### **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

March 11, 2019 Date of Report (Date of earliest event reported)

### 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, California 92121		
		(Address of principal executive offices, including zip code)		
		(858) 731-8389		
		(Registrant's telephone number, including area code)		
Che	ck the appropriate box below if the Form 8-K filing is in	tended to simultaneously satisfy the filing obligations of th	ne 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))			
Indicof 19		growth company as defined in Rule 405 of the Securities	Act of 1933 or Rule 12b-2 of the Securities Exchange Act	
Eme	rging growth company 🛛			
	emerging growth company, indicate by check mark if thunting standards provided pursuant to Section 13(a) of the	ne registrant has elected not to use the extended transition p he Exchange Act. ⊠	period for complying with any new or revised financial	

#### 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. The Company intends to place this investor presentation on its website. A copy of the presentation materials is attached hereto as Exhibit 99.1. The Company does not undertake to update the presentation materials.

The information under this Item 7.01 including Exhibit 00.1 is being furnished berowith and shall not be deemed "filed" for the ed

The information under this Item 7.01, including Exhibit 99.1, is being furnished herewith and shall not be deemed "filed" for the purposes of Section 18 of 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 deen 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 such filing.				
Item 9.01 Exhibits.				
(d) Exhibits				
Exhibit No.	Description			
99.1	Corporate Presentation Materials of aTyr Pharma, Inc. dated March 2019			

#### 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: <u>/s/ Sanjay S. Shu</u>kla

Sanjay S. Shukla, M.D., M.S. President and Chief Executive Officer

Date: March 11, 2019

NASDAQ: LIFE



# Translating New Immune Pathways into Meaningful Medicines

Corporate Presentation March 2019



### **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 we make regarding the potential therapeutic benefits of proteins derived from tRNA synthetase genes and our product candidates, including ATYR1923 and any other product candidates, the ability to successfully advance our product candidates, the timing within which we expect to initiate, receive and report data from, and complete our planned clinical trials, our ability to receive regulatory approvals for, and commercialize, our product candidates, our ability to identify and discover additional product candidates, and the ability of our intellectual property portfolio to provide protection are forwardlooking 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.

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  $^{\circ}$  and  $^{TM}$ , 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.



### **Accelerating Value Creation from Novel Biology**

### Platform of New Biology:

Discovery pipeline of novel therapeutic candidates based on proprietary knowledge of extracellular functions of tRNA synthetases (~300 protein compositions patented)

#### Lead Product Candidate: ATYR1923

Engineered, long acting, protein therapeutic, derived from the HARS gene, for the treatment of pulmonary sarcoidosis and other interstitial lung diseases

\$2-3b(1) global opportunity

#### Financials:

Cash, cash equivalents and investments at \$56.0m as of 9/30/2018

#### **Clinical Milestones:**

- ✓ Initiated P1b/2a Trial 4Q 2018
  - ☐ Interim Results 4Q 2019
  - ☐ Final Results mid-2020(2)



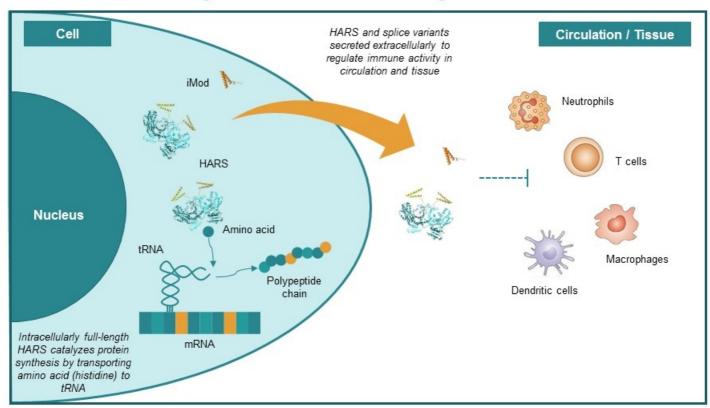
- (1) aTyr estimates for inflammatory ILD: Pulmonary Sarcoidosis, CHP, CTD-ILD; excludes IPF
- (2) Dependent on patient enrollment

# **Development Pipeline**

Program	Discovery	Preclinical	Phase 1	Phase 2	Phase 3
ATYR1923	Pulmonary Sarcoi	dosis sitivity Pneumonitis	(CHP)		
	Connective Tissue Disease ILD (CTD-ILD)				
CSL Behring Collaboration	Up to 4 tRNA Synthetases				
UNMC Collaboration	Undisclosed				



# Novel tRNA Synthetase Domains Secreted Extracellularly with Non-Catalytic Functions

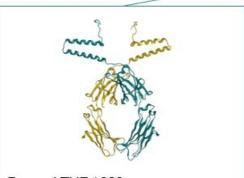




# Extracellular tRNA Synthetase Biology Associated with Disease in Multiple Tissues

### tRNA Synthetase Gene Families

### aTyr's current R&D focus



Drug: ATYR1923

Function: Immuno-modulatory
Disease: Interstitial Lung Disease

AARS	HARS	RARS
CARS	IARS	SARS
DARS	KARS	TARS
EPRS	LARS	VARS
FARS	MARS	WARS
FARSB	NARS	YARS
GARS	QARS	

a Tyrpatents cover>300 protein compositions

### Pipeline opportunities

#### Known disease connections:

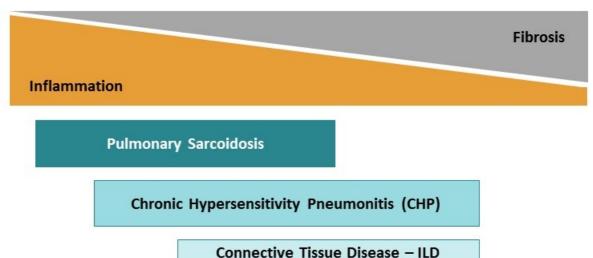
- Cancer
- · Autoimmune disease
- Liver disorders
- · Inflammatory disorders
- · Neurological disorders
- · Mitochondrial disorders

### CSL Behring Collaboration:

 Potential new drug candidates from up to 4 tRNA synthetase families



# Interstitial Lung Diseases Share Persistent Immune Engagement



(CTD-ILD)

Idiopathic Pulmonary Fibrosis (IPF)



Slide adapted from Dr. Steven Nathan, Medical Director, Advanced Lung Disease and Transplant Program at Inova Fairfax Hospital, Falls Church, VA

### **High Unmet Need in Interstitial Lung Disease**

#### **Pulmonary Sarcoidosis**

- Systemic inflammatory disorder characterized by non-caseating granulomas (CD4+T cell driven)
- US prevalence: ~200k
- ~30% of patients have chronic progressive disease, unresponsive to steroid treatment
- Current SOC: steroids cytotoxic agents TNF inhibitors (as disease progresses)

## Chronic Hypersensitivity Pneumonitis (CHP)

- Exaggerated immune response to environmental antigen
- US prevalence: ~60k
- 5-year mortality: ~20%
- · No effective therapeutic options

### Connective Tissue Disease-ILD (CTD-ILD)

- Common manifestation in CTD: Clinically relevant ILD in 10% of Rheumatoid Arthritis and >50% of Scleroderma patients
- US prevalence: ~150k
- 5-year mortality: ~20%
- Current SOC: Mycophenolate mofetil or cyclophosphamide for Ssc-ILD; no SOC for RA-ILD

### Idiopathic Pulmonary Fibrosis (IPF)

- Irreversible, progressive fibrotic disease of unknown cause
- US prevalence: ~135k
- 5-year mortality: 60-80%
- Current SOC: Nintedanib or pirfenidone (>\$2b combined 2017 sales)

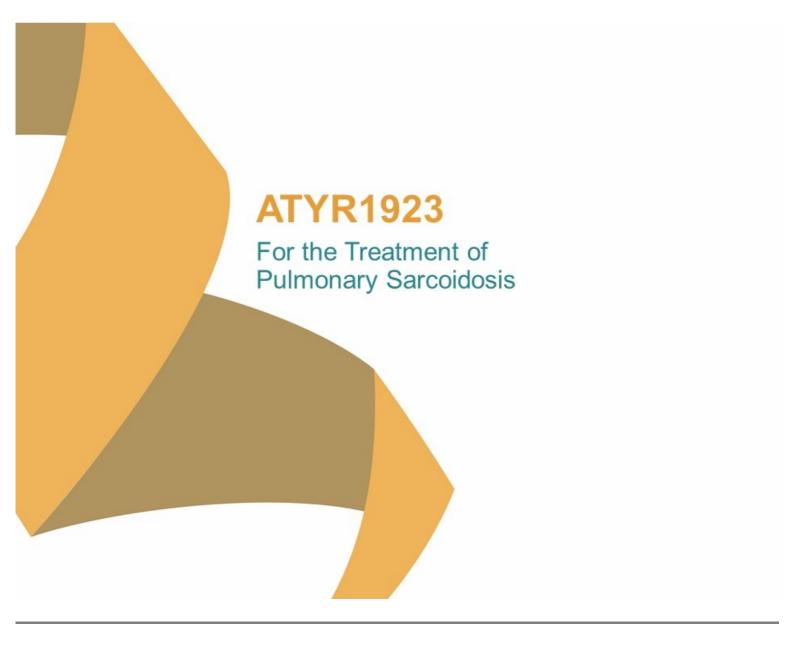


# Pre-Clinical Translational Estate Supports Clinical Development in ILD

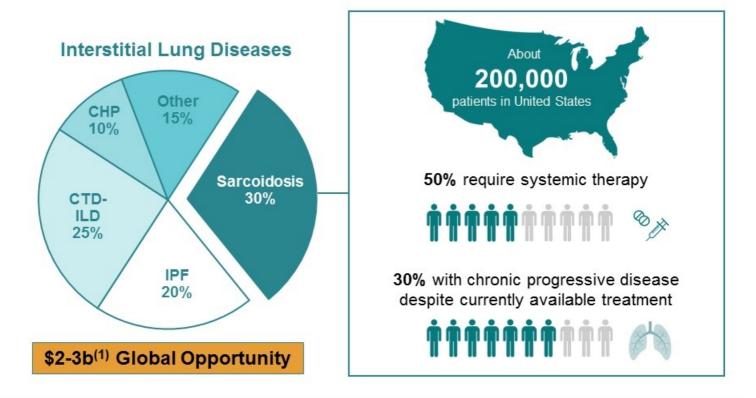
Bleomycin-Induced Lung Injury (Mouse)	<ul> <li>ATYR1923 vs. pirfenidone<sup>(1)</sup></li> <li>ATYR1923 reduced fibrosis and inflammation</li> <li>Presented at ATS, May 2017</li> </ul>
Bleomycin-Induced Lung Injury (Rat)	<ul> <li>ATYR1923 vs. nintedanib<sup>(2)</sup></li> <li>ATYR1923 returned lung function to normal and reduced fibrosis and inflammation</li> <li>Presented at ATS, May 2018</li> </ul>
Sclerodermatous chronic- graft vs host disease (Mouse)	<ul> <li>ATYR1923 vs. nintedanib<sup>(2)</sup></li> <li>ATYR1923 reduced lung and skin fibrosis</li> <li>Presented at Scleroderma Foundation Patient Conference, July 2018</li> </ul>



(1) 2017 annual sales of Esbriet® (pirfenidone) ~869M CHF, 13% increase YoY (2) 2017 annual sales of Ofev® (nintedanib) ~920M Euros, 52.3% increase YoY



# Sarcoidosis: The Most Common Form of Interstitial Lung Disease





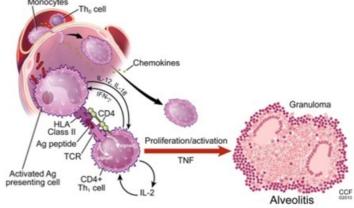
(1) aTyr estimates for inflammatory ILD: Pulmonary Sarcoidosis, CHP, CTD-ILD; excludes IPF

# First-in-Patient Population: Pulmonary Sarcoidosis

- Systemic inflammatory disorder characterized by the formation of granulomas (clumps of inflammatory cells) in one or more organs of the body
- CD4+ (Th1 / Th17) T-cell driven
- Usually begins in the lungs, skin or lymph nodes
- Sarcoidosis in the lungs is called pulmonary sarcoidosis and occurs in ~90% of patients

#### Unmet needs(1):

- Better understanding of pathogenesis
- Prognostic stratification and targeted management
- Better therapies, with quicker onset of action and less toxicity



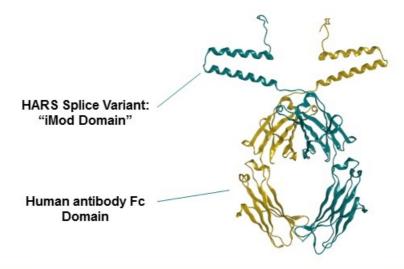
Baughman RP, Culver DA, Judson MA. AM J Respir Crit Care Med 2011



(1) Dr. Dan Culver, Cleveland Clinic

### **ATYR1923: Novel Engineered Protein Therapeutic**

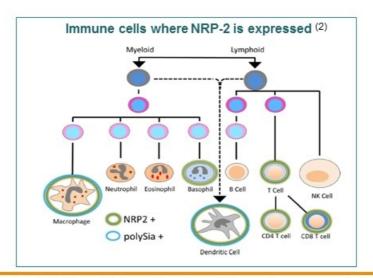
- Active domain (iMod) is naturally occurring splice-variant of HARS that is enriched in the human lung
- Binds selectively to Neuropilin-2 (NRP2)
- Regulates a number of immune cell-types, including: T cells, Neutrophils, Macrophages, Dendritic cells





# Receptor: Importance of NRP-2 as a Binding Partner for ATYR1923

- Pleiotropic receptor that can bind to a number of different ligands
- · Well-established role in the development of the neural and lymphatic systems
- Emerging role in the immune system; present on a number of immune cell types
- Expressed on alveolar macrophages; may play role in regulating lung inflammation (1)



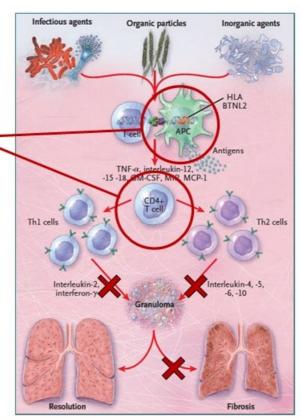


- Immormino et al. Neuropilin-2 regulates airway inflammatory responses to inhaled lipopolysaccharide.
   Am J Physiol Lung Cell Mol Physiol 315: L202-L211. 2018.
- (2) Schellenberg et al. Role of Neuropilin-2 in the immune system. Mol. Immunol. 90, 239-244, 2017.

# **ATYR1923 Intervention in Pulmonary Sarcoidosis**

# ATYR1923 Therapeutic Hypothesis<sup>(1):</sup>

Downregulates inflammatory insult and prevents progression to fibrosis



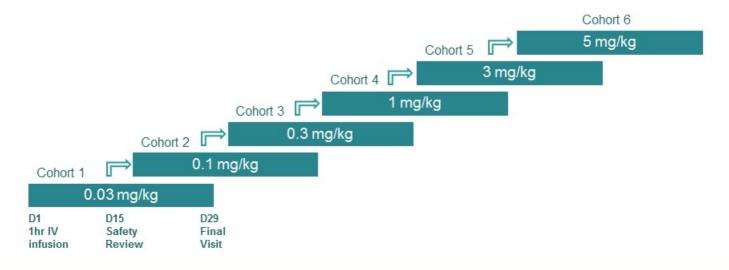


(1) Hypothesized Immunopathogenesis of Sarcoidosis adapted from lannuzzi et al, NEJM, 2007.

### **PK Profile Supports Potential Once-Monthly Dosing**

### Phase 1 Healthy Volunteer Study Completed

- Positive data announced in June 2018
- Randomized, double-blind, placebo-controlled, single ascending dose (N=36 HVs)
- ATYR1923 was generally well-tolerated with no significant adverse events





# ATYR1923 Phase 1b/2a Study in Pulmonary Sarcoidosis

### **Objectives**

- Evaluate safety, tolerability, PK, and immunogenicity of multiple ascending doses of ATYR1923
- Evaluate signals of drug activity through steroid dose reduction and FDG-PET/CT changes

### Design

Randomized, double-blind, placebo-controlled, multiple ascending dose

### **Population**

- Histologically confirmed pulmonary sarcoidosis
- Requiring ≥10 mg prednisone (steroid) treatment; capable of steroid taper
- Symptomatic/active disease at baseline by <sup>18F</sup>-FDG-PET/CT, Pulmonary Function Tests

### Dosing

- · 3 sequential cohorts, 12 patients each
- 2:1 randomization
- ATYR1923 doses: 1.0, 3.0, and 5.0 mg/kg

### Duration

- 24-week study period
- · Steroid taper phase down to 5 mg by week 8
- 16-week maintenance phase

#### Sites

- Up to 15 leading pulmonary sarcoidosis centers in US
- · Collaboration with the Foundation for Sarcoidosis Research



### ATYR1923 Phase 1b/2a Study Endpoints

### **Primary**

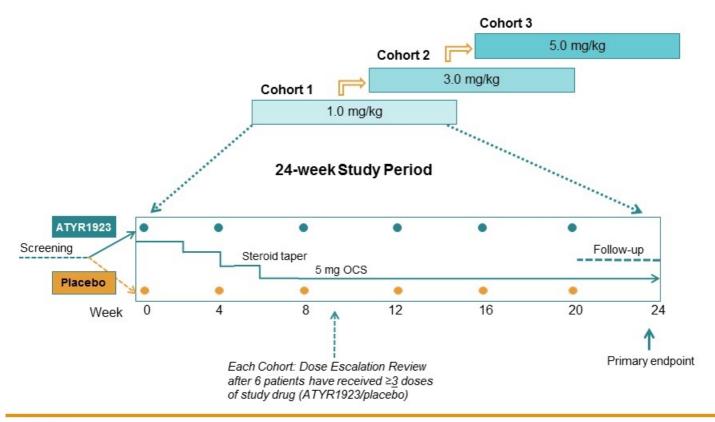
Safety and tolerability of multiple ascending IV ATYR1923 doses

### **Secondary**

- · Steroid-sparing effect
- Immunogenicity
- Pharmacokinetics (PK)
- Exploratory efficacy measures: FDG-PET/CT imaging; Lung function (FVC); Serum biomarkers; Health-related quality of life scales



### ATYR1923 Phase 1b/2a Study Schema





# ATYR1923 Phase 1b/2a Study in Pulmonary Sarcoidosis Initiated

Status	<ul> <li>Up to 15 leading Pulmonary Sarcoidosis centers in US</li> <li>Site initiation activities ongoing</li> <li>Recruiting activities initiated</li> </ul>
Timelines	Interim data: 4Q 2019     Study completion: mid-2020 <sup>(1)</sup>
Possible Future Development	<ul> <li>Registrational trial in Pulmonary Sarcoidosis</li> <li>Initiate P2 studies in other types of interstitial lung disease (e.g. CTD-ILD; CHP)</li> </ul>



(1) Dependent on patient enrollment

### **CSL Behring Collaboration**

### Goal

Identify new IND candidates from up to four tRNA synthetases from aTyr's proprietary pipeline of novel proteins (non-HARS derived)

### Terms

- CSL Behring to fund all R&D costs
- aTyr eligible for up to \$17m in option fees if CSL Behring advances all four programs (\$4.25m per synthetase program)
- aTyr grants CSL Behring an option to negotiate licenses for worldwide rights to each IND candidate that emerges from the collaboration

### About CSL

- CSL Behring is a global biotherapeutics leader specializing in immunology, hematology and other rare and serious medical conditions
- CSL Behring employs >22,000 people globally, and delivers its therapies to more than 60 countries



# Mission: Generate Value for Patients and Shareholders

- ✓ aTyr owns IP estate directed to a potential pipeline of proteins derived from 20 tRNA synthetase genes
- ✓ ATYR1923 in-vitro and in-vivo studies support clinical development in ILD
- Identification of NRP-2 receptor for ATYR1923 elucidates greater understanding of MOA
- ✓ Positive Phase 1 data for ATYR1923
- Initiated Phase 1b/2a study of ATYR1923 in patients with pulmonary sarcoidosis
- Goal is to demonstrate safety and preliminary clinical activity in ATYR1923 pulmonary sarcoidosis trial
- Potential to expand ATYR1923 into other ILD indications
- Potential new pipeline opportunities through academic (UNMC) and industry (CSL Behring) collaborations



