Präsentationen unterstreichen das Potenzial von Efzofitimod bei pulmonaler Sarkoidose

Die Therapie könnte den Bedarf an sichereren Behandlungsmöglichkeiten decken, sagt ihr Entwickler

von Lindsey Shapiro, PhD | 20. Mai 2025

Viele Menschen mit mittelschwerer oder schwerer Lungensarkoidose - dem Zielmarkt für das Prüfpräparat Efzofitimod - sind durch die Krankheit stark belastet und auf Kortikosteroide angewiesen, die schwerwiegende Nebenwirkungen haben können, wie Analysen aus der Praxis zeigen.

„Neue Erkenntnisse aus der Praxis unterstreichen die wachsende Belastung der Patienten, die mit Lungensarkoidose leben, und die anhaltende Abhängigkeit von oralen Kortikosteroiden als Standardbehandlung, trotz ihrer begrenzten klinischen Evidenz und toxischen Nebenwirkungen“, sagte Sanjay S. Shukla, MD, Präsident und CEO des Entwicklers von Efzofitimod, Atyr Pharma, in einer Pressemitteilung des Unternehmens.

Das Unternehmen ist der Ansicht, dass seine experimentelle Behandlung einen Bedarf an wirksameren und sichereren Behandlungsmöglichkeiten für diese Patientengruppe decken könnte.

Ergebnisse auf der Konferenz der American Thoracic Society vorgestellt
Die Teilnehmer an der klinischen Phase-3-Studie EFZO-FIT (NCT05415137), in der Efzofitimod im Vergleich zu einem Placebo bei 264 Lungensarkoidose-Patienten getestet wird, sind im Allgemeinen repräsentativ für diese Zielgruppe. Atyr hat sich bereits mit den US-Zulassungsbehörden über den Haupterfolgsmaßstab der Studie verständigt, und die Ergebnisse werden im Laufe dieses Jahres erwartet.

„Wir glauben, dass Efzofitimod ein vielversprechendes Mittel ist, um diesen unterversorgten Markt zu verändern, und wir freuen uns darauf, im dritten Quartal dieses Jahres [Juli bis September] erste Ergebnisse zu veröffentlichen“, sagte Shukla.

Alle diese Ergebnisse werden in drei Posterpräsentationen auf der internationalen Konferenz der American Thoracic Society 2025, die vom 16. bis 21. Mai in San Francisco stattfindet, diskutiert.

Bei der Sarkoidose sammeln sich abnorme Klumpen von Immunzellen, so genannte Granulome, in verschiedenen Geweben an und können Entzündungen und Narbenbildung (Fibrose) verursachen. Die pulmonale Sarkoidose, bei der die Krankheit die Lunge befällt, führt zu Symptomen wie Kurzatmigkeit, Husten und Brustschmerzen.

Orale Kortikosteroide haben eine starke immunsuppressive Wirkung und sind derzeit die erste Behandlungsoption, können aber bei langfristiger Anwendung oder hohen Dosen schwere Nebenwirkungen verursachen.
Andere Behandlungen können den Bedarf an Kortikosteroiden minimieren, haben aber ihre eigenen Nachteile, darunter ein erhöhtes Infektionsrisiko aufgrund der umfassenden Immunsuppression.

In zwei der Posterpräsentationen untersuchten die Wissenschaftler Daten aus der Praxis, um die Häufigkeit, die Belastung und die Behandlungsmuster der pulmonalen Sarkoidose in den USA weiter zu bewerten.

Die Ergebnisse des Posters „Incidence, Prevalence, and Mortality of Pulmonary Sarcoidosis with Parenchymal Involvement in the US“ (Inzidenz, Prävalenz und Mortalität der pulmonalen Sarkoidose mit parenchymaler Beteiligung in den USA) zeigen, dass in den USA fast 160.000 Menschen an pulmonaler Sarkoidose mit Beteiligung des mit dem Gasaustausch verbundenen Lungengewebes erkrankt sind, wobei jedes Jahr schätzungsweise 30.000 neue Fälle auftreten. Die Krankheit betrifft überproportional häufig Frauen und Schwarze, und 40 % der Patienten sind älter als 65 Jahre.

Etwa jeder achte Patient mit Lungensarkoidose wird innerhalb von drei Jahren ins Krankenhaus eingeliefert, und bei Patienten im Alter von 65 bis 74 Jahren ist die Sterblichkeitsrate fast doppelt so hoch wie in der Allgemeinbevölkerung.

Kortikosteroide werden häufiger eingesetzt als bisher angenommen In einem Poster mit dem Titel „Real-World Treatment Patterns Among Pulmonary Sarcoidosis Patients with Parenchymal Involvement in the US“ (Behandlungsmuster bei Lungensarkoidose-Patienten mit parenchymaler Beteiligung in den USA) wurden reale Behandlungsmuster auf der Grundlage von Versicherungsdaten vorgestellt.

Die Ergebnisse zeigen, dass Kortikosteroide die am häufigsten eingesetzte Behandlung der pulmonalen Sarkoidose sind, aber die Anwendungsraten sind noch höher als bisher angenommen. „Nur 8 % der Patienten verwenden keine Glukokortikoide als erste Behandlungsform“, schreiben die Forscher.

Darüber hinaus verwenden 75 % der Patienten, die andere Medikamente als Zweitlinientherapie erhalten, weiterhin Kortikosteroide, was trotz Sicherheitsbedenken und Behandlungsrichtlinien auf die Schwierigkeiten beim Auslaufen der Behandlung hinweist“, heißt es in der Mitteilung.

Patienten, die eine Erstlinientherapie benötigten, schienen danach schnell weitere Therapien zu benötigen, wobei Zweitlinientherapien innerhalb von sieben Monaten nach der Erstlinientherapie und Drittlinientherapien innerhalb eines Jahres nach der Zweitlinientherapie begonnen wurden.

„Diese Ergebnisse machen deutlich, dass ein dringender Bedarf an sichereren und wirksameren Behandlungen für Patienten mit dieser chronischen Krankheit besteht“, so Shukla.

Efzofitimod, das direkt in den Blutkreislauf infundiert wird, moduliert die Aktivität von Immunzellen, die an der Sarkoidose beteiligt sind, indem es an ein Protein auf ihrer Oberfläche namens Neuropilin-2 bindet. Es wird erwartet, dass dies dazu beiträgt, Entzündungen zu heilen und die Entwicklung von Fibrose zu verhindern, ohne die gesunden Immunreaktionen zu beeinflussen, die zur Bekämpfung von Infektionen erforderlich sind.
Diese Ergebnisse unterstreichen den klaren und dringenden Bedarf an sichereren und wirksameren Behandlungen für Patienten mit dieser chronischen Krankheit.

In der EFZO-FIT-Studie, in die im vergangenen Jahr 268 Personen aufgenommen wurden, werden die Sicherheit und Wirksamkeit von Efzofitimod (3 mg/kg oder 5 mg/kg), das alle vier Wochen infundiert wird, im Vergleich zu einem Placebo bei Erwachsenen mit Lungensarkoidose untersucht.
Das Hauptziel der Studie besteht darin, die Fähigkeit der Patienten zu bewerten, die Kortikosteroide nach fast einem Jahr Behandlung abzusetzen, wobei die Lungenfunktion und die Lebensqualität als sekundäre Zielgrößen dienen.

In dem Poster „EFZO-FIT, the Largest Placebo-Controlled Trial in Pulmonary Sarcoidosis“ (EFZO-FIT, die größte Placebo-kontrollierte Studie bei Lungensarkoidose) zeigen die Forscher, dass die 264 Teilnehmer, die an der Studie teilnahmen, eine Population mit mittelschwerer bis schwerer chronischer symptomatischer Lungensarkoidose repräsentieren.

Das Durchschnittsalter der Teilnehmer beträgt 53,8 Jahre, 56,8 % sind Männer und 64 % sind weiß. Mehr als ein Drittel (38,3 %) nahm zusätzlich zu den oralen Kortikosteroiden kortikosteroidsparende Immunsuppressiva ein, deren durchschnittliche Dosis zu Beginn der Studie 10,55 mg betrug.

„Wir freuen uns, berichten zu können, dass wir eine Gruppe von Lungensarkoidose-Patienten in unsere laufende Phase-3-EFZO-FIT-Studie aufgenommen haben, die unserer Meinung nach ... eine mittelschwere bis schwere Patientenpopulation widerspiegelt, die wir als Zielmarkt für Efzofitimod ansehen“, sagte Shukla.

Ein unabhängiges Daten- und Sicherheitsüberwachungsgremium hat die Sicherheitsergebnisse der Studie bisher ebenfalls viermal überprüft. Bei jeder Überprüfung wurden keine signifikanten Sicherheitsrisiken festgestellt, und es wurde empfohlen, die Studie wie geplant ohne Änderungen fortzusetzen.

Sarcoidosis NEWS
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Presentations highlight efzofitimod's potential for pulmonary sarcoidosis

Therapy could fill need for safer treatment options, its developer says

by Lindsey Shapiro, PhD | May 20, 2025

Many people with moderate or severe pulmonary sarcoidosis — the target market for the investigational therapy efzofitimod — are highly burdened by the disease and are dependent on corticosteroids that can have serious side effects, according to real-world analyses.

"New real-world evidence underscores the growing burden of patients living with pulmonary sarcoidosis and the continued reliance on oral corticosteroids as the standard of care, despite their limited clinical evidence and toxic side effects," Sanjay S. Shukla, MD, president and CEO of efzofitimod's developer, Atyr Pharma, said in a company press release.
The company believes its experimental treatment could fill a need for more efficacious and safer treatment options in this patient population.

Findings shared at American Thoracic Society conference

Participants in the Phase 3 EFZO-FIT clinical trial (NCT05415137), which is testing efzofitimod against a placebo in 264 pulmonary sarcoidosis patients, are generally representative of this target population. Atyr has already aligned with U.S. regulators on the study's main outcome measure, and results are due later this year.

"We believe efzofitimod shows great promise to be a transformative therapy in this underserved market and we look forward to sharing topline results in the third quarter of this year [July to September]," Shukla said.

All these findings are being discussed in three poster presentations at the American Thoracic Society 2025 International Conference, being held May 16-21 in San Francisco.

In sarcoidosis, abnormal clumps of immune cells called granulomas accumulate in various tissues and can cause inflammation and scarring (fibrosis). Pulmonary sarcoidosis, where the disease affects the lungs, leads to symptoms like shortness of breath, coughing, and chest pain.
Oral corticosteroids have strong immunosuppressive effects and are the current first-line treatment option, but they can cause serious side effects when used long term or at high doses.
Other treatments may be used to minimize the need for corticosteroids, but have their own drawbacks, including an increased risk of infections due to broad immunosuppression.

In two of the poster presentations, scientists looked at real-world data to further assess the frequency, burden, and treatment patterns of pulmonary sarcoidosis in the U.S.
Results detailed in the poster "Incidence, Prevalence, and Mortality of Pulmonary Sarcoidosis with Parenchymal Involvement in the US" showed that nearly 160,000 people in the U.S. have pulmonary sarcoidosis with involvement of gas exchange-related lung tissue, with an estimated 30,000 new cases every year. The disease disproportionately affects women and Black people, and 40% of patients are older than 65 years.
About one in every eight people with pulmonary sarcoidosis are hospitalized within three years, and patients ages 65 to 74 have a mortality rate nearly twice as high as that of the general population.

Corticosteroids more commonly used than previously thought
Real-world treatment patterns, based on insurance claims data, were presented in a poster, titled "Real-World Treatment Patterns Among Pulmonary Sarcoidosis Patients with Parenchymal Involvement in the US."
Corticosteroids are the most commonly used pulmonary sarcoidosis treatment, results showed, but usage rates are even higher than previously estimated. "Only 8% of patients do not use glucocorticoids as their initial treatment type," the researchers wrote.

In addition, 75% of patients given other medications as their second-line treatment continue to use corticosteroids, “highlighting challenges with tapering despite safety concerns and treatment guidelines,” the release stated.
Patients needing first-line treatment seemed to progress quickly to needing additional therapies thereafter, with second-line therapies begun within seven months of first-line treatment, and third-line therapies begun within one year of second-line treatment.

“These findings highlight a clear and urgent need for safer, more effective treatments for patients with this chronic disease,” Shukla said.

Infused directly into the bloodstream, efzofitimod works to modulate the activity of immune cells implicated in sarcoidosis by binding to a protein found on their surface called neuropilin-2. This is expected to help resolve inflammation and prevent fibrosis development without influencing healthy immune responses needed to fight infections.
These findings highlight a clear and urgent need for safer, more effective treatments for patients with this chronic disease.
EFZO-FIT, which completed enrollment of 268 people last year, is assessing the safety and efficacy of efzofitimod (3 mg/kg or 5 mg/kg), infused once every four weeks, against a placebo in adults with pulmonary sarcoidosis who are on corticosteroids.
The main efficacy goal is to assess patients’ ability to taper off corticosteroids after nearly a year of treatment, with lung function and life quality as secondary outcome measures.

In the poster “EFZO-FIT, the Largest Placebo-Controlled Trial in Pulmonary Sarcoidosis,” researchers showed the 264 dosed participants were reflective of a population with moderate to severe chronic symptomatic pulmonary sarcoidosis.
Participants’ mean age is 53.8, 56.8% are men, and 64% are white. More than a third (38.3%) were on corticosteroid-sparing immunosuppressants on top of oral corticosteroids, whose mean dose at the study’s start was 10.55 mg.

“We are pleased to report that we have enrolled a [group] of pulmonary sarcoidosis patients in our ongoing Phase 3 EFZO-FIT study that we believe is … reflective of a moderate to severe patient population that we see as the target market for efzofitimod,” Shukla said.

An independent data and safety monitoring board has reviewed safety findings from the trial four times to date as well. With each review, it found no significant safety risks and recommended the study proceed as planned without modifications.

About the Author
Lindsey Shapiro, PhD Lindsey earned her PhD in neuroscience from Emory University in Atlanta, where she studied novel therapeutic strategies for treatment-resistant forms of epilepsy. She was awarded a fellowship from the American Epilepsy Society in 2019 for this research. Lindsey also previously worked as a postdoctoral researcher, studying the role of inflammation in epilepsy and Alzheimer’s disease.

Poster Board # P51

Real-World Treatment Patterns Among Pulmonary Sarcoidosis Patients with Parenchymal Involvement in the US

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Introduction

- Pulmonary sarcoidosis **treatment guidelines recommend systemic glucocorticoids** for first-line treatment, but **glucocorticoid toxicity warrants careful consideration** of treatment selection
- The **extent of glucocorticoid utilization as first-line and in later-line treatment** is not well documented

Objective

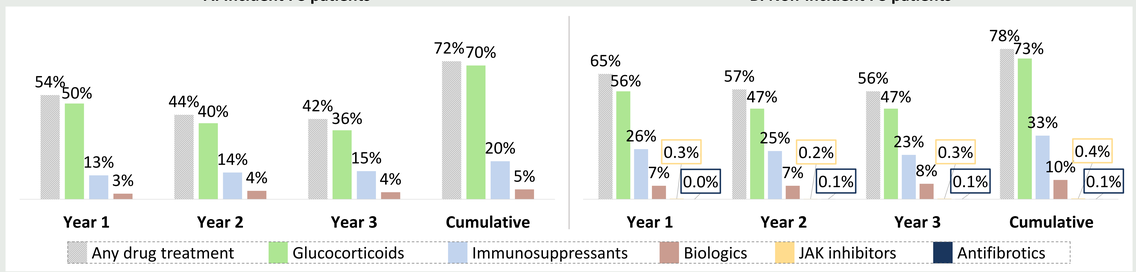
- Evaluate **treatments used in real-world clinical management** for pulmonary sarcoidosis patients with parenchymal involvement in the US

Methods

- Pulmonary sarcoidosis patients with parenchymal involvement were **identified using ICD-10 diagnosis code for sarcoidosis of the lung without (D86.0) or with (D86.2) lymph involvement** in the July 2017 – June 2023 MarketScan Commercial Claims and Encounters database
  - For each patient, the service date of the **first identified claim in July 2019 – June 2020** with one of these diagnosis codes **was defined as the index date**
  - Patients **without a lung sarcoidosis diagnosis** for at least 2 years prior to index were considered the **incident subgroup**
  - Patients with a lung sarcoidosis within 2 years prior to index were the non-incident subgroup
- **Use rates among treatments** for pulmonary sarcoidosis management were assessed in **medical and pharmacy claims for three years** following index
  - Drug classes evaluated were glucocorticoids, immunosuppressants, biologics, repository corticotrophin injections, JAK inhibitors, anti-fibrotics
  - **Glucocorticoid use was further distinguished by route of administration** (ROA): oral, intravenous, subcutaneous, intra-arterial, intramuscular, inhaled, sublingual
  - Each drug class, and the glucocorticoids by ROA, were considered different lines of treatment
  - In combination regimens, drug classes and glucocorticoids by ROA were assessed separately

Results

Figure 1: Proportion of PS patients on each treatment class, by year and cumulatively for 3 years



- Of 1,166 pulmonary sarcoidosis patients with parenchymal lung involvement identified, 136 were incident and 1,030 non-incident
- **Over half (54%) of incident patients required treatment** within the first year following diagnosis; of these, **92% used glucocorticoids** (Figure 1A)
  - **72% of patients required treatment within three years of diagnosis**, with **97% of those receiving glucocorticoids**
- In the non-incident patient population, **over 56% of patients required treatment** in a given year, with the **3-year rate rising to 78%** (Figure 1B)
  - **One-third of non-incident patients required immunosuppressants**, and **one in 10 required biologics** in a three-year period

Figure 2: Distribution of treatment type within each treatment line among incident patients

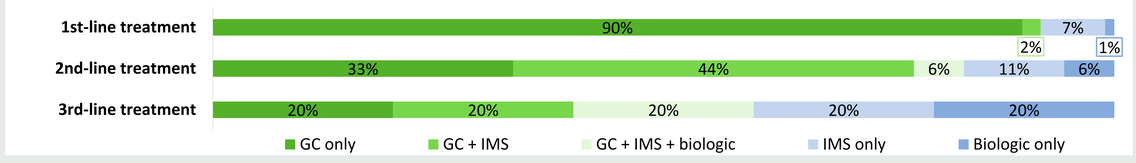
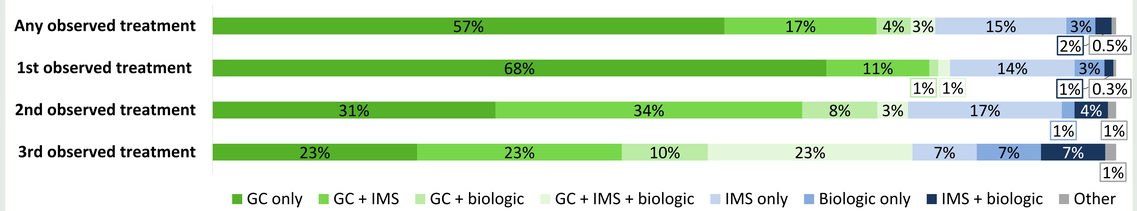


Figure 3: Distribution of treatment type within each treatment line among non-incident patients



- **Glucocorticoids are a mainstay of first-line treatment**, and only 8% of patients do not use glucocorticoids as their initial treatment type (Figure 2 and 3)
- Of incident patients treated with immunosuppressants or biologics in their second-line, **75% required continued use of glucocorticoids**
- The second-observed treatment for **non-incident patients frequently involved immunosuppressants (58%)** whether alone or with other therapies, and **64% of those were in combination with glucocorticoids**

Results *(cont.)*

Figure 4: Percentage of incident patients by number of treatment lines

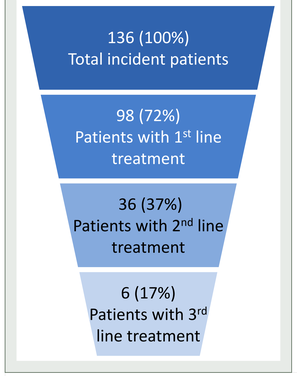
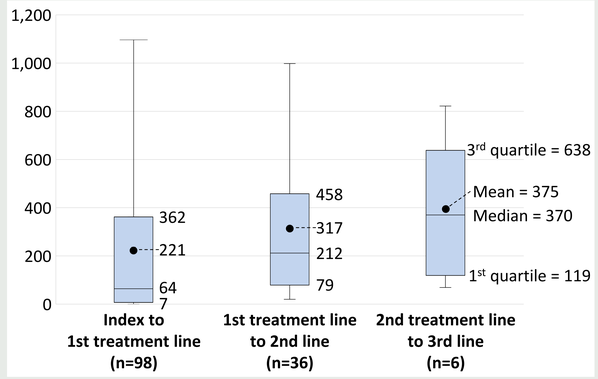


Figure 5: Days between lines of treatment among incident patients



- Over **one-third (37%) of treated incident patients required escalation beyond first-line therapy** in the first three years following diagnosis (Figure 4)
- Patients who **start treatment do so quickly**; the median time to treatment initiation was ~2 months following their incident diagnosis (Figure 5)
  - Of incident patients **escalating to second-line treatment**, most do so **within 7 months** (212 days) after starting their first-line treatment
  - Most patients **escalating to third-line treatment** do so **within one year (370 days)** following the start of their second-line treatment

Conclusions

- Glucocorticoids remain the **most common treatment for patients with pulmonary sarcoidosis** with parenchymal involvement, with higher rates of treatment than previously reported for US populations
- The **majority of patients using advanced therapies** in their second line of treatment also **have to maintain use of glucocorticoids**, emphasizing the **inability to taper glucocorticoids despite known safety risks**
- Patients who require later-line therapies tend to **accelerate through treatments quickly**, even among newly incident patients, suggesting that first-line **glucocorticoid treatment is insufficient or unsustainable**
- Rates of overall treatment and of **later-line immunosuppressant and biologic treatments** are even **higher among non-incident patients**, demonstrating **escalating treatment needs over time despite continued widespread use of glucocorticoids**

Disclosures

Funding for this work was provided by aTyr Pharma, Inc.

ES and YY are employees of aTyr. TMY, KM, BK, and MC are employees of Guidehouse Inc., which received funding for this work.

Poster Board # P536

EFZO-FIT™, the Largest Placebo-Controlled Trial in Sarcoidosis

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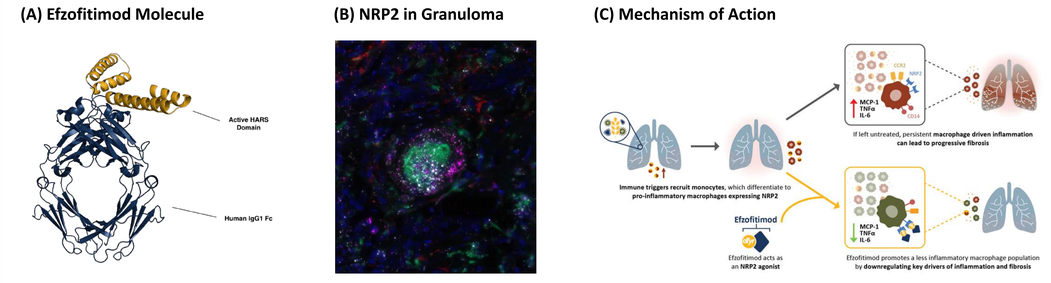
Introduction

Background: Sarcoidosis is a chronic inflammatory granulomatous disease. Oral corticosteroids (OCS) are potent anti-inflammatory agents, that are first line treatment for sarcoidosis. Chronic OCS use is associated with considerable side effects and steroid reduction is an important goal in managing sarcoidosis.

In an earlier Phase 1/2 study, efzofitimod showed favorable dose- and exposure-response results across multiple efficacy endpoints, including the ability to reduce steroids [1,2]. Efzofitimod is currently being evaluated in EFZO-FIT, the largest, interventional, placebo-controlled Phase 3 clinical trial. Enrollment was completed in July 2024; blinded follow-up continues for one year.

Figure 1. Efzofitimod is a first-in-class biologic immunomodulator for ILD

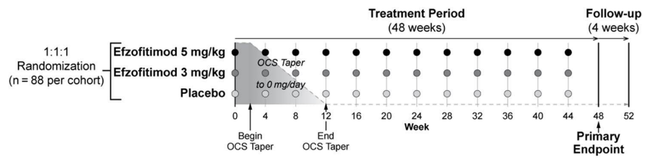


(A) Efzofitimod, a biologic immunomodulator, comprised of an active moiety derived from histidyl-tRNA synthetase (HARS), fused to the Fc region of human immunoglobulin G1 (IgG1). Efzofitimod's target receptor is neuropilin-2 (NRP2). **(B)** NRP2 RNA (white dots) is colocalized with macrophage markers CD68 (green) and CD163 (orange) in granulomas from pulmonary sarcoidosis patients. **(C)** Efzofitimod downregulates the expression of the inflammatory and profibrotic markers implicated in the pathology of inflammatory-fibrotic lung diseases: interleukin (IL)-6, TNF-α, IFN-γ, monocyte chemoattractant protein-1 (MCP-1), and IFN γ-induced protein 10 kDa (IP 10) [3,4].

Methods

- EFZO-FIT is a global, randomized, double-blind, placebo-controlled trial evaluating the efficacy and safety of efzofitimod in patients with pulmonary sarcoidosis (NCT05415137).
- Randomization was stratified based on the OCS dose at baseline (< 10 mg/day versus ≥ 10 mg/day [prednisone or equivalent]) and the presence or absence of concomitant immunosuppressants. Eligible patients were randomized 1:1:1 to efzofitimod 3.0 or 5.0 mg/kg, or placebo, dosed intravenously every 4 weeks for 12 doses (Figure 2).
- Steroid reduction is the primary efficacy parameter of EFZO-FIT. The primary endpoint is change from baseline in mean daily OCS dose at Week 48. Other key efficacy parameters are forced vital capacity and quality of life measures.
- The study was designed to include adults (≥ 18 years) with chronic (duration ≥ 6 months), symptomatic (modified medical research council [MRC] dyspnea score ≥1, King's sarcoidosis questionnaire [KSQ]-Lung Score ≤70), pulmonary sarcoidosis (biopsy proven) on OCS for 3 months (stable for 4 weeks) with a FVC percent predicted ≥50%. The starting dose for OCS was ≥ 7.5 and ≤ 25 mg/day (except Japan, ≥ 5 and ≤ 25 mg/day). Up to one concomitant immunosuppressant was allowed. Patients with active cardiac, neuro, or renal sarcoidosis requiring organ-specific therapy in the prior two years; or with cutaneous or ocular sarcoidosis, which the Investigator deemed at risk for exacerbation, necessitating OCS or other systemic therapy, were excluded.

Figure 2. Study Design



Results

The study enrolled 268 patients. Four were randomized but not dosed. The study population was consistent with moderate to severe chronic symptomatic pulmonary sarcoidosis (Table 1). Of the 264 patients, 101 (38.3%) were on concomitant immunosuppressants.

Unblinded reviews were conducted by an external independent Data Safety Monitoring Board (DSMB) (Figure 3). The last scheduled DSMB review of safety data occurred after all patients had been enrolled, with the last enrolled patient having completed 6 months. Following review of the unblinded data, the DSMB recommended – *"To continue trial unmodified until the next scheduled or triggered meeting (study does did not pose any undue risk to the patient that warrants additional safety measures)".*

Table 1. Baseline Demography (n=264)[1]

Demographics	
Age (years)	
Mean (SD)	53.8 (10.6)
Range	32-75
Gender (%)	
Female	114 (43.2)
Male	150 (56.8)
Weight (kg)	
Mean (SD)	85.5 (19.2)
Range	40.4-139
BMI (kg/m^2)	
Mean (SD)	29.1 (5.6)
Range	17.2-49.8
Race (%)	
White	169 (64)
Black or African American	42[2] (15.9)
Asian (Japanese)	36 (13.6)
Other[3]/Mixed/Unknown	17 (6.4)

Table 2. Disease Characteristics (n=264)[1]

Disease Characteristics	
Baseline OCS dose (prednisone equivalent, mg)	
Mean (SD)	10.55 (4.21)
Range	5–25
MRC dyspnea score (%)	
0	2 (0.7)[4]
1	132 (50)
2	100 (37.9)
3	28 (10.6)
4	2 (0.7)
Extrapulmonary sarcoidosis – at enrollment	
Lymph nodes	44
Cutaneous	16
Ophthalmic	11
Bone and joint	11
Hepatic	11
Cardiac	1
Neurological -peripheral	1
Other	10

[1] Data subject to change prior to database lock

[2] 36 from USA (31.9% of 113 USA patients)

[3] Includes Other + American Indian/Alaska native (2), Asian (2), Native Hawaiian/Other Pacific Islander (1)

[4] Patients met the eligibility criteria at screening

Figure 3. DSMB review - unblinded safety review

* duration of safety data of last enrolled patient

Conclusions

EFZO-FIT is the largest, interventional, placebo-controlled clinical trial in patients with pulmonary sarcoidosis. The study population comprising patients with chronic symptomatic pulmonary sarcoidosis on long term steroids is appropriate for evaluating the primary end point of steroid reduction.

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Presented at the 2025 American Thoracic Society (ATS) International Conference; May 16-21, 2025; San Francisco, CA, USA

Acknowledgements: This work was supported by aTyr Pharma, Inc.