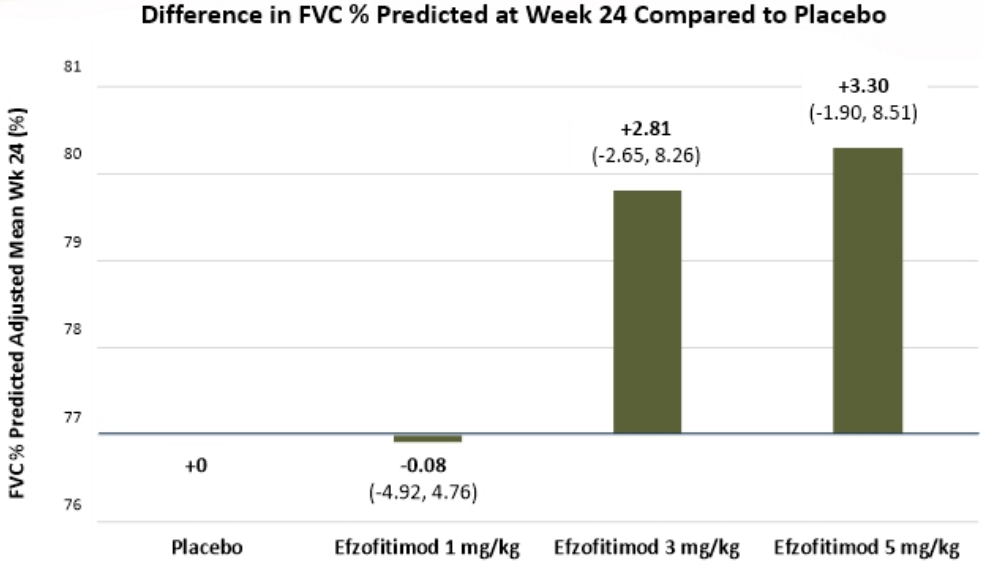
Dose-dependent Reduction in Steroid Utilization Compared with Placebo

Post-taper Period	Placebo N=12	Efzofitimod 1 mg/kg N=8	Efzofitimod 3 mg/kg N=8	Efzofitimod 5 mg/kg N=9
Average daily dose (mg), adjusted mean	7.17	6.83	6.54	5.62
- relative reduction vs placebo (%)	-	-5%	-9%	-22%
Change from baseline (%), mean	-46	-41	-49	-58
- difference in adjusted means (%), mean (95% CI)	-	1.2 (-20, 22)	-2.3 (-23, 19)	-12.3 (-33, 8)
Tapered to 0 mg and maintained taper, n (%)	0	0	0	3 (33)

- 58% overall steroid reduction from baseline and 22% relative reduction compared to placebo in steroid utilization post taper in the 5 mg/kg treatment group
- 33% of patients able to taper off of steroids completely in 5 mg/kg treatment group while controlling disease symptoms

D51-EOS; adjusted mean refers to least squares mean from ANCOVA adjusting for baseline steroid use

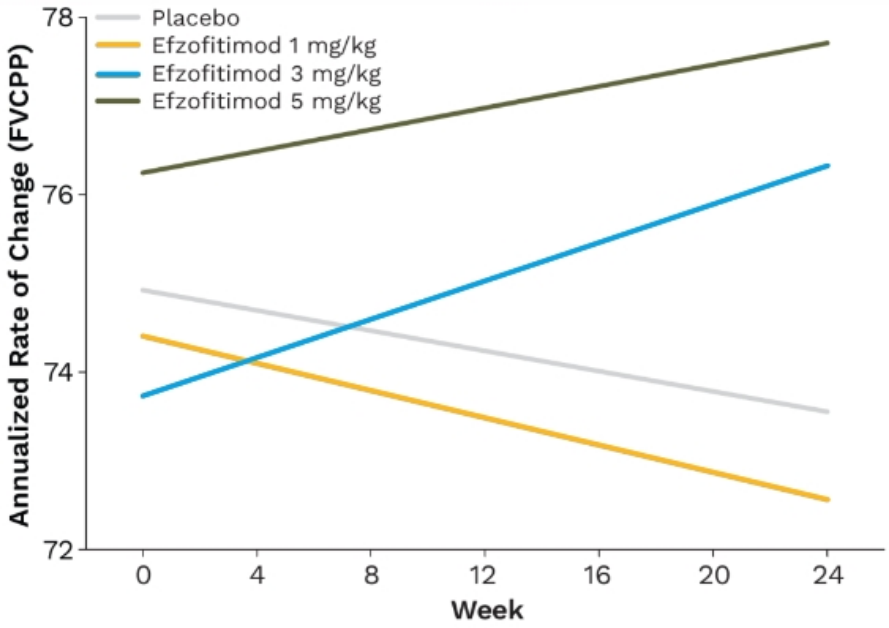
Dose-dependent Improvement in FVC % Predicted Compared to Placebo



FVC % predicted adjusted mean at week 24 in the placebo arm = 76.8%

Differences represent from MMRM adjusting for baseline FVC % Predicted, mean (95% CI)

Higher Efzofitimod Doses Show Trends of Improvement in FVC % Predicted



Dose-dependent Improvements in PFTs Over Time Compared with Placebo

FVC, mean (SD)	Placebo N=12	Efzofitimod 1 mg/kg N=8	Efzofitimod 3 mg/kg N=8	Efzofitimod 5 mg/kg N=9
Absolute CFB at Week 24 (mL)	-40 (230)	-80 (160)	120 (130)	110 (250)
FVC % predicted, mean (SD)				
Absolute CFB at Week 24 (%)	-0.9 (6.1)	-2.3 (3.9)	2.6 (2.5)	2.6 (5.6)
Dlco % predicted, mean (SD)				
Absolute CFB at Week 24 (%)	-6.2 (14.4)	-6.1 (4.0)	-1.4 (5.0)	4.4 (14.6)

PFTs = Pulmonary Function Tests; CFB = Change From Baseline

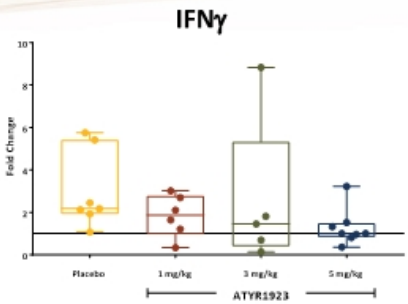
Dose-dependent Symptom Improvements Compared with Placebo

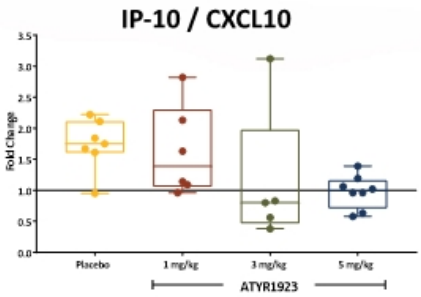
Differences in Adjusted Means vs Pbo at Week 24	Efzofitimod 1 mg/kg N=8	Efzofitimod 3 mg/kg N=8	Efzofitimod 5 mg/kg N=9
Dyspnea (TDI)	-0.76	3.33	4.49
Cough (LCQ)	-3.49*	2.98*	2.05
Fatigue (FAS)	0.76	-4.78	-7.77*
King's Sarcoidosis Score: Lung	-6.41	11.29	16.17*
King's Sarcoidosis Score: General Health	-5.1	2.13	18.33*

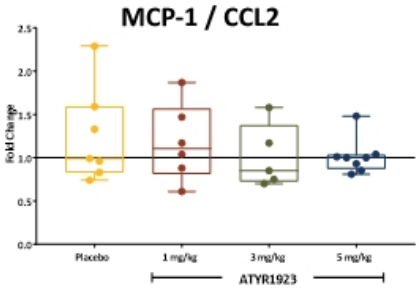
= clinically meaningful improvement based on published MCID

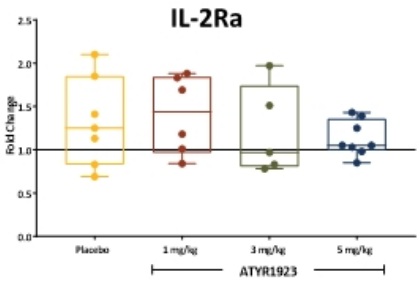
*p<0.05 on difference between adjusted means from MMRM; Pbo = Placebo
MCIDs: TDI - Witek 2003; LCQ – Raj 2009; FAS - de Kleijin 2011 (Negative score is better for Fatigue); KSQ Lung – Baughman 2021; KSQ Lung – Baughman 2021

Dose-dependent Control of Key Disease and Inflammatory Biomarkers









Graphs represent fold change at Week 24 compared to Baseline

Phase 1b/2a Data Supports Proof-of-Concept and Clinical Advancement

- Efzofitimod was safe and well-tolerated
- Strong suggestion of efficacy: Dose-response and consistent positive trends across key efficacy endpoints and multiple analysis populations
- Clinically meaningful symptom improvements in dyspnea, cough, fatigue and King's Sarcoidosis scores
- Dose dependent control of inflammatory biomarkers confirms anti-inflammatory effect

Efzofitimod (ATYR1923, KRP-R120)

Phase 3 EFZO-FIT™ Study

Robert P. Baughman, M.D.
Emeritus Professor of Medicine
University of Cincinnati

Dose-dependent Reduction in Steroid Utilization Compared with Placebo

Post-taper Period	Placebo N=12	Efzofitimod 1 mg/kg N=8	Efzofitimod 3 mg/kg N=8	Efzofitimod 5 mg/kg N=9
Average daily dose (mg), adjusted mean	7.17	6.83	6.54	5.62
- relative reduction vs placebo (%)	-	-5%	-9%	-22%
Change from baseline (%), mean	-46	-41	-49	-58
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Tapered to 0 mg and maintained taper, n (%)	0	0	0	3 (33)

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- 33% of patients able to taper off of steroids completely in 5 mg/kg treatment group while controlling disease symptoms

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Dose-dependent Symptom Improvements Compared with Placebo

Differences in Adjusted Means vs Pbo at Week 24	Efzofitimod 1 mg/kg N=8	Efzofitimod 3 mg/kg N=8	Efzofitimod 5 mg/kg N=9
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= clinically meaningful improvement based on published MCID

*p<0.05 on difference between adjusted means from MMRM; Pbo = Placebo
MCIDs: TDI - Witek 2003; LCQ – Raj 2009; FAS - de Kleijin 2011 (Negative score is better for Fatigue); KSQ Lung – Baughman 2021; KSQ Lung – Baughman 2021

EFZO-FIT™ : Phase 3 Study of Efzofitimod in Pulmonary Sarcoidosis

Clinical POC Established	• Phase 1b/2a study was first in sarcoidosis to demonstrate effects on physiologic and quality of life measures concurrent with steroid reduction
FDA Alignment	• Positive FDA End-of-Phase 2 meeting supports advancement of clinical development • Aligned on prioritization of endpoints that are most clinically meaningful to patients and providers
Global Pivotal Trial	• Multiple sites in North America, Europe and Japan • Expected to initiate in Q3 2022

Trial Design

Objectives	• Primary: Assess the efficacy of efzofitimod in patients with pulmonary sarcoidosis • Secondary: Assess the safety and tolerability of efzofitimod in patients with pulmonary sarcoidosis • Exploratory: Explore the utility of serum biomarkers in evaluation of interventions to treat pulmonary sarcoidosis
Design	• Phase 3, randomized, double-blind, placebo-controlled, multicenter study
Randomization	• Target enrollment of 264 patients • 1:1:1 efzofitimod 3 mg/kg, efzofitimod 5 mg/kg, or placebo, with 88 patients assigned to each arm • Randomization stratum: ○ Presence or absence of concomitant immunosuppressant therapy, and ○ OCS dose at baseline (< 10 mg/day versus ≥ 10 mg/day [prednisone or equivalent])
Duration	• Screening: up to 4 weeks • Treatment Period: 48 weeks (12 monthly doses through Week 44); Primary Assessment at Week 48 • Final Visit: Week 52 (8 weeks post-dose follow-up)

Still under discussion with Kyorin clinical team

Major Efficacy Endpoints

Primary Endpoint

- Change from baseline in mean daily OCS dose post-taper

Secondary Endpoints

- Annual rate of change in absolute value of FVC
- Percent change from baseline in mean daily OCS dose post-taper at Week 48
- Change from baseline in KSQ-Lung score at Week 48

Key Inclusion / Exclusion Criteria

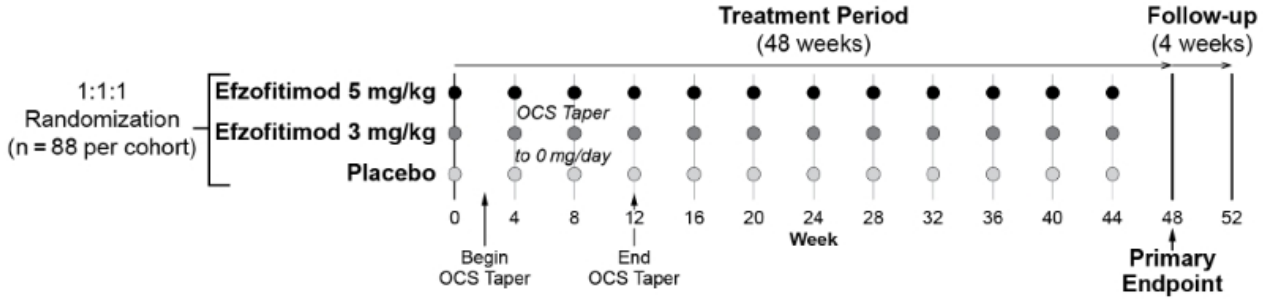
Inclusion

- Adults ages 18-75, inclusive
- Diagnosis of pulmonary sarcoidosis for ≥6 months
- Requiring stable treatment with ≥7.5 but ≤25 mg/day oral corticosteroids
- Medical Research Council (MRC) Dyspnea Scale ≥ 1
- KSQ Lung Score ≤ 70

Exclusion

- Extent of fibrosis > 20%
- Forced Vital Capacity < 50%
- Treatment > 1 oral immunomodulator
- Clinically significant pulmonary hypertension
- Patients with cardiac/neuro/renal sarcoidosis
- Treatment with biological immunomodulators

Phase 3 Study Schema



OCS = oral corticosteroids

Multi-center Trial with Sites in North America, Europe and Japan

Anticipating 60-80 centers in 10 countries

Thank You