
**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**

**October 6, 2016
Date of Report (Date of earliest event reported)**

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.)

**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)

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))
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Item 7.01 Regulation FD Disclosure.

On October 6, 2016, aTyr Pharma, Inc. (the “Company”) announced that additional clinical data from the Company’s Phase 1b/2 Trial (002) in adult patients with facioscapulohumeral muscular dystrophy (FSHD) were presented in a poster presentation at the 21st Internal Annual Congress of the World Muscle Society in Granada, Spain. The press release related to this announcement is attached as Exhibit 99.1

The information under this Item 7.01, including Exhibit 99.1 hereto is being furnished and shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall such information 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 poster referenced above is titled “A Randomized, Double-blinded, Placebo-controlled, Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Immunogenicity, and Biological Activity of ATYR1940 (Resolaris™) in Adult Patients with Facioscapulohumeral Muscular Dystrophy,” and is filed as Exhibit 99.2 and incorporated herein by reference.

The poster presentation includes additional detailed data from the Company’s adult FSHD (002) trial covering safety, tolerability, PK, and clinical assessments. Encouraging activity was seen in the patient-reported outcomes, known as the Individualized Neuromuscular Quality of Life Assessment (INQoL), and the physician-reported functional assessment Manual Muscle Testing (MMT).

Patients treated with Resolaris were generally improved compared with placebo as assessed by INQoL, with patients in cohort 3 (3.0 mg/kg for 12 weeks) showing the greatest improvement compared with cohort 1 and cohort 2 (0.3 mg/kg and 1.0 mg/kg for 4 weeks respectively). Patients in cohort 3 reported a ~9.9% improvement in INQoL compared with a ~15.6% worsening in the placebo group at week 14. Five out of the six patients on Resolaris in cohort 3 showed overall improvement in their INQoL score at week 14, versus zero out of two patients on placebo.

A trend for improvement in MMT results with Resolaris treatment was also observed compared with placebo, especially in the upper limbs. In general, there was an association between changes in INQoL and MMT, whereby all patients who experienced an improvement in muscle function also showed improvement in INQoL scores. Patients in cohort 3 reported ~0.7% improvement in MMT compared with ~1.4% worsening in the placebo group at week 14. Three out of the six patients on Resolaris in cohort 3 showed overall improvement in their MMT score at week 14, versus zero out of two patients on placebo.

Item 9.01 Exhibits.

(d) Exhibits.

- 99.1 Press Release of aTyr Pharma, Inc. dated October 6, 2016.
- 99.2 Poster presentation titled “A Randomized, Double-blinded, Placebo-controlled, Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Immunogenicity, and Biological Activity of ATYR1940 (Resolaris™) in Adult Patients with Facioscapulohumeral Muscular Dystrophy.”

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/ JOHN D. MENDLEIN

John D. Mendlein, Ph.D.
Chief Executive Officer

Date: October 6, 2016

INDEX TO EXHIBITS

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**IMMEDIATE RELEASE****Contact:****Mark Johnson**

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aTyr Pharma Presents Additional Data for Resolaris™ Phase 1b/2 Trial in Adult Patients with Facioscapulohumeral Muscular Dystrophy at the 21st International Annual Congress of the World Muscle Society

SAN DIEGO – October 6, 2016 – aTyr Pharma, Inc. (Nasdaq: LIFE), today announced that additional clinical data from aTyr's Phase 1b/2 Trial (002) in adult patients with FSHD were presented at the 21st International Congress of the World Muscle Society in Granada, Spain. The poster presentation is titled "A Randomized, Double-blinded, Placebo-controlled, Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Immunogenicity, and Biological Activity of ATYR1940 (Resolaris™) in Adult Patients with Facioscapulohumeral Muscular Dystrophy."

"In today's presentation we have provided additional data analyses which reaffirm encouraging trends in two meaningful clinical assessments from our adult FSHD (002) trial," commented John Mendlein, PhD, CEO of aTyr Pharma. "In December, we look forward to sharing further top-line updates from our Phase 1b/2 clinical program with Resolaris in three different rare myopathies from our early onset FSHD (003) trial, our LGMD2B/FSHD (004) trial, and our first FSHD extension (005) trial."

Today's presentation includes additional detailed data from the adult FSHD (002) trial covering safety, tolerability, PK, and clinical assessments. Encouraging activity was seen in the patient-reported outcomes, known as the Individualized Neuromuscular Quality of Life Assessment (INQoL), and the physician-reported functional assessment Manual Muscle Testing (MMT).

Patients treated with Resolaris were generally improved compared with placebo as assessed by INQoL, with patients in cohort 3 (3.0 mg/kg for 12 weeks) showing the greatest improvement compared with cohort 1 and cohort 2 (0.3 mg/kg and 1.0 mg/kg for 4 weeks respectively). Patients in cohort 3 reported a ~9.9% improvement in INQoL compared with a ~15.6% worsening in the placebo group at week 14. Five out of the six patients on Resolaris in cohort 3 showed overall improvement in their INQoL score at week 14, versus zero out of two patients on placebo.

A trend for improvement in MMT results with Resolaris treatment was also observed compared with placebo, especially in the upper limbs. In general, there was an association between changes in INQoL and MMT, whereby all patients who experienced an improvement in muscle function also showed improvement in INQoL scores. Patients in cohort 3 reported ~0.7% improvement in MMT compared with ~1.4% worsening in the placebo group at week 14. Three out of the six patients on Resolaris in cohort 3 showed overall improvement in their MMT score at week 14, versus zero out of two patients on placebo.

Conclusions of the Adult FSHD (002) Trial:

- Over the dose and duration studied, Resolaris was found to be generally safe in adult patients with FSHD, and was generally well tolerated with the exception of one patient who experienced infusion related reactions as previously reported and as discussed in more detail in our poster presentation.
- PK properties were dose-proportional and generally consistent throughout the study, with no measurable impact from anti-drug antibodies (ADAs).
- Clinical activity was supported by signals of improvement in INQoL questionnaire responses and MMT measures.
- Other exploratory measures, including lower extremity targeted MRI, did not demonstrate activity. Variability in image acquisition may have diminished the opportunity to show activity in this measurement.
- Patients in cohorts 2 and 3 were allowed to enroll in the ongoing long-term extension study (005) investigating the safety and efficacy of Resolaris, for which aTyr expects to provide an update in December 2016.

“We are excited to have observed signals of activity across two clinical assessments with both INQoL and MMT, which is a first for FSHD patients,” said Sanjay Shukla, MD, MS, Chief Medical Officer of aTyr Pharma. “Directional improvement in two separate assessments that should otherwise decline over time may be evidence of how clinically meaningful Resolaris could be for FSHD patients, and we look forward to building upon the clinical activity and safety data with our additional data later this year.”

For additional information please refer to aTyr Pharma’s investor relations website (www.atyrpharma.investorroom.com) to access today’s full poster presentation.

About FSHD

Facioscapulohumeral muscular dystrophy (FSHD) is a rare genetic myopathy affecting an estimated 19,000 people in the United States for which there are no approved treatments. The primary clinical phenotype of FSHD is debilitating skeletal muscle deterioration and weakness. The symptoms of FSHD often appear early in the face, shoulder blades, upper arms, lower legs and trunk, and can affect certain muscles while adjacent muscles remain healthy. In addition to muscle weakness, FSHD patients often experience debilitating fatigue and chronic pain. The disease is typically diagnosed by the presence of a characteristic pattern of muscle weakness and other clinical symptoms, as well as through genetic testing. Early onset FSHD occurs in individuals who experience symptoms of progressive muscle involvement as juveniles, and some of these patients suffer from a particularly severe form of the disease. To learn more about FSHD, please visit www.fshsociety.org.

About Resolaris™

aTyr Pharma is developing Resolaris as a potential first-in-class intravenous protein therapeutic for the treatment of rare myopathies with an immune component. Resolaris is derived from a naturally occurring protein released *in vitro* by human skeletal muscle cells. aTyr believes Resolaris has the potential to provide therapeutic benefit to patients with rare myopathies with an immune component characterized by excessive immune cell involvement.

About aTyr Pharma

aTyr Pharma is engaged in the discovery and clinical development of innovative medicines for patients suffering from severe rare diseases using its knowledge of Physiocrine biology, a newly discovered set of physiological modulators. The Company’s lead candidate, Resolaris™, is a potential first-in-class intravenous protein therapeutic for the treatment of rare myopathies with an immune component. Resolaris is currently in a Phase 1b/2 clinical trial in adult patients with

facioscapulohumeral muscular dystrophy (FSHD); a Phase 1b/2 trial in adult patients with limb-girdle muscular dystrophy 2B (LGMD2B or dysferlinopathies) or FSHD; and a Phase 1b/2 trial in patients with an early onset form of FSHD. To protect this pipeline, aTyr has built an intellectual property estate comprising over 80 issued or allowed patents and over 230 pending patent applications that are owned or exclusively licensed by aTyr, including over 300 potential Physiocrine-based protein compositions. aTyr's key programs are currently focused on severe, rare diseases characterized by immune dysregulation for which there are currently limited or no treatment options. For more information, please visit <http://www.atyrpharma.com>.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Litigation Reform Act. Forward-looking statements are usually identified by the use of words such as “anticipates,” “believes,” “estimates,” “expects,” “intends,” “may,” “plans,” “projects,” “seeks,” “should,” “will,” and variations of such words or similar expressions. We intend these forward-looking statements to be covered by such safe harbor provisions for forward-looking statements and are making this statement for purposes of complying with those safe harbor provisions. These forward-looking statements, including statements regarding the potential of Resolaris, the ability of the Company to undertake certain development activities (such as clinical trial enrollment and the conduct of clinical trials) and accomplish certain development goals, and the timing of initiation of additional clinical trials and of reporting results from our clinical trials reflect our current views about our plans, intentions, expectations, strategies and prospects, which are based on the information currently available to us and on assumptions we have made. Although we believe that our plans, intentions, expectations, strategies and prospects as reflected in or suggested by those forward-looking statements are reasonable, we can give no assurance that the plans, intentions, expectations or strategies will be attained or achieved. Furthermore, actual results may differ materially from those described in the forward-looking statements and will be affected by a variety of risks and factors that are beyond our control including, without limitation, risks associated with the discovery, development and regulation of our Physiocrine-based product candidates, as well as those set forth in our most recent Annual Report on Form 10-K for the year ended December 31, 2015 and in our subsequent SEC filings. Except as required by law, we assume no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

A Randomized, Double-blinded, Placebo-controlled, Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Immunogenicity, and Biological Activity of ATYR1940 (Resolaris™) in Adult Patients With Facioscapulohumeral Muscular Dystrophy

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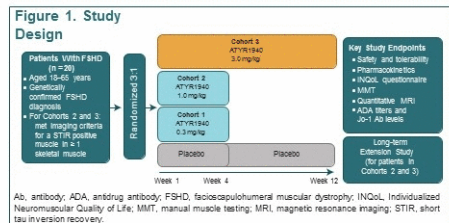
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Introduction

- Facioscapulohumeral muscular dystrophy (FSHD) is a rare genetic myopathy in which immune cells invade diseased skeletal muscle and for which there are no approved treatments. The primary clinical phenotype of FSHD is debilitating skeletal muscle deterioration and weakness:
 - Estimates of FSHD prevalence vary between 1:14,000 and 1:20,000.¹
- ATYR1940 (Resolaris™) is a slightly truncated form of human histidyl tRNA synthetase (HARS), which is 100% identical to the naturally occurring wild type molecule over the common protein sequence:
 - Aside from its established intracellular role in protein synthesis, we believe HARS also plays extracellular roles, including modulating immune responses in skeletal muscle.
 - Because the immune component may play a central role in FSHD pathophysiology,² immunomodulators, including ATYR1940, are being investigated as potential therapies for this disease.
- In preclinical experiments using a rat model of statin-induced myopathy, ATYR1940 reduced skeletal muscle degeneration and necrosis, reduced the numbers of immune cells in muscle, and downregulated immune regulatory proteins in diseased tissue in a dose-dependent manner.
- This first-in-patient study evaluated the safety, tolerability, pharmacokinetic (PK) properties, immunogenicity, and biological activity of ATYR1940 in adult patients with FSHD (ClinicalTrials.gov: NCT02239224).

Methods

- This Phase 1b/2, double-blinded, placebo-controlled, multiple ascending dose study randomly assigned eligible patients 3:1 to receive weekly 1:V ATYR1940 (Cohort 1: 0.3 mg/kg; Cohort 2: 1 mg/kg; Cohort 3: 3 mg/kg) or placebo (Figure 1).



- Key study endpoints were the evaluation of safety and tolerability as assessed by incidence of adverse events (AEs), antidrug antibody (ADA) titers, Jo-1 antibody (Ab) levels, ATYR1940 PK properties, and measures of clinical activity:
 - Manual Muscle Testing (MMT):**
 - Motor function was assessed in 14 muscle groups and graded based on a 5-point scale.
 - For patients in Cohorts 1 and 2, MMT was assessed during screening, at Week 3; Week 4, Day 4, and Week 6; for patients in Cohort 3, MMT was assessed during screening, at Week 6, Week 10, and Week 14.
 - Individualized Neuromuscular Quality of Life (INQoL) Questionnaire:**
 - A validated muscle disease-specific quality of life measure, with 45 questions within 10 sections. The questionnaire focuses on 4 dimensions: Symptoms, Life Domains, Treatment Effects, and Overall Quality of Life. Overall INQoL score is derived from Life Domains and comprises 5 subsections: Activities, Independence, Social Relationships, Emotions, and Body Image.
 - The self-administered questionnaire was completed during screening and at Week 6 in all cohorts as well as at Week 14 for patients in Cohort 3.
 - Muscle Surveillance and Targeted Magnetic Resonance Imaging (MRI):**
 - Lower extremity surveillance MRI was performed during screening to identify active immune responses (as evidenced by short tau inversion recovery [STIR] positive signal).
 - The presence of ≥ 1 STIR-positive muscle as assessed by a central reviewer was an inclusion criterion for this study (Cohorts 2 and 3).
 - STIR-positive muscles were monitored using targeted quantitative MRI for the analysis of fatty infiltration, inflammation, and muscle volume.

Results

- All patients completed the study; however, 1 patient did not receive all doses of study drug due to an AE of infusion-related reaction (IRR).
- All patients had FSHD Type 1; patient demographics and characteristics are shown in Table 1.

Characteristic	Placebo (n=5)	COHORT 1 ATYR1940 0.3 mg/kg (n=3)	COHORT 2 ATYR1940 1.0 mg/kg (n=5)	COHORT 3 ATYR1940 3.0 mg/kg (n=6)
Median age, years (range)	52.0 (39–86)	53.0 (25–55)	46.0 (33–52)	39.5 (25–72)
Male, %	80.0	66.7	33.3	66.7
White, %	100	100	100	100

Safety and Tolerability Profile

- ATYR1940 was generally well tolerated across all dose groups (Table 2).
- All treatment-emergent AEs (TEAEs) were Grades 1 or 2 (mild or moderate in intensity):
 - No dose-response relationship was suggested in the intensity and incidence of events.
- One patient experienced 3 successive IRR events; this was assessed as an AE by the investigator, but was considered a medically important event by the sponsor and was upgraded to a serious AE.
- No trends in hematology or serum chemistries were observed.
- No signals or trends in electrocardiograms or pulmonary function tests were observed.
- TEAEs reported for ≥ 2 patients treated with ATYR1940 are shown in Table 2.

Table 2. Summary of Safety

Parameter, n (%)	Placebo (n=5)	COHORT 1 ATYR1940 0.3 mg/kg (n=3)	COHORT 2 ATYR1940 1.0 mg/kg (n=5)	COHORT 3 ATYR1940 3.0 mg/kg (n=6)
TEAEs	5 (100)	3 (100)	6 (100)	6 (100)
Treatment-related	0	0	0	0
Grade ≥ 3 TEAEs	0	0	0	0
Treatment-related	0	0	0	0
SAEs	0	0	0	1*
Deaths	0	0	0	0
Most common TEAEs				
Cough	0	1 (33.3)	0	2 (33.3)
Headache	2 (40.0)	0	1 (16.7)	2 (33.3)
Presyncope	0	0	0	2 (33.3)
Arthralgia	0	2 (66.7)	0	1 (16.7)
Flushing	0	0	1 (16.7)	1 (16.7)
Nausea	0	0	2 (33.3)	0
Back pain	1 (20.0)	1 (33.3)	3 (50.0)	0
Myalgia	0	1 (33.3)	1 (16.7)	0

*Number of patients. †Designated as SAE by sponsor. SAE, serious adverse event; TEAE, treatment-emergent adverse event.

PK Properties

- PK was generally consistent throughout the study, with dose-proportional increases in exposure.
- The mean clearance was low, and mean volume of distribution at steady state was small, with a mean terminal half-life of 3–5 hours.

Immunogenicity Profile

- Of the 15 patients treated with ATYR1940, 6 were confirmed positive for ADA, but Ab levels fell upon cessation of therapy. No patient had titers high enough to trigger testing in a neutralizing Ab assay.
- No patients had Jo-1 Ab levels considered positive or equivocal for the assay.
- No impact of Ab levels on ATYR1940 PK was detected.

Clinical Activity

- A trend for improvement in MMT results with ATYR1940 treatment was observed compared with placebo, especially in the upper limb (Figure 2 and 3).

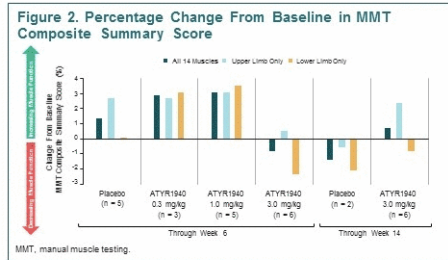
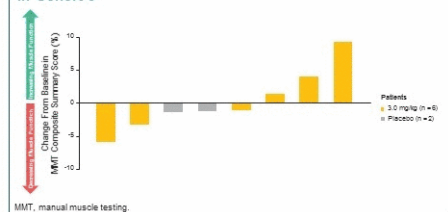
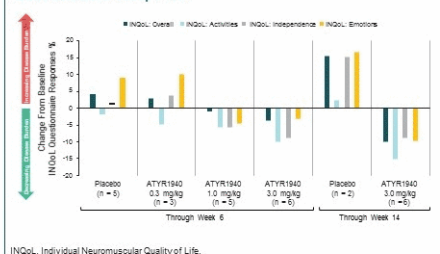


Figure 3. Percentage Change From Baseline to Week 14 in MMT Composite Summary Score for Individual Patients in Cohort 3



- Patients treated with ATYR1940 were generally improved compared with placebo as assessed by INQoL, with patients in Cohort 3 (12 weeks) showing the greatest improvement compared with Cohort 1 and Cohort 2 (4 weeks) (Figure 4):
 - Patients in Cohort 3 reported $\sim 10\%$ improvement in INQoL overall responses compared with $\sim 15\%$ worsening in the placebo group.

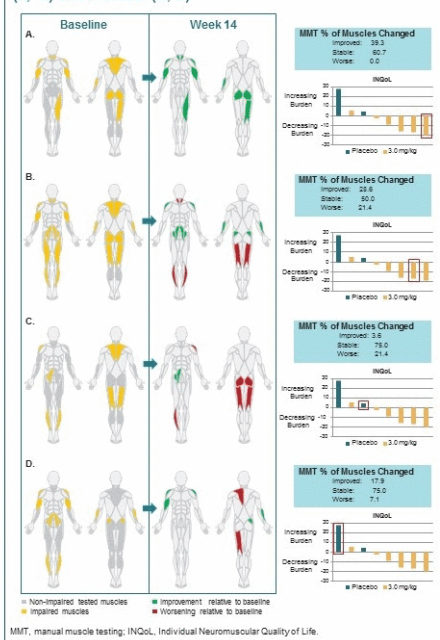
Figure 4. Percentage Change From Baseline in INQoL Questionnaire Response



- In surveillance and targeted quantitative MRI scans of patients treated with placebo or ATYR1940, we observed:
 - Significant measurement variability was seen, driven in part by alignment, motion artifact, and muscle heterogeneity.
 - Little change in STIR, Dixon fat fraction percentage, or quantitative T2 (indicative of the presence of inflammation) in targeted muscles in either the ATYR1940 or placebo groups.

- No elevation from baseline in circulating human biomarker levels in plasma was observed.
- Patient profiles are shown in Figure 5.

Figure 5. Efficacy Results: Change From Baseline to Week 14 in Representative Patients Treated With ATYR1940 (A, B) and Placebo (C, D)



Conclusions

- ATYR1940 (Resolaris™) is generally safe in adult patients with FSHD, and was well tolerated with the exception of 1 patient who experienced 3 IRR events.
- ATYR1940 PK properties were dose-proportional and consistent throughout the study, with no measurable impact from ADA.
- Clinical activity of ATYR1940 was supported by signals of improvement in INQoL questionnaire responses and MMT measures.
- Other exploratory measures, including lower extremity targeted MRI, did not demonstrate activity:
 - Variability in image acquisition may have diminished the opportunity to demonstrate a treatment effect at 3 months.
- Patients in Cohorts 2 and 3 were allowed to enroll in the ongoing, long-term extension study investigating the safety and efficacy of ATYR1940.

References

- Tawil R et al. *Skeletal Muscle* 2014;4:12.
- Frisulio G et al. *J Clin Immunol* 2011;31:155.

Acknowledgements

This study was funded by atYr Pharma, Inc.

Mean BMI, kg/m ² (SD)	28.9 (3.2)	28.6 (1.8)	25.3 (4.6)	22.5 (5.0)
Median disease duration, years (range)	18.6 (4.4–24.8)	6.2 (2.8–21.8)	22.6 (10.2–41.1)	23.0 (9.3–56.4)
Mean FSHD clinical severity score (SD)	2.7 (0.7)	2.5 (0.9)	3.7 (0.5)	3.0 (0.8)

BMI, body mass index; FSHD, facioscapulohumeral muscular dystrophy; SD, standard deviation.

– The largest differences between Cohort 3 and placebo were seen in the Activities, Independence, and Emotions domains.

– In general, there was a good correlation between changes in INQoL and MMT, whereby all patients who experienced an improvement in muscle function also showed improvement in INQoL scores.

Editorial support was provided by Oxford PharmaGenesis, Inc. and was funded by aTyr Pharma, Inc.

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Presented at the 21st International Congress of the World Muscle Society; 4–8 October 2016; Granada, Spain.

