

**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): September 26, 2023

**ATYR PHARMA, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-37378**  
(Commission File Number)

**20-3435077**  
(IRS Employer  
Identification No.)

**10240 Sorrento Valley Road, Suite 300**  
**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 or Rule 12b-2 of the Securities Exchange Act of 1934.

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 7.01 Regulation FD Disclosure.**

aTyr Pharma, Inc. (the Company) intends to use an investor presentation to conduct meetings with investors, stockholders and analysts and at investor conferences, and which the Company intends to place on its website. A copy of the presentation materials is attached hereto as Exhibit 99.1 and is incorporated herein by reference. The Company does not undertake to update the presentation materials.

The information under this Item 7.01, including Exhibit 99.1, is being furnished and shall not be deemed “filed” for the purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, or the Exchange Act, or otherwise subject to the liabilities of that section, nor shall they be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing

**Item 8.01. Other Events.**

The Company recently initiated its Phase 2 proof-of concept study of efzofitmod (the EFZO-CONNECT study) in patients with systemic sclerosis (SSc, also known as scleroderma)-associated ILD (SSc-ILD) with the activation of a trial site that is actively recruiting patients. The EFZO-CONNECT study is a randomized, double-blind placebo-controlled proof-of-concept study to evaluate the efficacy, safety and tolerability of efzofitmod in patients with SSc-ILD. This will be a 28-week study with three parallel cohorts randomized 2:2:1 to either 270 mg or 450 mg of efzofitmod or placebo dosed intravenously monthly for a total of six doses. The study intends to enroll 25 patients at multiple centers in the United States. The primary objective of the study will be to evaluate the efficacy of multiple doses of intravenous efzofitmod on pulmonary, cutaneous and systemic manifestations in patients with SSc-ILD. Secondary objectives will include safety and tolerability.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

<b>Exhibit No.</b>	<b>Description</b>
99.1	<a href="#">Corporate Presentation Materials of aTyr Pharma, Inc. dated September 2023</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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**SIGNATURE**

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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: September 26, 2023



*The Evolutionary Intelligence Biotech*

September 2023

# 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 and development programs; 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 subsequently filed 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.

We own various U.S. federal trademark applications and unregistered trademarks, including our company name. All other trademarks or trade names referred to in this presentation are the property of their respective owners. Solely for convenience, the trademarks and trade names in this presentation are referred to without the symbols ® and ™, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.

This presentation discusses product candidates that are under clinical study and which have not yet been approved for marketing by the U.S. Food and Drug Administration. No representation is made as to the safety or effectiveness of these product candidates for the uses for which they are being studied. This presentation also contains estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. This data involved a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk.

# Translating tRNA Synthetases into New Therapies for Fibrosis and Inflammation

## Proprietary tRNA synthetase platform



- Novel extracellular functions gained through evolutionary intelligence
- Potential new class of medicines
- IP directed to protein compositions from all 20 tRNA synthetase genes

## Therapeutic focus: inflammation and fibrosis



- Vast therapeutic potential
- Differentiated approach
- Multiple blockbuster opportunities

## Efzofitimod: first-in-class biologic immunomodulator for ILD



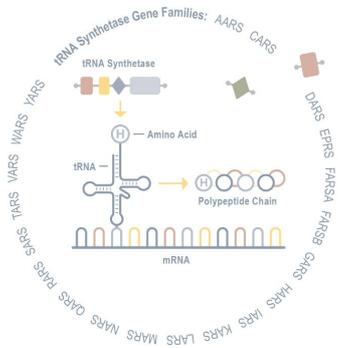
- Clinical proof of concept established
- Phase 3 EFZO-FIT™ study in pulmonary sarcoidosis enrolling
- Phase 2 EFZO-CONNECT™ study in SSc-ILD initiated

~\$112.0m in cash, restricted cash, cash equivalents and investments as of June 30, 2023  
Company projects cash runway into 2026

# Evolutionary Intelligence: tRNA Synthetases Evolved to Regulate Complex Systems

- **Novel tRNA synthetase domains evolved** as biology became more complex

- Domains **persisted through evolutionary pressure**, indicating biological importance



- Domains are **released locally** from full-length proteins enabling their function as **extracellular signaling molecules**

- Growing evidence that domains function to **restore homeostasis** through **new therapeutic intervention points** across multiple organ systems



# Increasing Validation of aTyr Science in Peer Reviewed Journals

SARCOIDOSIS VASCULITIS AND DIFFUSE LUNG DISEASES 2023; 40 (1); e2023002 DOI: 10.36141/svldd.v40i1.13617 © Matrioli 1885

## EFZOFITIMOD: A NOVEL ANTI-INFLAMMATORY AGENT FOR SARCOIDOSIS

*Robert P. Baughman<sup>1</sup>, Vis Niranjani<sup>2</sup>, Gennyne Walker<sup>3</sup>, Christoph Burkart<sup>3</sup>, Suzanne Paz<sup>3</sup>, Yeeting E. Chong<sup>3</sup>, David Siefker<sup>3</sup>, Eileen Sun<sup>3</sup>, Leslie Nangle<sup>3</sup>, Sarah Förster<sup>4</sup>, Michael H. Muders<sup>4</sup>, Carol F. Farver<sup>5</sup>, Elyse E Lower<sup>1</sup>, Sanjay Shukla<sup>3</sup>, Daniel A. Culver<sup>5</sup>*

**CHEST** JOURNAL

DIFFUSE LUNG DISEASE: ORIGINAL RESEARCH | ARTICLES IN PRESS

## Efzofitimid for the Treatment of Pulmonary Sarcoidosis

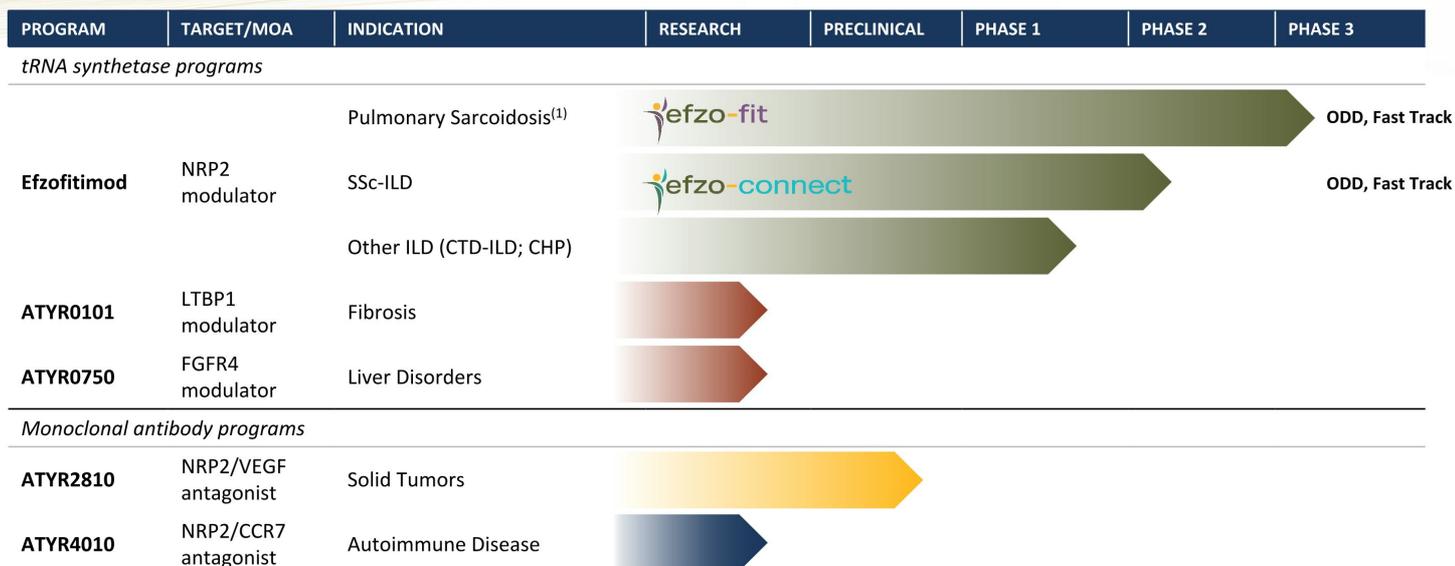
Daniel A. Culver, DO   • Shambhu Aryal, MD • Joseph Barney, MD • ... Nelson Kinnersley, PhD •

Gennyne Walker, PhD • Robert Baughman, MD • Show all authors



5 "Efzofitimid: a novel anti-inflammatory agent for sarcoidosis" – first major review article for efzofitimid (<https://doi.org/10.36141/svldd.v40i1.14396>); "Efzofitimid for the treatment of pulmonary sarcoidosis" – Phase 1b/2a data publication (<https://doi.org/10.1016/j.chest.2022.10.037>); ATYR2810's target NRP2 biology featured on the cover of Science Translational Medicine (<https://www.science.org/doi/10.1126/scitranslmed.adf1128>)

# Growing Pipeline of First-in-Class tRNA Synthetase Derived Biologics



<sup>(1)</sup> In partnership with Kyorin Pharmaceutical Co., Ltd. for the development and commercialization of efzofitimod for ILD in Japan

ODD = orphan drug designation; SSc-ILD = Scleroderma-related ILD; CTD-ILD = Connective Tissue Disease-ILD; CHP = Chronic Hypersensitivity Pneumonitis

The logo for aTyr, featuring the lowercase letters 'aTyr' in a bold, sans-serif font. The 'a' is orange, and 'Tyr' is dark green. The logo is positioned on the left side of the page, with a decorative background of thin, flowing lines in shades of orange and green that sweep across the top half of the image.

**aTyr**

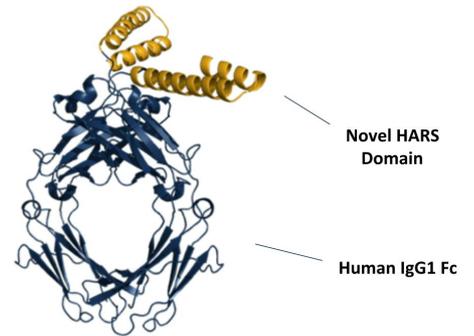
**Efzofitimod**

**First-in-Class Biologic Immunomodulator for  
Interstitial Lung Disease (ILD)**

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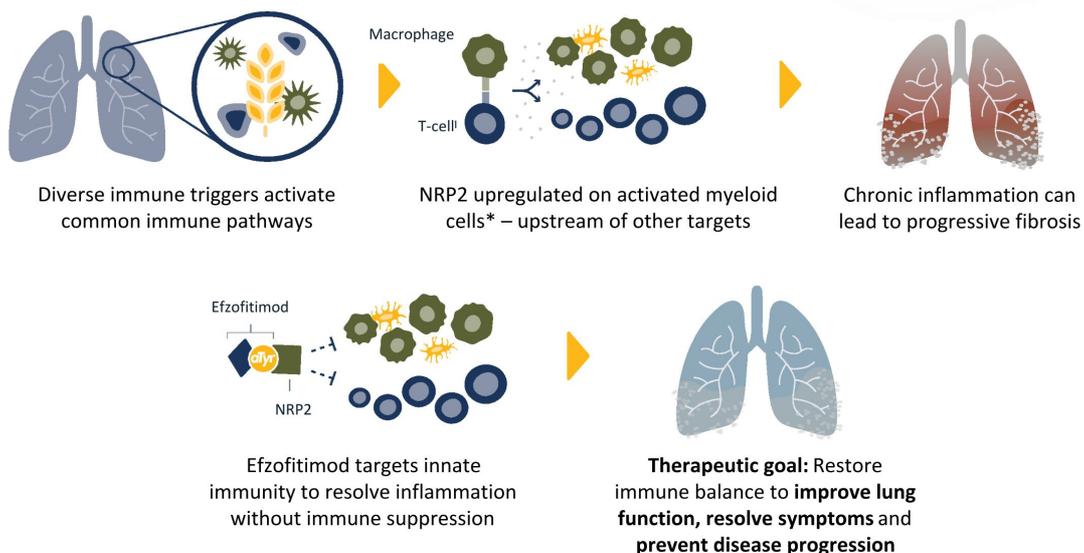
# Efzofitimod: First-in-Class Biologic Immunomodulator for ILD

- Fc fusion protein
- Active domain is naturally occurring, lung enriched domain of HARS
- Downregulates activated myeloid cells via NRP2
- Anti-inflammatory and anti-fibrotic effects demonstrated in multiple ILD models
- Dosed once-monthly via 60 minute IV infusion
- Clinical proof of concept demonstrated in pulmonary sarcoidosis



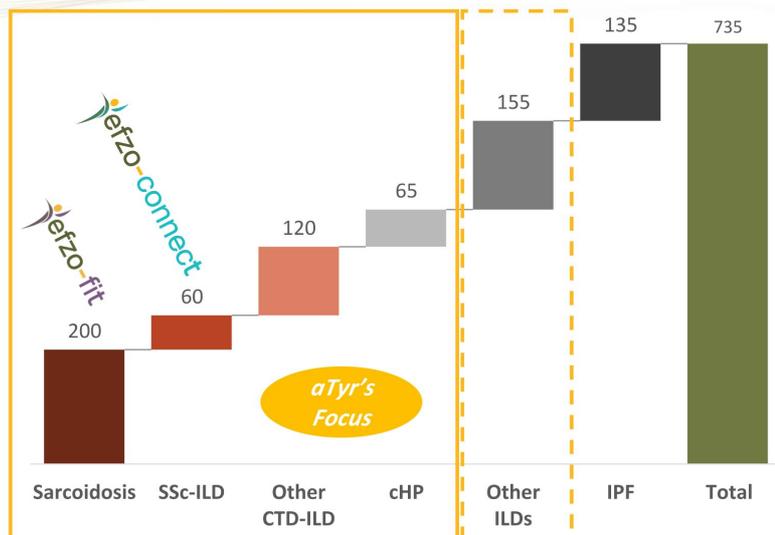
# Efzofitimid Therapeutic Hypothesis: Restore Immune Balance to Prevent Fibrosis

## ILDs share common immune pathology that can lead to progressive fibrosis



# aTyr is Advancing Efzofitimid as the Standard-of-Care for ILD

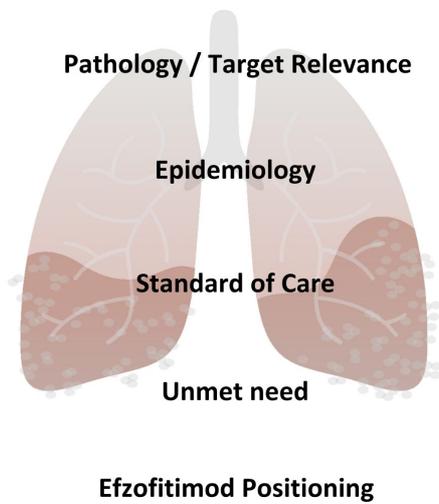
Number of U.S. ILD Patients by Types ('000)



- ILD is an umbrella term for >200 types of rare lung diseases that span a spectrum of inflammation and fibrosis
- Patients experience high morbidity and mortality
- No disease-modifying therapies available; current options have significant toxicities
- aTyr's focus estimated at \$2-3B global market opportunity
- Upside potential in other ILD and related autoimmune diseases (e.g., SSc, lupus, RA)

*Inflammation* *Fibrosis*

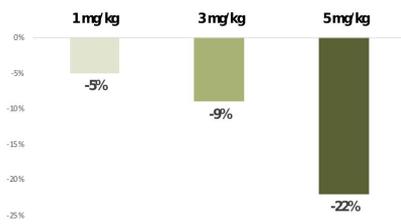
# Significant Market Opportunity in Pulmonary Sarcoidosis Alone



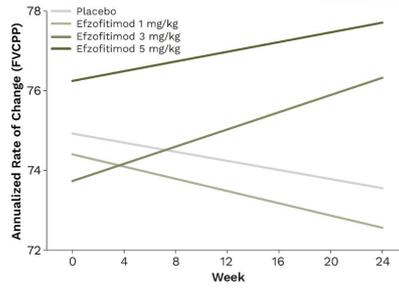
Pulmonary Sarcoidosis	
• Inflammatory disease characterized by non-caseating granulomas	• NRP2 upregulated in sarcoid granulomas
• 200K pts in the U.S.; >1M globally	• Lung predominant in >90%
• Up to 20% develop lung fibrosis	
• Oral corticosteroids (OCS) (50-75% of patients)	• Immunosuppressants (30% of patients)
• anti-TNF antibodies (10% of patients)	
• No disease modifying therapies available	• Significant toxicity with current treatment options
• 1 <sup>st</sup> line as steroid sparing agent	• Avoid current 2 <sup>nd</sup> / 3 <sup>rd</sup> line therapies

# Clinical Proof of Concept Demonstrated in Phase 1b/2a Pulmonary Sarcoidosis Trial

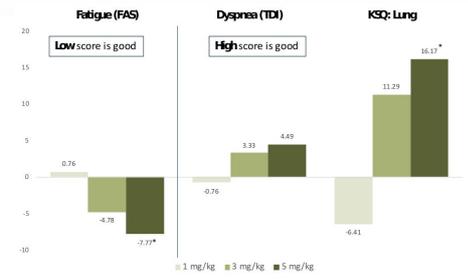
## Steroid Sparing



## Lung Function

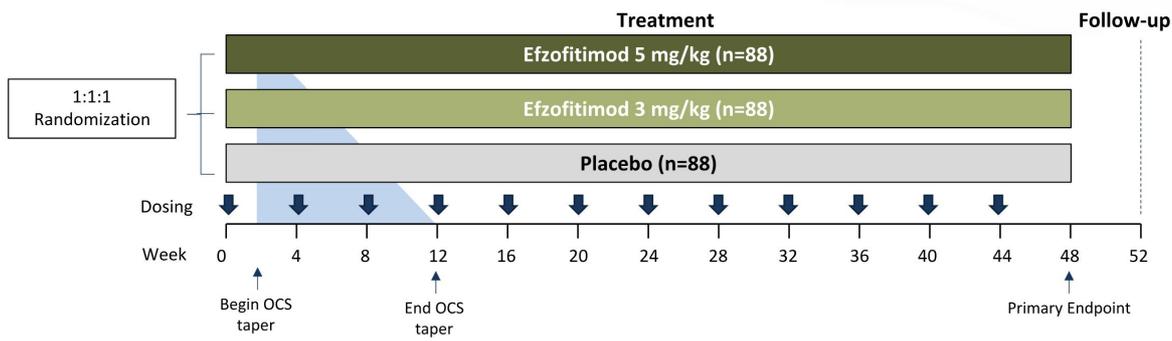


## Symptom Control



- Primary objective met: Efzofitimid was **safe and well-tolerated** (n=37)
- Secondary objectives met: **Dose-response observed** across all three families of pre-specified endpoints
- Dose-dependent **improvement of inflammatory biomarkers**
- **Robust results:** Pre-specified analysis plan, trends consistent across analysis populations and imputation methods

**Primary objective:** Assess the efficacy of efzofitimid in patients with pulmonary sarcoidosis



**Population: moderate to severe pulmonary sarcoidosis**

- Diagnosis of pulmonary sarcoidosis for  $\geq 6$  months
- Stable treatment with  $\geq 7.5$  and  $\leq 25$  mg/day OCS
- Extent of fibrosis  $< 20\%$

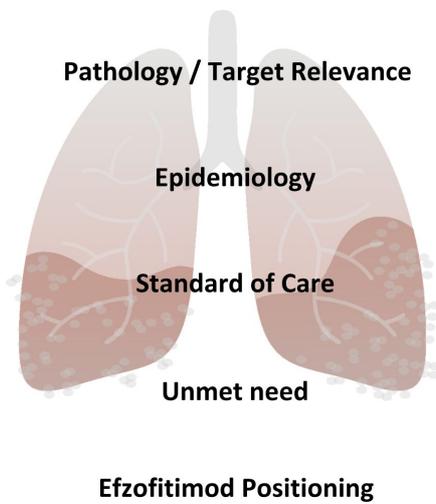
**Primary Endpoint**

- Steroid burden: change in daily steroid dose

**Key Secondary Endpoints**

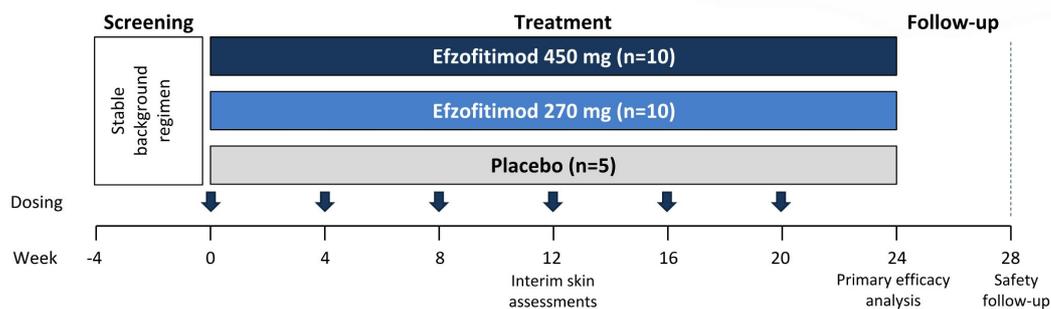
- Lung function: forced vital capacity
- Symptom control: KSQ-Lung score

# SSc-ILD Represents Expanded Commercial Opportunity



SSc-ILD
<ul style="list-style-type: none"><li>• Lung manifestation of systemic sclerosis (SSc), an autoimmune disease characterized by scarring of skin and other organs</li><li>• NRP2 upregulated in skin macrophages</li></ul>
<ul style="list-style-type: none"><li>• &gt;60K in the U.S.; &gt;1.5M globally</li><li>• 25-30% develop lung fibrosis</li></ul>
<ul style="list-style-type: none"><li>• Mycophenolate (MMF) (80% of pts in U.S.)</li><li>• Cyclophosphamide (CYC)</li><li>• Rituximab; nintedanib; tocilizumab</li></ul>
<ul style="list-style-type: none"><li>• No disease modifying therapies available</li><li>• Significant toxicity with current treatment options</li></ul>
<ul style="list-style-type: none"><li>• 2<sup>nd</sup> line in pts not controlled on MMF / CYC</li><li>• 1<sup>st</sup> line to replace MMF / CYC</li></ul>

**Primary objective:** Assess the efficacy of efzofitimod on pulmonary, cutaneous, and systemic manifestations in SSc-ILD



### Population: SSc with progressive ILD

- Patients with SSc (ACR/EULAR criteria), and ILD (baseline HRCT)
- Progressive disease (recent onset, evidence for inflammation, diffuse cutaneous SSc)
- On background mycophenolate therapy

### Primary Endpoint

- Lung function: forced vital capacity

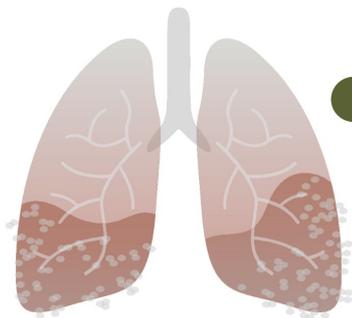
### Key Secondary Endpoints

- Symptom control: PROs
- Skin: histopathology, gene profiling, biomarkers, mRSS

# Efzofitimod Target Value Proposition

## Binds new target for ILD

- upstream
- not repurposed or failed

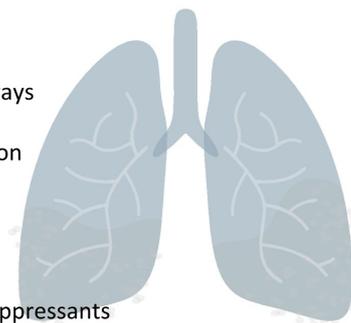


## Targets innate immunity at site of inflammation

- downregulates pro-inflammatory and pro-fibrotic pathways
- addresses complex immune pathology
- restores immune balance without evidence of suppression

## Robust efficacy

- Improves lung function
- Resolves symptoms
- Reduces OCS or other immune suppressants



No known safety issues



Pre-Clinical Pipeline  
Generating New Treatments for  
Inflammation and Fibrosis

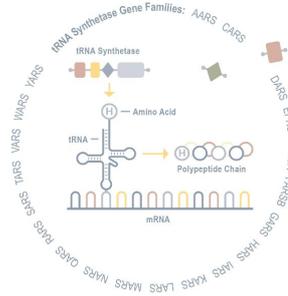
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# tRNA Synthetase Platform



## Unique drug discovery platform leveraging evolutionary intelligence

- Extracellular tRNA synthetases can unlock new targets and / or signaling pathways
- Low bias towards biology or indication



## Approach validated through efzofitimod clinical POC

- HARS derived NRP2 modulator efzofitimod currently in Phase 3 in pulmonary sarcoidosis



## Pipeline of candidates targeting high-value markets

- Differentiated MoAs could potentially lead to superior results vs. SOC
- Selectively target activated systems



## Deep research capabilities with a proprietary molecule library

- IP directed to protein compositions from all 20 tRNA synthetase genes
- Research Collaboration with Dualsystems Biotech AG aims to identify target receptors for tRNA synthetases



**aTyr**

*Translating tRNA Synthetase Biology into  
New Therapies for Inflammation and Fibrosis*

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# Translating tRNA Synthetases into New Therapies for Inflammation and Fibrosis

## **Evolutionary intelligence drug discovery platform**

- Extracellular tRNA synthetases represent potential new class of medicines
  - aTyr owns IP directed to entire class

## **Lead program in pivotal development for untapped blockbuster markets**

- Clinical POC established in pulmonary sarcoidosis
- Global Phase 3 EFZO-FIT™ study enrolling in pulmonary sarcoidosis
- Expansion to second indication with initiation of Phase 2 EFZO-CONNECT™ study in SSc-ILD

## **Growing pipeline of tRNA synthetase derived candidates**

- Multiple next-generation programs targeting inflammation and fibrosis
  - Unlocking new therapeutic intervention points

## **Robust financial position through multiple inflection points**

- ~\$112.0m in cash, restricted cash, cash equivalents and investments as of June 30, 2023
  - Company projects cash runway into 2026
- Partnership for efzofitmod in Japan with Kyorin Pharmaceutical



Thank You