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

December 13, 2016
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)

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))

Item 7.01 Regulation FD Disclosure.

On December 13, 2016, aTyr Pharma, Inc. (the "Company") announced clinical trial data in a press release, a copy of which furnished herewith as Exhibit 99.1.

In addition, on December 13, 2016, the Company conducted a conference call with corporate presentation materials which the Company placed on its website. A copy of the presentation materials is furnished herewith as Exhibit 99.2. The Company does not undertake to update the presentation materials.

The information under this Item 7.01, including Exhibit 99.1 and 99.2, 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.

In connection with the announcement of clinical trial data described above, the Company announced clinical results from exploratory trials assessing the safety and potential activity of Resolaris™, including:

- Top-line results from a completed Phase 1b/2 trial for adult patients with limb-girdle muscular dystrophy 2B (LGMD2B/dysferlinopathy) or facioscapulohumeral muscular dystrophy (FSHD) (the "004 Trial");
- Interim data from an ongoing Phase 1b/2 trial with early onset FSHD (the "003 Trial"); and
- Interim data from an ongoing long-term safety extension study (the "005 Trial") for patients from aTyr's adult FSHD trial completed earlier this year (the "002 Trial").

The results announced today highlight the potential of Resolaris, an immuno-modulator of activated T cells, as a single treatment for multiple rare myopathies with an immune component (RMIC).

Clinical Activity Assessments:

As part of clinical assessments in these studies, manual muscle testing (MMT), a validated assessment tool that measures muscle strength, was performed across 14 selected muscle groups. In addition, a validated patient reported outcome measure designed specifically for neuromuscular disease, the individualized neuromuscular quality of life (INQoL) questionnaire, was utilized. Note that an increase in MMT score represents an increase in muscle strength, whereas a decrease in INQoL score represents a decrease in disease burden. Given that the 003, 004 and 005 Trials are small and open-label in nature and that the clinical assessments expressed in this release, MMT and INQoL, although clinically validated, are subject to variability over time, including intra-patient and inter-physician variability, it is important to temper any definitive conclusions made with respect to the clinical activity of Resolaris.

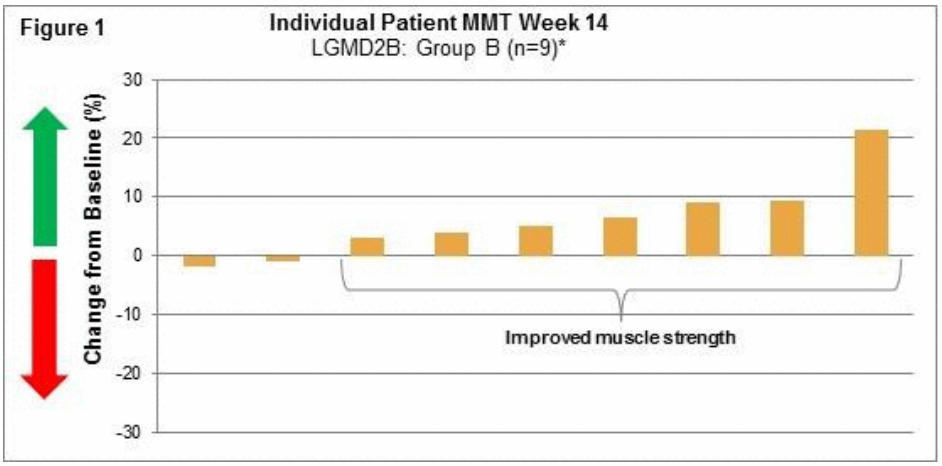
LGMD2B/FSHD (004) Trial:

This international Phase 1b/2 clinical trial at 6 clinical sites was an open-label, intra-patient, placebo run-in, dose escalation study designed to assess the safety, tolerability, immunogenicity and exploratory assessments of clinical activity of intra-patient dose escalations to twice weekly (biw) intravenous infusions of Resolaris in LGMD2B and FSHD adult patients. Patients were assigned to two treatment groups each with 12 weeks of treatment:

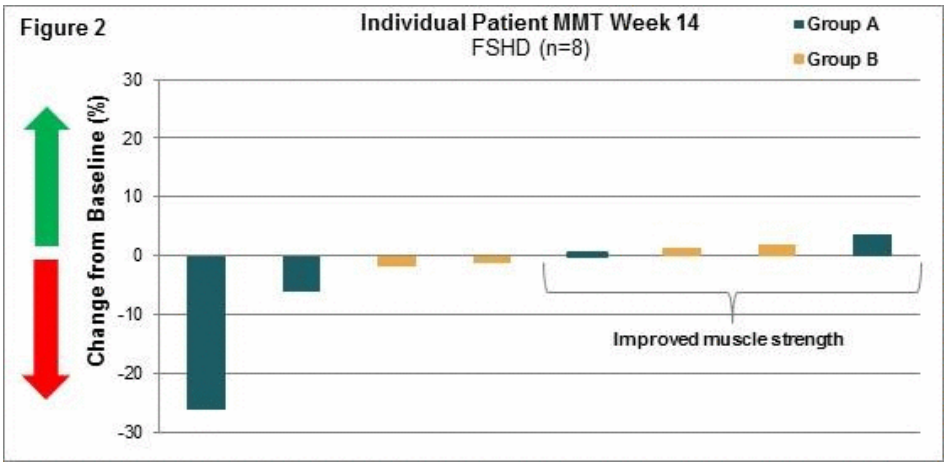
- Group A: 4 patients with FSHD received infusions of Resolaris with the highest dosing up to 1.0 mg/kg biw for a period of 4 weeks; and
- Group B: 10 patients with LGMD and 4 patients with FSHD received infusions of Resolaris with the highest dosing up to 3.0 mg/kg biw for a period of 4 weeks.

Manual Muscle Testing, MMT, Assessment 004 Trial:

(See Figure 1 and Figure 2)



**One patient in the LGMD2B group (Figure 1) was wheelchair bound and did not complete the MMT evaluation.*



Individualized Quality of Life, INQoL, Assessment 004 Trial:

- LGMD2B Patients: Overall INQoL score was relatively stable for these 10 patients with overall approximately equal proportions of patients with decreases in disease burden compared to increases in disease burden
- FSHD Patients: Overall INQoL score was relatively stable for these 8 patients with 5 of 8 patients presenting with a small decrease in disease burden over the length of the trial

Biomarker Summary in 004 Trial:

Various exploratory biomarkers (including targeted muscle T2 and STIR MRI and various plasma proteins) did not generally establish sufficiently high or consistent levels or robust signals across a sufficient number of patients to determine test article effects. Peripheral cell based biomarkers will be assessed at a later date. Targeted muscle T2/STIR MRI will not be prioritized as a biomarker in the near-term.

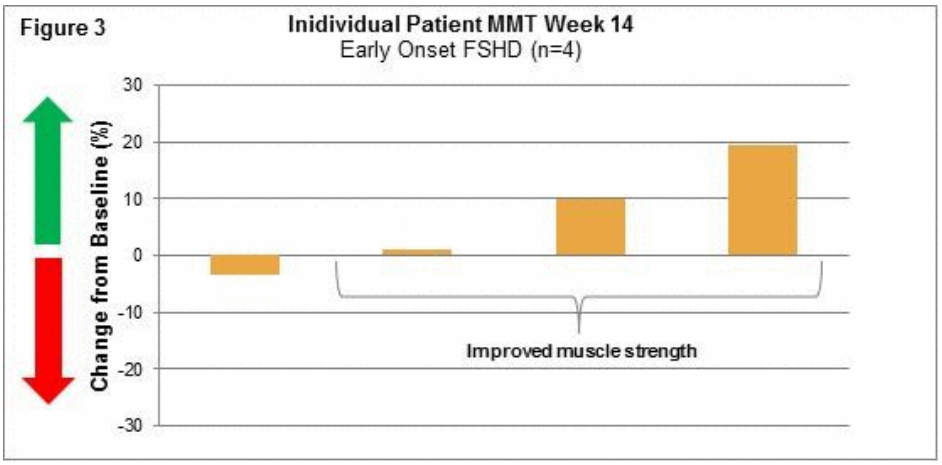
Early Onset FSHD (003) Trial:

This ongoing international, multi-center, open-label, intra-patient, placebo run-in, dose escalation Phase 1b/2 study is designed to evaluate the safety, tolerability, immunogenicity and exploratory assessments of clinical activity of Resolaris at weekly doses of 0.3, 1.0 and 3.0 mg/kg in patients with early onset FSHD for a total of 12 weeks.

An interim data cut was conducted for the first four early-onset FSHD patients that completed treatment with Resolaris (age range of 16 to 20).

Manual Muscle Testing, MMT, Assessment 003 Trial:

(See Figure 3)



Individualized Quality of Life, INQoL, Assessment 003 Trial:

Patient's INQoL scores were relatively stable. Two patients had slight decreases in disease burden and one patient showed an increase. The fourth patient did not have a baseline INQoL assessment.

Adult FSHD Long Term Safety Extension (005) Trial:

This ongoing international, multi-center, open-label extension clinical trial is designed to assess the long-term safety, effects on biomarkers and systemic exposure of Resolaris in adult FSHD patients from the completed 002 Trial. Patients receive weekly doses of 3.0 mg/kg on an ongoing basis.

- 3 of the 9 patients enrolled from the adult FSHD (002) Trial are still receiving treatment
- Of the 4 patients who received at least 6 months of therapy in the 005 Trial, there were no significant trends in worsening or improvement in either MMT or INQoL scores
- Peripheral cell based biomarkers and other biomarkers will be assessed at a later date

Safety and Tolerability Summary

- As of December 1, 2016, 44 patients have received Resolaris, across all trials, for a total drug exposure of 149 patient months
- Resolaris continues to demonstrate a favorable safety profile and was generally well-tolerated across all doses tested in adult FSHD, early onset FSHD (younger population ages 16 – 25) and adult LGMD2B for 3 months of dosing, as well as with long-term exposure in adult FSHD patients
- No Serious Adverse Events (SAEs) were reported by investigators in the 003, 004 and 005 Trials
    - Adverse Events (AE) reported were in general mild or moderate in intensity
    - No notable differences in AEs between adult FSHD, adult LGMD2B and early onset FSHD patients
- Protocol related discontinuations
    - Per protocol, patients:
        - are not medicated before or during infusion for infusion related reactions (IRRs);
        - discontinue upon occurrence of an IRR and 4 FSHD patients and 1 LGMD patient discontinued for this reason; and
        - reaching Jo-1 antibody unit levels above the designated protocol cut-off must discontinue treatment and 5 FSHD patients discontinued for this reason.
    - 1 LGMD patient discontinued from the 004 Trial for non-drug related reasons
    - All IRRs were mild to moderate and transient
    - Elevated Jo-1 antibody observations were without associated clinical symptoms
    - After changing the infusion protocol to a 90-minute infusion, 9.1% experienced IRRs (previously the rate was 16.7% with an infusion rate of 30 minutes)
    - The overall discontinuation rate in the 003, 004 and 005 Trials under all protocols is 11 out of 35 patients (31%)
    - In the 003, 004 and 005 Trials, low level anti-drug antibody (ADA) titer signals were observed in 19 of 35 (54%) patients dosed (13 FSHD and 6 LGMD); these low level signals did not warrant neutralizing ADA assays and no clinically significant findings were associated with these ADA assay signals

Resolaris Summary

After reviewing the entire clinical program for Resolaris, which spans 44 patients in four separate interventional trials, aTyr believes that these results are supportive of the advancement of Resolaris as a single treatment for various rare myopathies with an immune component. Next steps for the company include completing the evaluation of the 003, 004 and 005 biomarker data, particularly peripheral cell based data using one or more mechanistic assays currently under development at aTyr for agonists of the Resokine pathway and T cell activity. Future trials will be designed using one or more of these mechanistic assays, as well as the option to assess local immune components in skeletal muscle directly with biopsies. In addition, aTyr plans to meet with the FDA in 2017 to discuss a regulatory path towards a Biologics License Application (BLA).

2017 Outlook

In 2017, aTyr looks forward to:

- Emphasizing one RMIC indication in the Resolaris program to enhance its multiple rare myopathies, single treatment strategy;
- Advancing its iMod.Fc program into the clinic (including completion of GLP safety studies and GMP manufacturing for early clinical work) for rare lung diseases; and
- Furthering its clinical and R&D pipeline by partnering one or more of its programs, thereby driving value for its stockholders and ultimately making meaningful medicines available for patients.

In addition, selected slides from corporate presentation with respect to the clinical trial data referenced above are filed herewith as Exhibit 99.3. The Company does not undertake to update the presentation materials.

Forward-Looking Statements

This Current Report on Form 8-K contains 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 Physiocrines and our product candidates, including Resolaris™ and iMod. Fc, the ability to successfully advance our pipeline or product candidates, the timing within which we expect to initiate, receive and report data from, and complete our planned clinical trials, and 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 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 most recent Annual Report on Form 10-K, our most recent Quarterly Report on Form 10-Q and in our subsequent 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.

Item 9.01 Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of aTyr Pharma, Inc. dated December 13, 2016 (furnished herewith)
99.2	Corporate Presentation Materials of aTyr Pharma, Inc. dated December 13, 2016 (furnished herewith)
99.3	Selected Slides from the Corporate Presentation Materials of aTyr Pharma, Inc. dated December 13, 2016, entitled "Resolaris Clinical Program – Data Update" (filed herewith)

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: December 13, 2016

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Exhibit 99.1

IMMEDIATE RELEASE

Contact:

Mark Johnson

Sr. Director, Investor Relations

mjohnson@atyrpharma.com

+1-858-223-1163

aTyr Pharma Reports Promising Signals of Clinical Activity in Multiple Rare Genetically Distinct Myopathies with Resolaris™ in Exploratory Trials

- Improved Muscle Strength Observed in 50% to 78% of Patients in Two Rare Genetically Distinct Myopathies -

- Resolaris Continues to Demonstrate a Generally Well Tolerated Safety Profile in All Trials -

- Conference Call and Webcast Featuring Guest Speaker Professor John Vissing, MD, at 8:30 a.m. (EST) Today -

SAN DIEGO – December 13, 2016 – aTyr Pharma, Inc. (Nasdaq: LIFE), a biotherapeutics company engaged in the discovery and development of Physiocrine-based therapeutics to address severe, rare diseases, today announced clinical results from exploratory trials assessing the safety and potential activity of Resolaris™, including:

- Top-line results from a completed Phase 1b/2 trial for adult patients with limb-girdle muscular dystrophy 2B (LGMD2B/dysferlinopathy) or facioscapulohumeral muscular dystrophy (FSHD) (the "004 Trial");
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The results announced today highlight the potential of Resolaris, an immuno-modulator of activated T cells, as a single treatment for multiple rare myopathies with an immune component (RMIC).

"Congratulations to our team, collaborators and patients that helped us accomplish the fundamental objectives for these clinical trials: (1) to demonstrate the safety and tolerability of our product candidate, Resolaris, across different RMICs and (2) to explore different readouts of potential clinical activity and product candidate activity in different RMICs," said John Mendlein, PhD, CEO of aTyr Pharma. "We are very pleased to see RMIC patients with two entirely different genetic etiologies showing improvement in muscle strength in 3 months as measured by manual muscle testing. Taken together, our clinical data supports the exciting potential of Resolaris as a single treatment for multiple rare myopathies with an immune component and we believe our clinical results will help inform and direct the future clinical development of Resolaris in RMICs. Finally, we wish to personally thank all the FSHD and LGMD patients and health care professionals who have participated in our trials."

"aTyr's data, which shows potential clinical activity in genetically distinct myopathies characterized by an immune component, warrants additional clinical investigation," said Dr. John Vissing, Professor of the Department of Neurology at the University of Copenhagen and an investigator in aTyr's 004 Trial. "It is supportive of the hypothesis that administering a naturally occurring muscle homeostasis protein with immuno-modulator activities, which is normally secreted by skeletal muscle cells, has the potential to help patients across many rare myopathies with divergent genetic etiologies of disease."

Clinical Activity Assessments: As part of clinical assessments in these studies, manual muscle testing (MMT), a validated assessment tool that measures muscle strength, was performed across 14 selected muscle groups. In addition, a validated patient reported outcome measure designed specifically for neuromuscular disease, the individualized neuromuscular quality of life (INQoL) questionnaire, was utilized. Note that an increase in MMT score represents an increase in muscle strength, whereas a decrease in INQoL score represents a decrease in disease burden. Given that the 003, 004 and 005 Trials are small and open-label in nature and that the clinical assessments expressed in this release, MMT and INQoL, although clinically validated, are subject to variability over time, including intra-patient and inter-physician variability, it is important to temper any definitive conclusions made with respect to the clinical activity of Resolaris.

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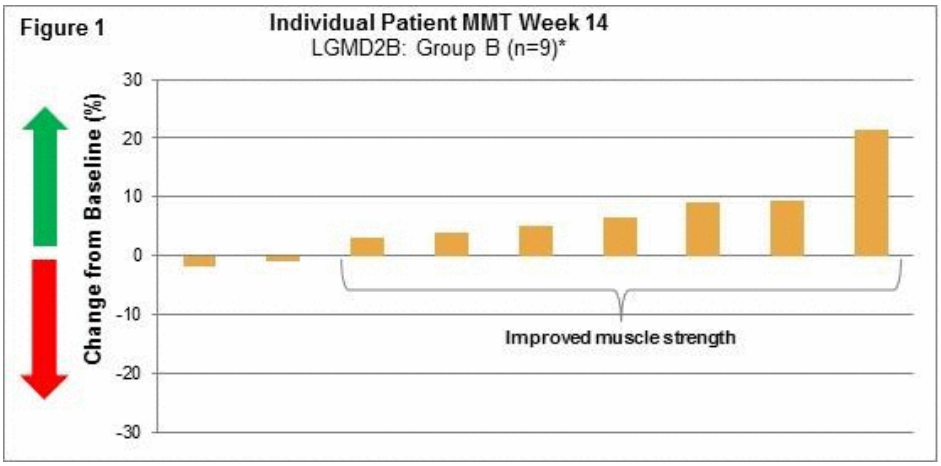

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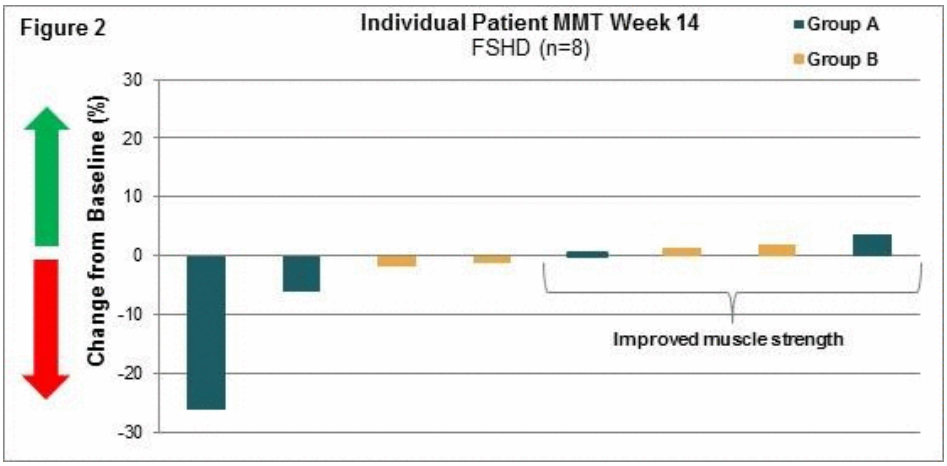

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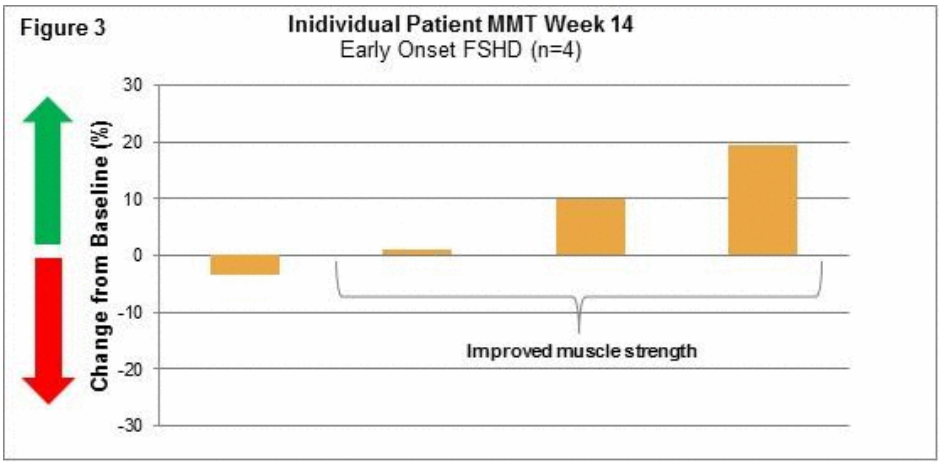

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    - The overall discontinuation rate in the 003, 004 and 005 Trials under all protocols is 11 out of 35 patients (31%)
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Resolaris Summary

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2017 Outlook

In 2017, aTyr looks forward to:

- Emphasizing one RMIC indication in the Resolaris program to enhance its multiple rare myopathies, single treatment strategy;
- Advancing its iMod.Fc program into the clinic (including completion of GLP safety studies and GMP manufacturing for early clinical work) for rare lung diseases; and
- Furthering its clinical and R&D pipeline by partnering one or more of its programs, thereby driving value for its stockholders and ultimately making meaningful medicines available for patients.

Conference Call and Webcast Information

Today at 8:30 a.m. EST, aTyr Pharma will host a conference call and webcast with an accompanying slide presentation to discuss the results of the Phase 1b/2 program of Resolaris™. The live webcast and slide presentation will be available on the “Investors” section of the company website at www.atyrpharma.com. Joining aTyr Pharma management will be Professor John Vissing, M.D., Professor of Neurology at the University of Copenhagen, Denmark. To access the call, please dial (877) 870-4263 (domestic) or (412) 317-0790 (international) and ask to join the aTyr Pharma call. A replay of the webcast will be archived on the company's website following the call.

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 iMod.Fc

aTyr Pharma established a discovery program to leverage its knowledge of the Resokine pathway to vary exposure and activity of the iMod domain through protein engineering. aTyr’s Fc fusion experiments helped delineate how to enhance the exposure of the iMod domain of Resokine while maintaining activity and provide insights into this domain harboring immuno-modulatory activity. aTyr plans to test the potential of this molecule in lung disease by developing it as a potential therapeutic for patients with rare pulmonary diseases with an immune component (RPICs).

About LGMD2B / Dysferlinopathy

Limb girdle muscular dystrophy (LGMD) refers to a group of rare genetic myopathies, of which there are more than 20 different subtypes, none with approved therapies. LGMD affects an estimated 16,000 patients in the U.S., approximately 3,000 of who have LGMD2B. LGMD2B is a recessive genetic disease caused by a toxic loss of function in the dysferlin gene. Patients experience progressive debilitating muscle weakness and atrophy as well as immune cell invasion in the skeletal muscle.

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. It is caused by a toxic gain of function in the DUX4 gene. 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.

About Early Onset FSHD

While FSHD can manifest at any age, the onset of symptoms in many patients occurs before the age of 18. We refer to this patient population as early onset FSHD. aTyr has selected those patients with onset of symptoms before the age of ten for its current clinical trial. Within the early onset population are individuals with symptom onset at less than five years of age, with progression in disease prior to age ten. These individuals have generally the most severe muscle symptoms and extra-muscular manifestations such as auditory deficits and retinal complications that may result in vision loss. This sub-group of early onset patients are often referred to as having "infantile onset" FSHD. Estimates of prevalence vary; however, aTyr believes the "infantile onset" FSHD population is approximately 1,000 in the U.S.

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. aTyr has built an intellectual property estate, to protect its pipeline, 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™ or iMod.Fc, 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, the timing of initiation of additional clinical trials and of reporting results from our clinical trials and 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 including our most recent Quarterly Report for the quarter ended September 30, 2016. 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.

Exhibit 99.2

New Hope For Patients with Rare Myopathies Characterized by an Immune Component

John Mendlein, PhD, CEO of aTyr Pharma
Sanjay Shukla, MD, MS, CMO of aTyr Pharma
Sanuj Ravindran, MD, CBO of aTyr Pharma

Guest: John Vissing, MD, Professor of Neurology at University of Copenhagen, Denmark
Principal Investigator for aTyr Pharma's 004 Trial

December 13, 2016

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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 Physiocrines and our product candidates, including Resolaris™ and iMod. Fc, the ability to successfully advance our pipeline or product candidates, the timing within which we expect to initiate, receive and report data from, and complete our planned clinical trials, and our ability to receive regulatory approvals for, and commercialize, our product candidates, our ability to identify and discover additional product candidates, our projected cash expenditures, 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 most recent Quarterly Report on Form 10-Q, Annual Report on Form 10-K 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.

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Our Agenda: 8:30am – 9:30am (EST)

Resolaris: Derived from the Resokine Pathway

- John Mendlein, PhD
  Chief Executive Officer at aTyr Pharma

Potential Therapeutic Approaches to Rare Myopathies with an Immune Component

- John Vissing, MD
  Professor of Neurology at the University of Copenhagen, Denmark

Resolaris Clinical Data Review from 3 Trials

- Sanjay Shukla, MD, MS
  Chief Medical Officer at aTyr Pharma

Resolaris Discussion and 2017 Outlook

- John Mendlein, PhD

Question and Answer Session

RESOLARIS: DERIVED FROM THE RESOKINE PATHWAY

JOHN MENDLEIN, PHD, CEO

DECEMBER 13, 2016

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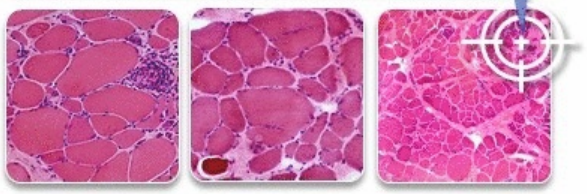
Rare Myopathies with an Immune Component

Chronic damage, homeostasis disrupted

Disruption of Homeostasis
(untapped therapeutic intervention point)

Genetic Mutation	Aberrant Protein Expression & Profile	Localized T Cell Invasion & Proliferation
Facioscapulohumeral Muscular Dystrophy (FSHD)	Aberrant expression of multiple proteins in muscle	
Limb Girdle Muscular Dystrophy 2B (LGMD2B)	Aberrant dysferlin proteins	
Duchenne Muscular Dystrophy (DMD)	Aberrant dystrophin proteins	



FSHD LGMD2B DMD

Potential to link genotype to specific T cell phenotype

Frisullo et al., J. Clin. Immunol., 2011 *Gallardo et al. Neurology, 2001*
Flanigan et al. Human Gene Therapy, 2013

Anti-Dystrophin T Cell Responses in Duchenne Muscular Dystrophy: Prevalence and a Glucocorticoid Treatment Effect

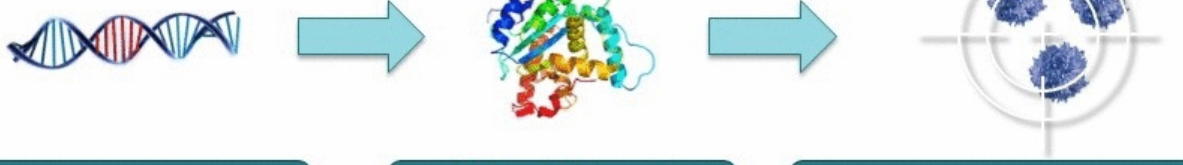
Kevin M. Flanigan,[1*] Katie Campbell,[2] Laurence Viollet,[1] Wei Wang,[3] Ana Maria Gomez,[1] Christopher M. Walker,[2] and Jerry R. Mendell[1*]

Abstract

Duchenne muscular dystrophy (DMD) typically occurs as a result of truncating mutations in the *DMD* gene that result in a lack of expression of the dystrophin protein in muscle fibers. Various therapies under development are directed toward restoring dystrophin expression at the subsarcolemmal membrane, including gene transfer. In a trial of intramuscular adeno-associated virus (AAV)-mediated delivery of a therapeutic minidystrophin construct, we identified in two of six subjects the presence of a population of T cells that had been primed to recognize dystrophin epitopes before transgene delivery. As the presence of preexisting T cell immunity may have a significant effect on the success of therapeutic approaches for restoring dystrophin, we sought to determine the prevalence of such immunity within a DMD cohort from our Muscular Dystrophy Association clinic. Dystrophin-specific T cell immunity was evaluated in subjects with DMD who were either receiving the glucocorticoid steroid prednisone ($n=24$) or deflazacort ($n=29$), or who were not receiving steroids ($n=17$), as well as from normal age-matched control subjects ($n=21$). We demonstrate that increasing age correlates with an increased risk for the presence of anti-dystrophin T cell immunity, and that treatment with either corticosteroid decreases risk compared with no treatment, suggesting that steroid therapy in part may derive some of its benefit through modulation of T cell responses. The frequency of dystrophin-specific T cells detected by enzyme-linked immunospot assay was lower in subjects treated with deflazacort versus prednisone, despite similar overall corticosteroid exposure, suggesting that the effects of the two corticosteroids may not be identical in patients with DMD. T cells targeted epitopes upstream and downstream of the dystrophin gene mutation and involved the $CD4^+$ helper and/or $CD8^+$ cytotoxic subsets. Our data confirm the presence of preexisting circulating T cell immunity to dystrophin in a sizable proportion of patients with DMD, and emphasize the need to consider this in the design and interpretation of clinical gene therapy trials.

Connecting Genotype to Immune Cell Phenotype in Duchenne Muscular Dystrophy Patients

Disruption of Homeostasis
(untapped therapeutic intervention point)



Genetic Mutation	Etiology of Aberrant Protein	Localized T Cell invasion & proliferation
DMD Patients: • Splice exon 12 • Del ex 45 • Del ex 46 – 50 • Del ex 49 – 54 • Nonsense ex 59 • Nonsense ex 69	**Locations of Immune Response:** • Exons 1 – 9 • Exons 17 – 26 • Exons 42 – 50 • Exons 50 – 59 • Exons 59 – 69 • Exons 70 - 79	**T Cell Phenotype:** CD4 and/or CD8

Frisullo et al., J. Clin. Immunol., 2011 *Gallardo et al. Neurology, 2001*
Flanigan et al. Human Gene Therapy, 2013

Resokine Pathway Paradigm

Directed at activated, local T cells in RMIC patient muscle

1ST PHYSIOCRINE BASED PRODUCT CANDIDATE

An extracellular homeostatic pathway that sets T cell responses as an agonist

Arising from histidine aminoacyl tRNA synthetase (HARS) gene

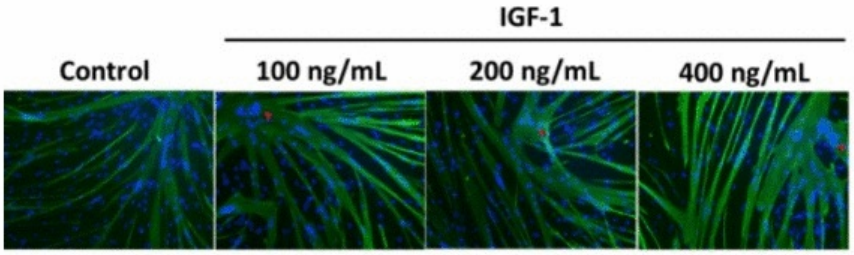
Changes activated T cell responses at levels <100pM

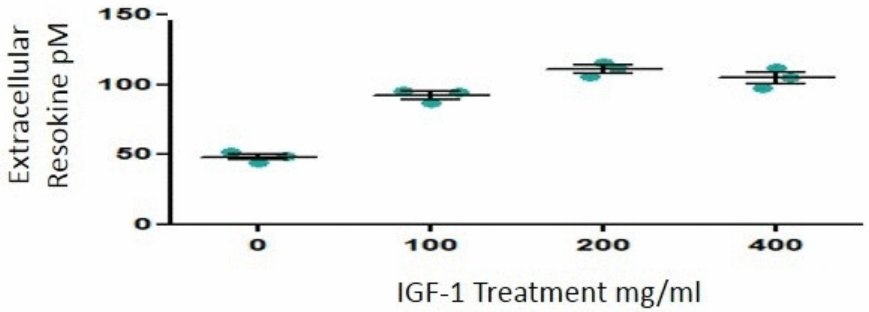
Pathway insufficiency leads to inappropriate immune responses

Resolaris, an agonist, is intended to promote homeostasis in muscle

IGF-1 Increases Resokine Release From Myoblasts Differentiating to Myotubes

Linking the Resokine pathway to muscle biology





Antibodies sufficient to block 100pM Resokine
block >50% of differentiation & growth (slower)

Human myoblasts were isolated from a healthy volunteer properly consented and not in a clinical trial

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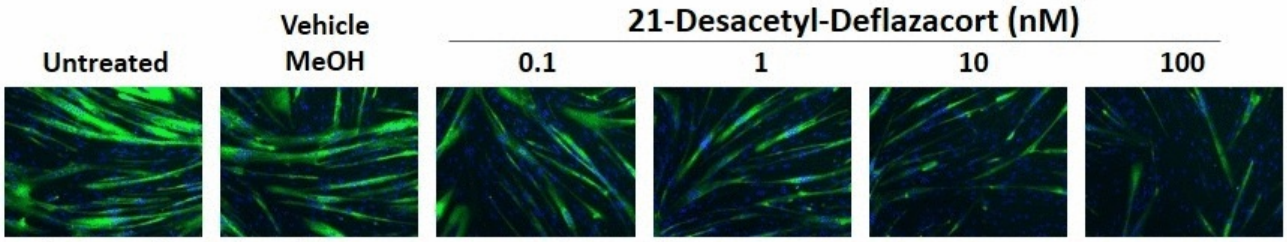
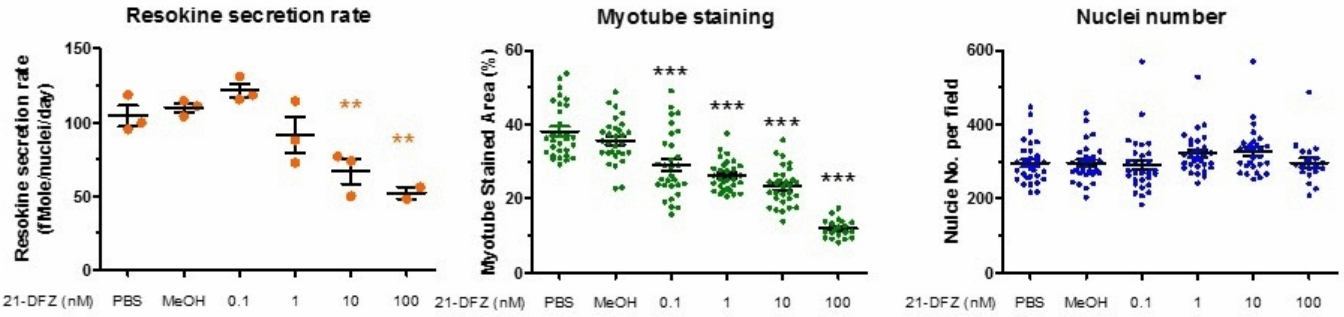
Deflazacort Inhibits Muscle Growth and Resokine Release

Steroid use to treat RMIC patients



Myotube (myosin)/Nuclei (Hoechst), Images at 100× magnification; **Differentiation Day 0-5**



*p<0.05, **p<0.01, ***p<0.001

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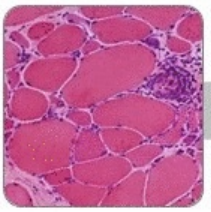
Muscle Franchise Strategy: Looking Into The Future

Resolaris: Potential to Promote Muscle Homeostasis

Aberrant protein expression from aberrant genetics
Phenotype dysfunction:
Muscle degeneration/regeneration
Immune dysregulation
Fibrosis



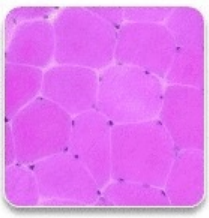
Diseased muscle

Genetic Modifiers

Growth Augmenters

Primed T cells Targeting muscle

Increased mass, Larger T cell target



Healthy muscle

Resolaris:
- Naturally designed homeostatic protein
- Single agent, multiple diseases
- Potentially helpful with other MOAs

John Vissing, MD

Professional:

- Professor of Neurology at the University of Copenhagen, Denmark
- Director of the Neuromuscular Clinic & Research Unit at National Hospital, Rigshospitalet

Disease Focus:

Facioscapulohumeral muscular dystrophy, Kennedy disease, Becker muscular dystrophy, different forms of limb girdle muscular dystrophy, myotonic dystrophy, mitochondrial myopathies and glycogenoses

Research:

Authored more than 250 scientific articles in international journals in the area of muscle disease

Education:

- MD degree from the Medical School at the University of Copenhagen
- Research fellowship training at University of Copenhagen and UT, Southwestern Medical Center, Dallas, US

Potential Therapeutic Approaches to Rare Myopathies With an Immune Component

John Vissing, MD, Professor of Neurology at University of Copenhagen, Denmark
Principal Investigator for aTyr Pharma's 004 Trial

December 13, 2016

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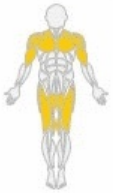
Facioscapulohumeral Muscular Dystrophy (FSHD) and Limb-Girdle Muscular Dystrophy 2B (LGMD2B)

	FSHD	LGMD2B
Genetics	Toxic gain of function (DUX4 region)	Loss of function mutations (Dysferlin gene)
Immune Pathology	Immune infiltration by activated T cells[1] (primarily $CD8^+$)	Immune infiltrates consisting of $CD4^+$, $CD8^+$ and macrophages[2]
Clinical	Debilitating, progressive skeletal muscle weakness Pain, fatigue, difficulty moving limbs, may have respiratory distress	
Standard of Care	No therapeutic treatments, only supportive care provided	
Disease Progression	Heterogeneous by muscle 	Homogeneous by muscle group 

[1]*Frisullo et al. J Clin Immunol (2011) 31:155–166*
[2]*Gallardo et al. Neurology 2001;57:2136–2138; Yin et al. Int J Clin Exp Pathol 2015;8(3):3069-3075*

LGMD2B Disease Progression Case History

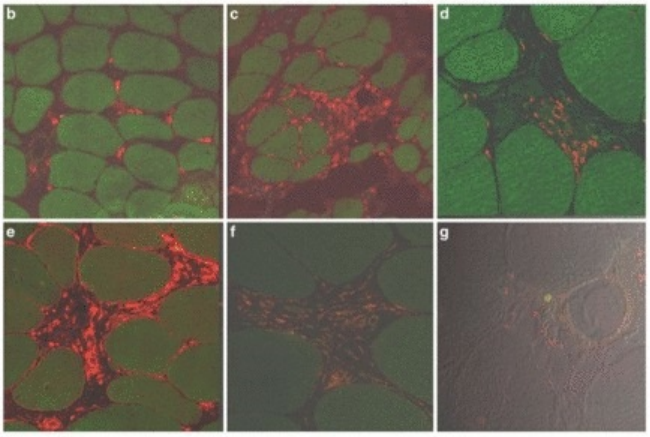
First symptoms	Misdiagnosed w/ polymyositis	LGMD2B Diagnosis	Part time wheelchair-bound	Full time wheelchair-bound	Full dependency due to severe physical disability
Age **<15**	**16 – 18**		**19 – 27**		**28 - 34**
• Walks normally, active childhood	• Abnormal gait • Knees locked • Difficulty climbing stairs and running	• Difficulty rising from a chair, raising hands above head • Uses a cane and leg braces	• Slight improvement when steroids stopped • Unable to rise from a chair	• Requires assistance in daily living	• Unable to turn over in a bed or raise hands above head • Uses service dog for daily activities

https://www.youtube.com/watch?v=JLqHis1yPUI
http://mwtn2013blisswelch.blogspot.com/

T Cell Involvement in the Pathophysiology of RMICs

(For example: FSHD, LGMD2B, DMD)

FSHD



Endomysial infiltrates, in which CD8+ cells predominated (Fig. 2b–d), and perivascular infiltrates, mainly constituted by CD4+ cells (Fig. 2f) in all samples

LGMD2B

***Table 2** Endomysial mononuclear cell infiltrates in clusters*

Cells	Polymyositis	Dysferlinopathies
Mean cells per cluster	141 ± 74	88.6 ± 48
$CD8^+$	46.5 ± 10.3	11.1 ± 6.6
$CD4^+$	27.3 ± 11.5	40.6 ± 22.8
Macrophages	27.7 ± 7.6	36.7 ± 23.7
$CD20^+$	≤0.1	0

LGMD2B & DMD

Table 2. Comparison of inflammatory cells in muscle biopsy samples of dysferlinopathy, DMD/BMD, and polymyositis patients

	$CD4^+$ cells (mean ± SD)	$CD8^+$ cells (mean ± SD)	B cells (mean ± SD)	Macrophages (mean ± SD)
Dysferlinopathy	5.7 ± 4.4[a]	1.3 ± 1.1[c]	2.3 ± 2.2	7.8 ± 4.3[d]
Polymyositits	12.3 ± 6.4	3.3 ± 1.8	2.6 ± 1.9	10.8 ± 6.5
DMD/BMD	4.9 ± 5.7[b]	2.0 ± 1.6	2.5 ± 3.4	3.7 ± 3.1[e]

[a]Dysferlinopathy versus polymyositis; $P = 0.009$; [b]DMD/BMD versus polymyositis; $P = 0.009$; [c]dysferlinopathy versus polymyositis; $P = 0.005$; [d]dysferlinopathy versus DMD/BMD; $P = 0.047$; [e]DMD/BMD versus polymyositis; $P = 0.006$. No other statistically significant differences were found among the different subgroups.

Gallardo et al. Inflammation in dysferlin myopathy: Immunohistochemical characterization of 13 patients. Neurol. 2001;57:2136–2138
Yin et al. CD4+ cells, macrophages, MHC-I and C5b-9 involve the pathogenesis of dysferlinopathy.Int J Clin Exp Pathol 2015;8(3):3069-3075
Frisullo et al. CD8+ T Cells in Facioscapulohumeral Muscular Dystrophy Patients with Inflammatory Features at Muscle MRI. J Clin Immunol (2011) 31:155–166

Treatment of dysferlinopathy with deflazacort: a double-blind, placebo-controlled clinical trial

Maggie C Walter[1*†], Peter Reilich[1†], Simone Thiele[1], Joachim Schessl[1], Herbert Schreiber[2], Karlheinz Reiners[3], Wolfram Kress[4], Clemens Müller-Reible[4], Matthias Vorgerd[5], Peter Urban[6], Bertold Schrank[7], Marcus Deschauer[8], Beate Schlotter-Weigel[1], Ralf Kohnen[9] and Hanns Lochmüller[10]

Abstract

Background: Dysferlinopathies are autosomal recessive disorders caused by mutations in the dysferlin (*DYSF*) gene encoding the dysferlin protein. DYSF mutations lead to a wide range of muscular phenotypes, with the most prominent being Miyoshi myopathy (MM) and limb girdle muscular dystrophy type 2B (LGMD2B).

Methods: We assessed the one-year-natural course of dysferlinopathy, and the safety and efficacy of deflazacort treatment in a double-blind, placebo-controlled cross-over trial. After one year of natural course without intervention, 25 patients with genetically defined dysferlinopathy were randomized to receive deflazacort and placebo for six months each (1 mg/kg/day in month one, 1 mg/kg every 2nd day during months two to six) in one of two treatment sequences.

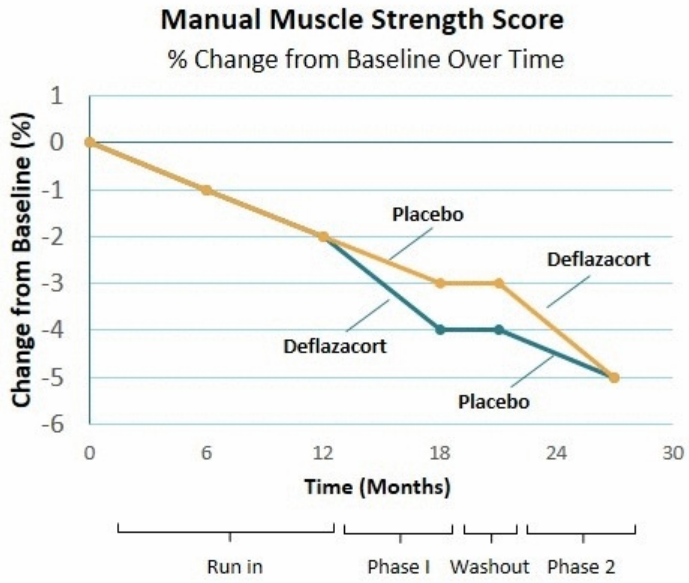
Results: During one year of natural course, muscle strength declined about 2% as measured by CIDD (Clinical Investigation of Duchenne Dystrophy) score, and 76 Newton as measured by hand-held dynamometry. Deflazacort did not improve muscle strength. In contrast, there is a trend of worsening muscle strength under deflazacort treatment, which recovers after discontinuation of the study drug. During deflazacort treatment, patients showed a broad spectrum of steroid side effects.

Conclusion: Deflazacort is not an effective therapy for dysferlinopathies, and off-label use is not warranted. This is an important finding, since steroid treatment should not be administered in patients with dysferlinopathy, who may be often misdiagnosed as polymyositis.

Trial registration: This clinical trial was registered at www.ClincalTrials.gov, identifier: NCT00527228, and was always freely accessible to the public.

Keywords: Limb girdle muscular dystrophy (LGMD), Dysferlinopathy, Therapy, Deflazacort, Muscle strength, Steroids

LGMD Patients Manual Muscle Strength* Decline at Double the Rate on Deflazacort vs Placebo



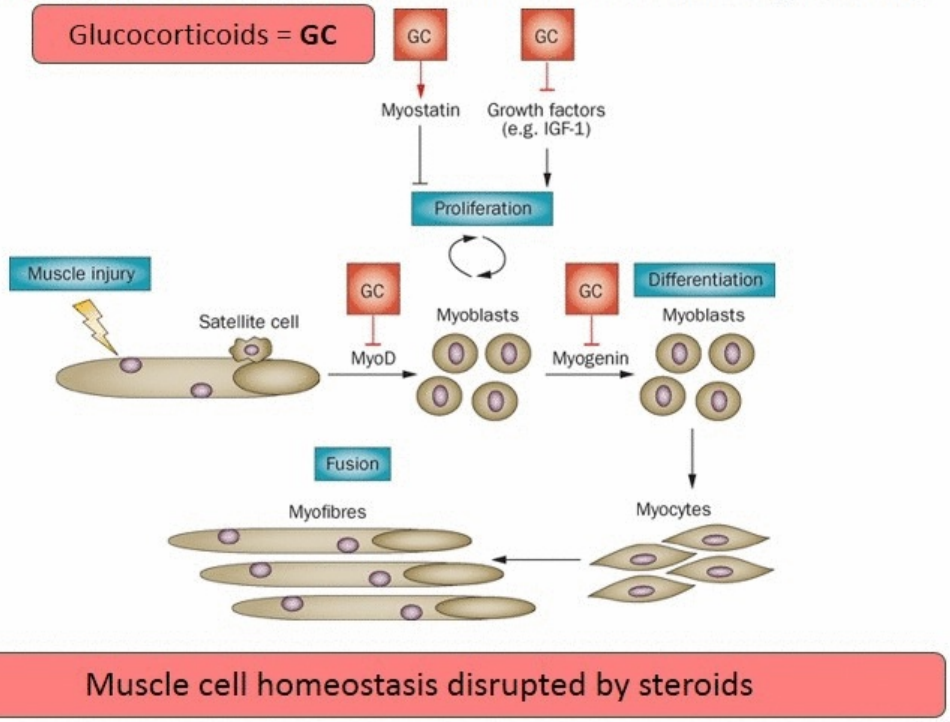
Treatment with Deflazacort was for 6 months in each arm
Single site, placebo controlled, cross over design (n=25)

**Manual muscle strength assessed bilaterally by the modified Medical Research Council Scales (MRC) CIDD (Clinical Investigation of Duchenne Dystrophy) score, graded from 0 (worst) to 10 (best)*

Walter et al, Orphanet Journal of Rare Diseases, 2013

Limitations of Steroids as Potential Treatment in RMICs

The effects of glucocorticoids on postnatal skeletal muscle regeneration[1]



Muscle cell homeostasis disrupted by steroids

[1]Hanaoka, B. Y. *et al.* (2012) Implications of glucocorticoid therapy in idiopathic inflammatory myopathies *Nat. Rev. Rheumatol.* doi:10.1038/nrrheum.2012.85

Different Approaches to Treating Rare Myopathies

1. **Genetic based modifiers: gene therapy & editing; oligo approaches**
   - Delivery of the agent
   - Immune response to new protein
   - Requires new molecules for many approaches

2. **Muscle modifiers: various pathways to promote muscle growth**
   - Such as myostatin blockade agents & other pathways
   - Potentially increases immune response from more diseased tissue
   - Potentially accelerate regeneration/degeneration cycles

3. **Treat immuno-pathophysiology of rare genetically distinct myopathies**
   A. Steroids act as immuno-suppressants
      - Limited by side-effects
      - May have negative effects on muscle
      - Used in DMD, often with drug holidays

   B. Resolaris as natural homeostasis factor & immuno-modulator
      - Safety and tolerability looks promising
      - Potential activity in multiple myopathies with an immune component
      - Recent Phase 1b/2 is promising
      - Would like to see as next step:
        - Larger trial with placebo-control
        - Endpoints to augment MMT: QMT, Timed Function Tests, etc.

RESOLARIS CLINICAL PROGRAM – DATA UPDATE

SANJAY SHUKLA, MD, MS, CMO

DECEMBER 13, 2016

aTyr Pharma

Resolaris Clinical Program Summary

Trial	Indication(s)	Patients	Highest Dose	Design	Data Timing
002	Adult FSHD	3 dose cohorts (n=20 Total)	3mg/kg weekly	Placebo controlled, Double blinded; Interpatient Dose Escalation	Announced 1Q 2016
003	Early onset FSHD	Stage 1 (n=8)	3mg/kg weekly	Open-label, Intrapatient Dose Escalation	Interim-Results Announced Today
004	Adult LGMD2B, Adult FSHD	LGMD2B (n=10) FSHD (n=8)	3mg/kg biweekly	Open-label, Intrapatient Dose Escalation	Top-line Results Announced Today
005	Adult FSHD	Rollover from 002	3mg/kg weekly	Long-term Safety Extension	Updated Today
006	LGMD2B, FSHD, Early onset FSHD	Rollover from 003 & 004	3mg/kg weekly	Long-term Safety Extension	TBD

Adult LGMD2B and FSHD (004) Trial

Objective & Rationale

Objective:

- Evaluate the safety/tolerability of total weekly exposure of 6.0mg/kg in LGMD2B and FSHD
- Assess drug activity more proximal to dosing

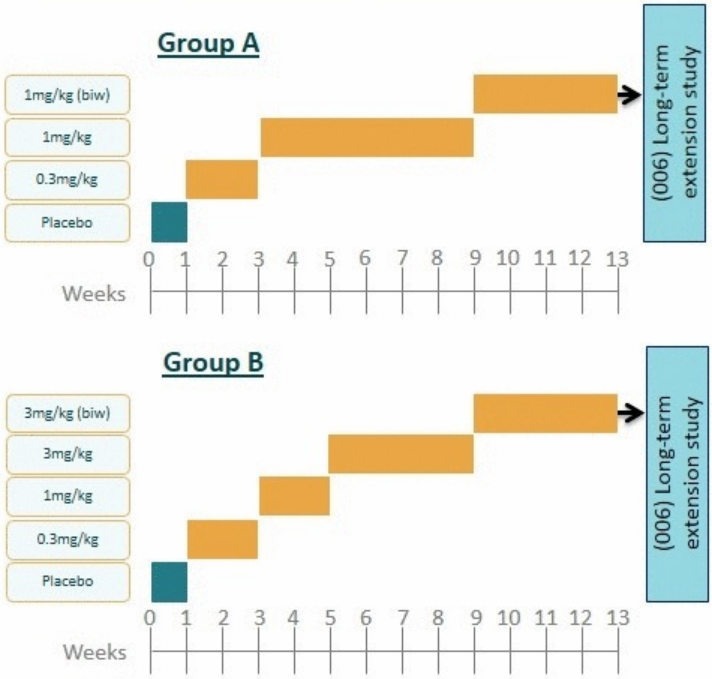
Rationale:

- To evaluate different dosing regimens

Study Design

- Open-label, intra-patient dose escalation
- Multiple sites in US & Europe
- N = 18 patients; enrollment complete
- **Group A:** 4 FSHD patients
- **Group B:** 4 FSHD patients / 10 LGMD2B patients
- 18-75 years of age
- Targeted MRI positive or circulatory markers*
  *(*in LGMD2B patients only)*

Dose Escalation



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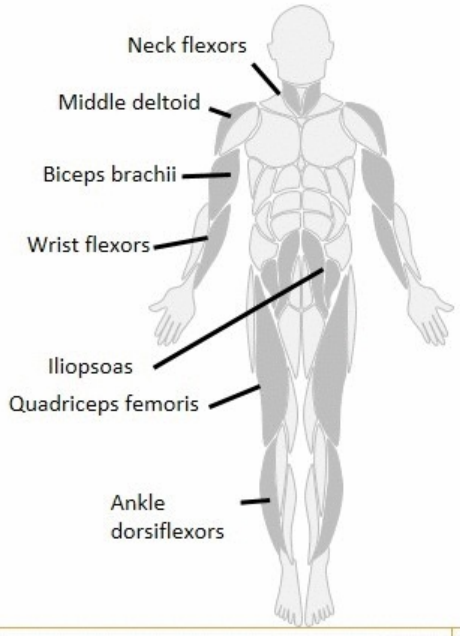
Demographics and Baseline Characteristics

Characteristic	Group A FSHD	Group B FSHD	Group B LBMD2B
Enrolled	4	4	10
Age (Mean years)	45.0	34.0	37.2
Median (Range)	45.0 (39, 51)	33.5 (33, 36)	33.5 (22, 62)
Male (number, %)	3, 75%	4, 100%	3, 30%
White (number, %)	4, 100%	4, 100%	9, 90%
BMI (kg/m^2), mean (SD)	23.38 (1.1)	24.83 (2.0)	27.67 (4.4)

Global Manual Muscle Testing

Muscle function/strength was formally assessed by investigators using Manual Muscle Testing (MMT)

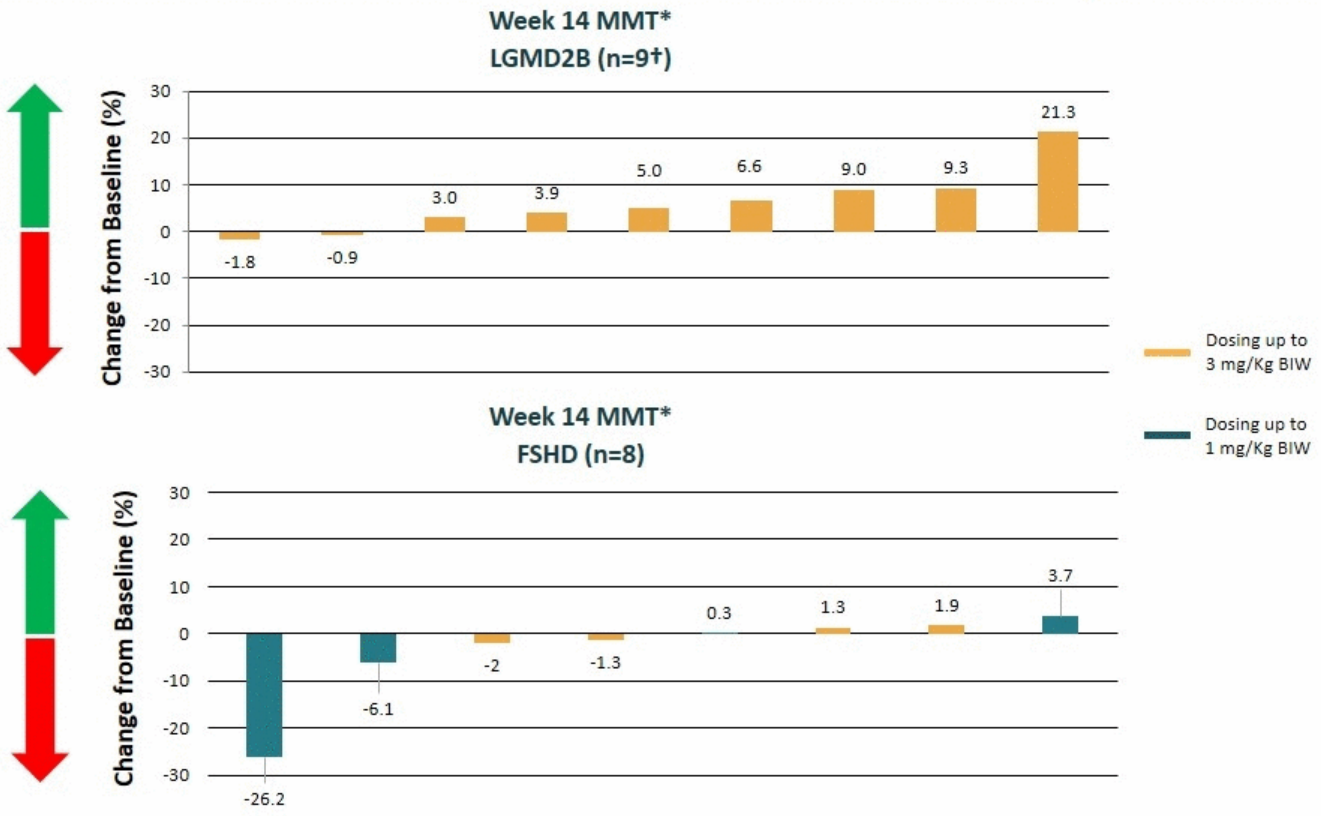
- 14 muscles evaluated at different time points in studies
- Muscles scored individually
- Composite score calculated
- Progression: lower scores
  - Negative change from baseline
- Improvement: higher scores
  - Positive change from baseline



On Back (not pictured):
Neck Extensors;
Trapezius;
Gluteus medialis;
Hamstrings;
Ankle plantar flexors;
Gluteus maximus

Light grey = untested muscles Dark grey = tested muscles

MMT Scores FSHD and LGMD2B (004 Trial)
Individual Patient Changes from Baseline (%)



1-week follow-up is earlier than week 14 for 2 early discontinuations

†One patient did not complete the MMT assessments due to being wheel chair bound

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Global Patient Reported Outcomes: INQoL

Individualized neuromuscular quality of life assessment

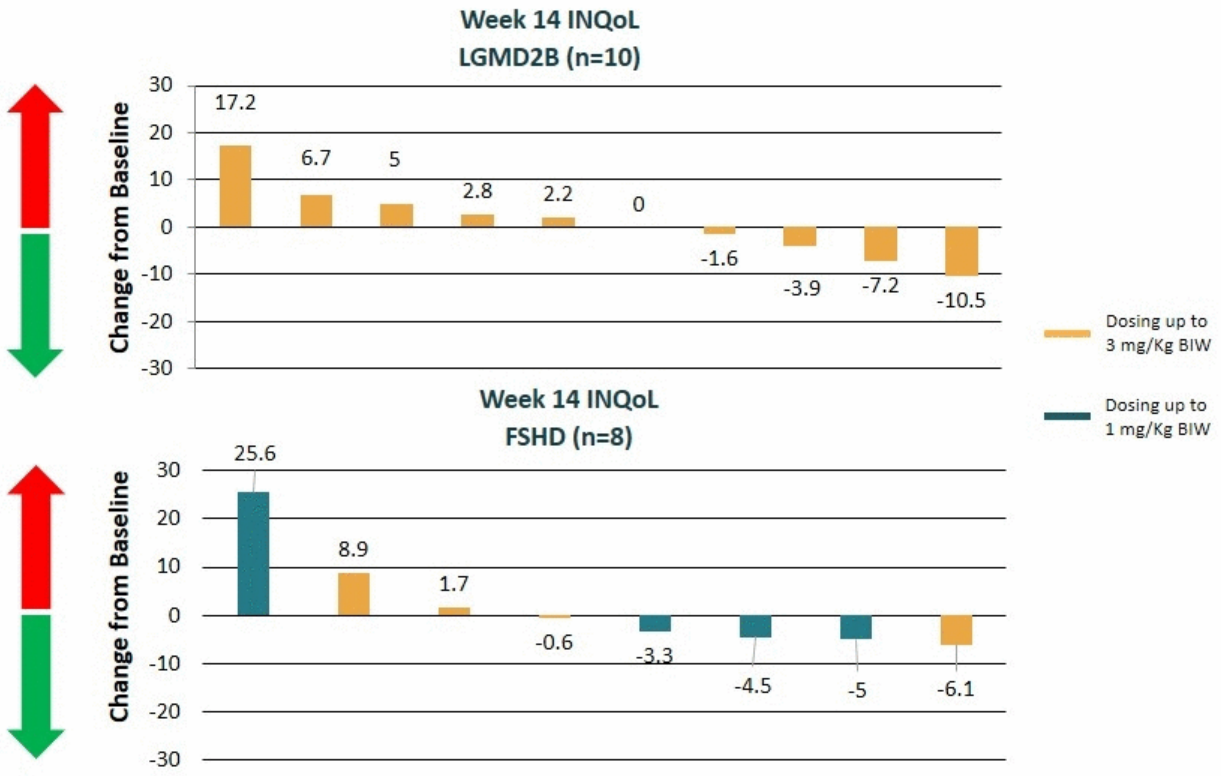
Validated Neuromuscular Assessment Tool*	• Global systematic assessment used in clinical studies and trials (to test for increased disease burden)
Self-Administered Questionnaire	• Questionnaire focuses on 4 dimensions: Symptoms, **Life Domains**, Treatment Effects, and Quality of Life • **Life Domains** comprised of 5 subsections: Activities, Independence, Social, Emotions, and Body Image
Improvement = <u>Decreased Scores</u> (Decreased Disease Burden)	• Overall INQoL score calculated from translating individual life domain scores into a 100 point scale

FDA: *"Generally, findings measured by a well-defined and reliable PRO instrument in appropriately designed investigations can be used to support a claim in medical product labeling if the claim is consistent with the instrument's documented measurement capability."***

** Vincent KA et al: Construction and Validation of a Quality of Life Questionnaire for Neuromuscular Disease (INQoL). Neurology 2007, 68:1051-1057.*

*** FDA Guidance for industry. Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims; 2009.*

Overall INQoL Score (004 Trial)
Individual Change from Baseline



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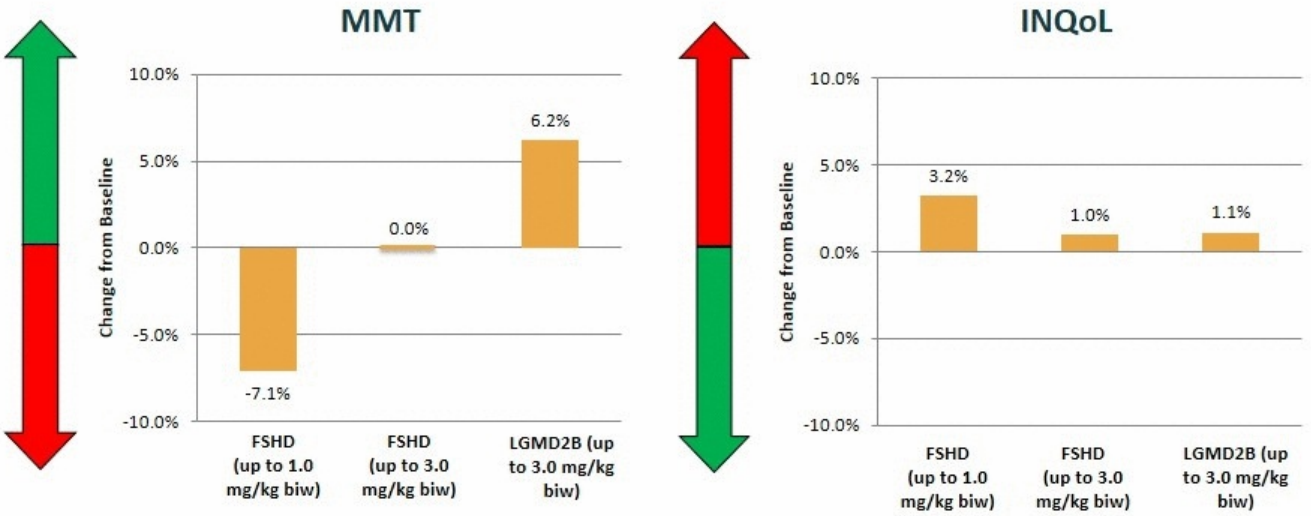
Summary 004 Trial Clinical Activity Assessments



Biomarker Evaluation 004 Trial

- 004 Trial included various exploratory biomarkers
- Exploratory biomarkers did not generally establish sufficiently high or consistent levels or robust signals across a sufficient number of patients to determine test article effects
  - Including targeted muscle T2 and STIR MRI; and various plasma proteins
- Targeted muscle T2/STIR MRI will not be prioritized as a biomarker in the near-term
- Peripheral cell based biomarkers will be assessed at a later date

Early Onset FSHD (003) Trial

Objective & Rationale

Objective:

- Evaluate the safety/tolerability in a potentially different indication Early Onset FSHD
- Assess drug activity in new patient population and with additional endpoints

Rationale:

- Investigate an often more severe form of disease, involves additional organ systems

Status:

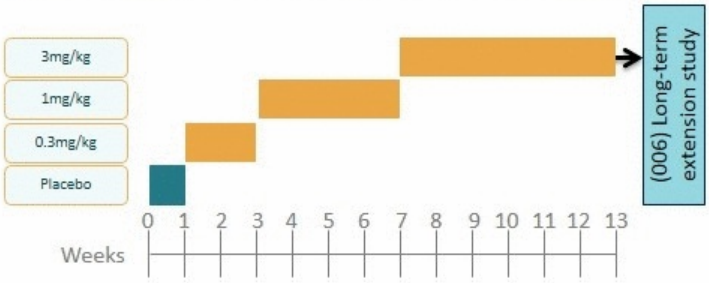
- Reported interim data analysis from the 4 patients today who completed treatment from Stage 1

Study Design

- Open-label, intra-patient dose escalation
- Multiple sites in US & Europe
- N = 16 patients
- **Stage 1:** 8 patients 16-25 years of age
- **Stage 2:** 8 patients 12-15 years of age

- Genetically confirmed diagnosis of FSHD and onset of symptoms prior to age 10

Dose Escalation



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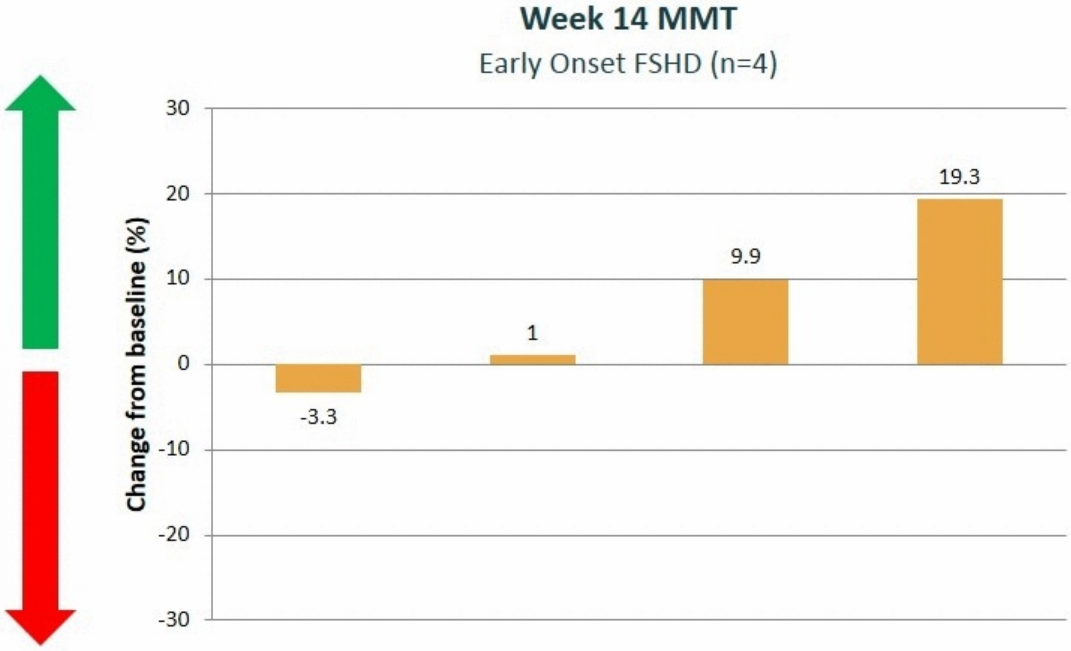
Overall MMT Score (003 Trial)

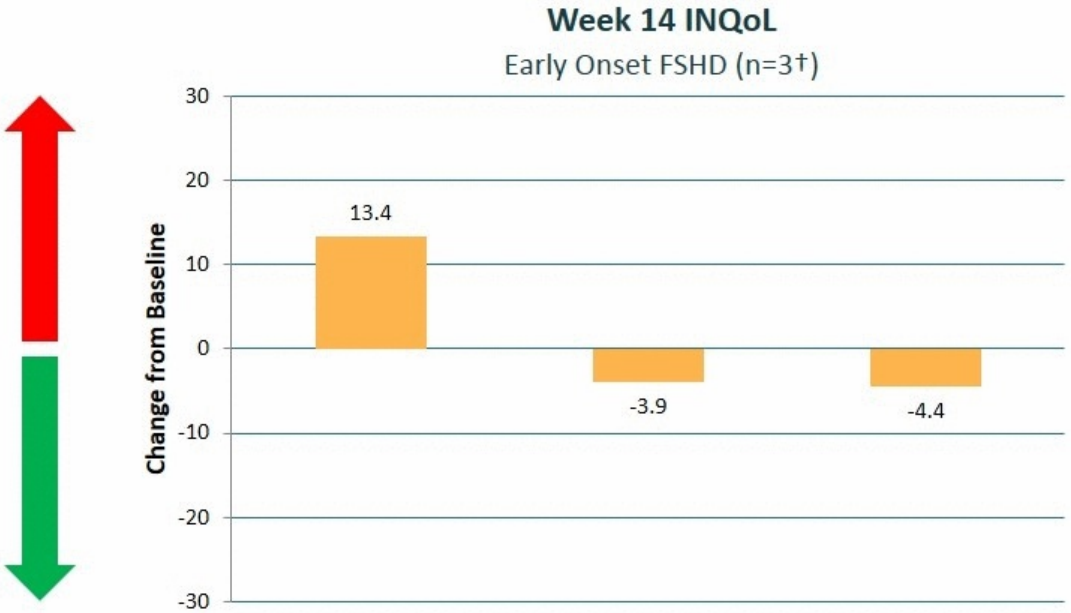
Individual Change from Baseline (%), Per Protocol Pop.

Early Onset FSHD



Overall INQoL Score (003 Trial)
Individual Change from Baseline, Per Protocol Pop.

Early Onset FSHD



† One patient did not complete INQoL at baseline

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Adult FSHD Long-Term Safety Extension (005) Trial

Study Design

- Patients receive weekly doses of 3.0 mg/kg
- Patients from Cohort 3 (3.0 mg/kg for 3 months) and Cohort 2 (1.0 mg/kg for 1 month) were eligible to roll-over to our long-term safety extension clinical trial
- Patients from Cohort 2 had greater than 12 months in between dosing (from end of 002 to initiation of 005)
- Patients from Cohort 3 were able to roll over directly into the 005 trial
- Open-label safety trial
- Initially 9 patients enrolled
- 3 sites in 3 countries

Study Objectives

Evaluate Safety and Tolerability:

- Build safety dossier for Resolaris

Evaluate Potential Activity Assessments:

1. Manual Muscle Test (MMT)
2. Individualized Neuromuscular Quality of Life (INQoL)
3. Biomarker Assessments

Clinical Findings

- 3 of the 9 patients enrolled from the adult FSHD (002) Trial are still receiving treatment
- Of the 4 patients who received at least 6 months of therapy, there were no significant trends in worsening or improvement in either MMT or INQoL scores

Safety & Tolerability Overview: 003, 004 & 005

As of December 1, 2016, 44 patients have received Resolaris, across all trials (including 002, 003, 004, and 005), for a total drug exposure of 149 patient months

Resolaris demonstrated a favorable safety profile and was generally well-tolerated across all doses tested in:

- ✓ Adult FSHD, Early onset FSHD (age range 16 to 20), and Adult LGMD2B
- ✓ Long-term exposure in adult FSHD patients (4 patients on drug ≥6 months)

No Serious Adverse Events (SAE) or deaths were reported

- ✓ All Adverse Events (AE) were in general mild or moderate in intensity
- ✓ No notable differences in AEs between adult FSHD, adult LGMD2B and early onset FSHD patients
- ✓ There were no dose limiting changes in lab parameters, vital signs or pulmonary tests

Protocol Discontinuations & Related Changes Going Forward

Protocol related discontinuations:

- Discontinued with a single IRR*(4 FSHD/1 LGMD): all IRRs mild to moderate, transient
- If Jo-1 Ab unit levels reach cut-off (5 FSHD): without associated clinical symptoms
- One LGMD patient discontinued from the 004 Trial for non-drug related reasons

- After changing the infusion protocol to a 90-minute infusion, 3 of 31 patients 9.1% experienced IRRs (previously the rate was 16.7% with an infusion rate of 30 minutes)

- Discontinuation rate in the 003/004/005 Trials under all protocols is 11 out of 35 patients (31%)

- Low level anti-drug antibody (ADA) assay signals 19/35 (54%; 13 FSHD and 6 LGMD) without associated clinical symptoms

Potential Safety & Tolerability Related Protocol Changes Going Forward:

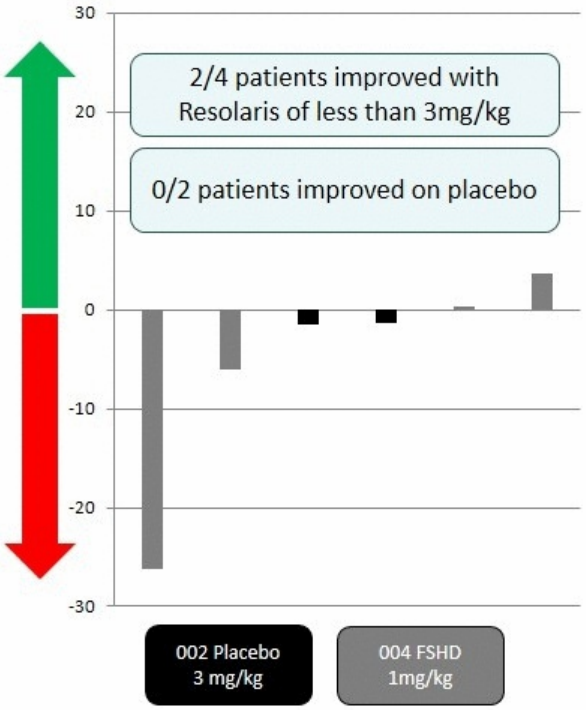
- Potential for pre-medicating patients
- Potential to continue dosing depending on the nature of the IRR
- Raising threshold for Jo-1 Levels above 1.5 U/mL (current cut off)

**Infusion Related Reaction*

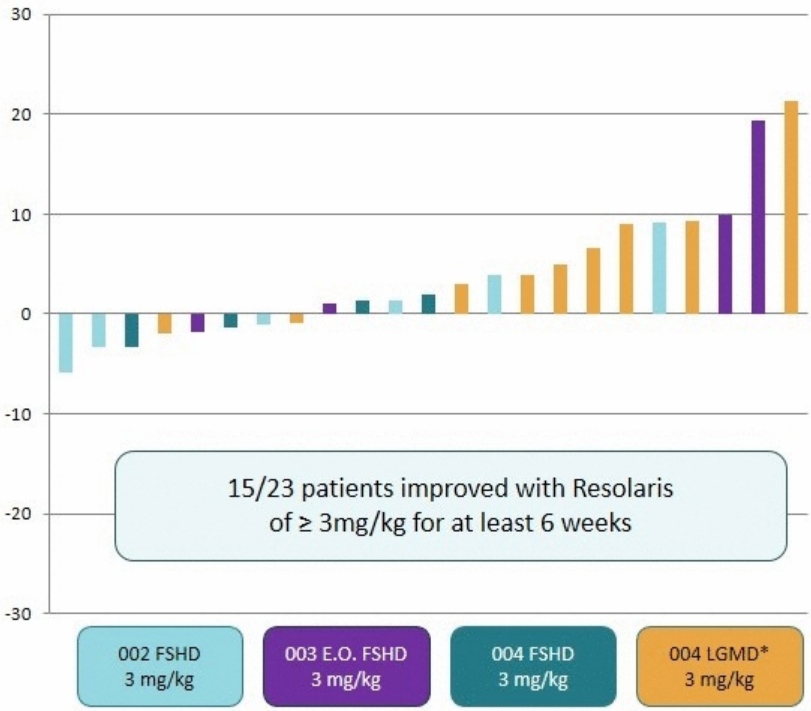
Overall MMT: FSHD, LGMD2B & Placebo

Change from baseline at week 14

Individual Patient MMT Change Week 14
FSHD & LGMD Patients Taking Placebo or Less Than 3mg/kg (002, 004 Trials)



Individual Patient MMT Change Week 14
FSHD & LGMD Patients Taking ≥ 3mg/kg for at least 6 weeks (002, 003, 004 Trials)



**One patient in 004 Trial did not have an MMT measurement due to being wheelchair bound*

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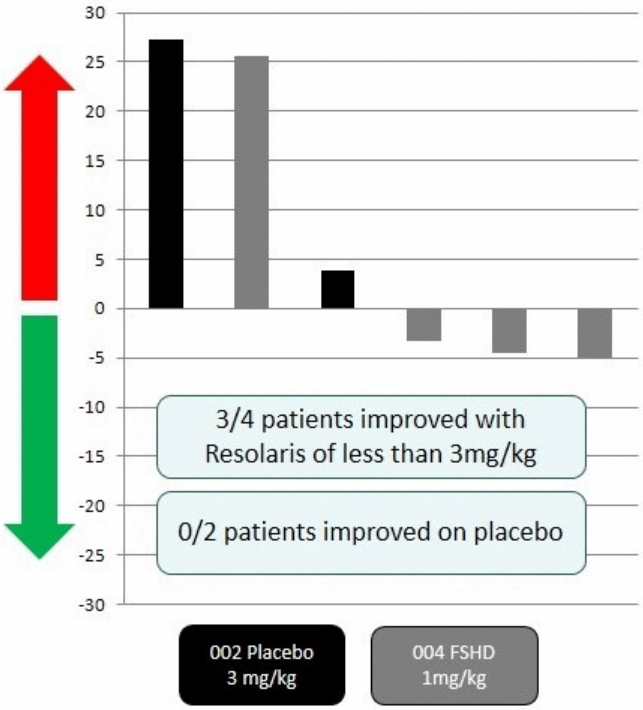
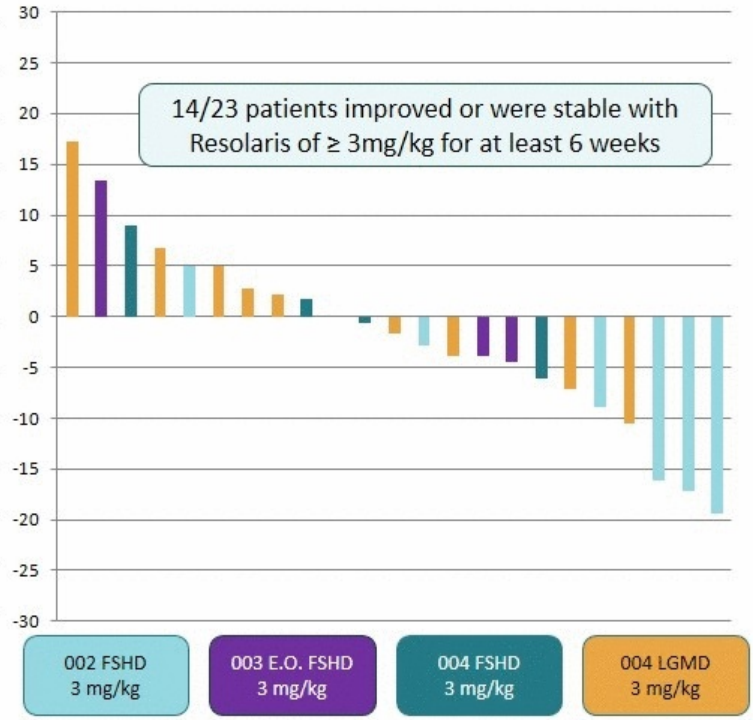
Overall INQoL: FSHD, LGMD2B & Placebo

Change from baseline at week 14

Individual Patient INQoL Change Week 14
FSHD & LGMD Patients Taking Placebo or Less Than 3mg/kg (002, 004 Trials)



Individual Patient INQoL Change Week 14
FSHD & LGMD Patients Taking ≥ 3mg/kg for at least 6 weeks (002, 003, 004 Trials)



RESOLARIS DISCUSSION AND NEXT STEPS

JOHN MENDLEIN, PHD, CHIEF EXECUTIVE OFFICER AT ATYR PHARMA

DECEMBER 13, 2016

aTyr Pharma

2017 Rationale and Plan

Emphasis on Single RMIC Indication in 2017, dependent on:

- Leverage safety and activity data reviewed today
- Natural history & disease progression; favor homogeneous phenotype
- Ability to examine MOA with mechanistic assay in patients
  - Peripheral cell and or biopsy samples
  - Ideally, ability to connect genotype to immune cell

Advancement of iMod.Fc into Humans:

- Program for rare lung diseases with an immune component (i.e. interstitial lung diseases)

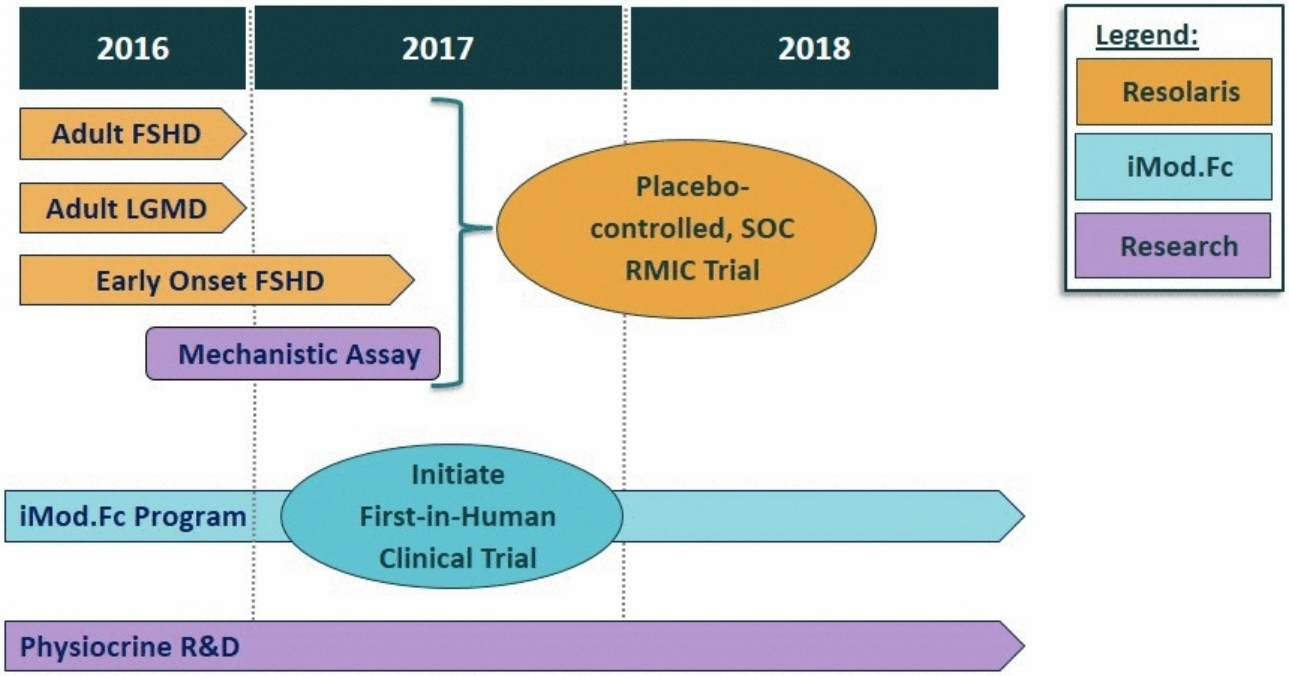
Advancement of Preclinical Pipeline:

- Potential for novel applications of Physiocrines

Cost of Capital Considerations for Pipeline Advancement:

- $80.9M in cash, cash equivalents, and investments as of 9/30/16; runway into 3Q 2018
- Partnering one or more of our programs to enhance the advancement of the pipeline

Next Steps: Potential Clinical Development Strategy*



**Clinical advancement will be linked with the development of a mechanistic assay and prudent cost of capital considerations*

QUESTIONS?

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APPENDIX: REFERENCE PAPERS

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Anti-Dystrophin T Cell Responses in Duchenne Muscular Dystrophy: Prevalence and a Glucocorticoid Treatment Effect

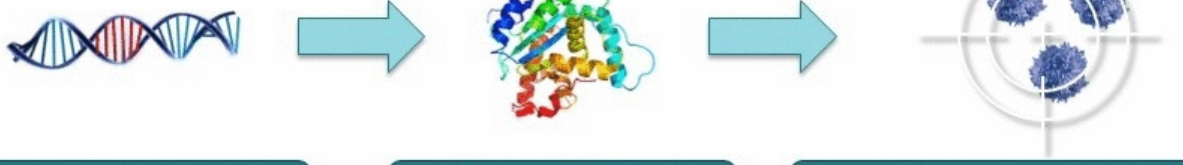
Kevin M. Flanigan,[1*] Katie Campbell,[2] Laurence Viollet,[1] Wei Wang,[3] Ana Maria Gomez,[1] Christopher M. Walker,[2] and Jerry R. Mendell[1*]

Abstract

Duchenne muscular dystrophy (DMD) typically occurs as a result of truncating mutations in the *DMD* gene that result in a lack of expression of the dystrophin protein in muscle fibers. Various therapies under development are directed toward restoring dystrophin expression at the subsarcolemmal membrane, including gene transfer. In a trial of intramuscular adeno-associated virus (AAV)-mediated delivery of a therapeutic minidystrophin construct, we identified in two of six subjects the presence of a population of T cells that had been primed to recognize dystrophin epitopes before transgene delivery. As the presence of preexisting T cell immunity may have a significant effect on the success of therapeutic approaches for restoring dystrophin, we sought to determine the prevalence of such immunity within a DMD cohort from our Muscular Dystrophy Association clinic. Dystrophin-specific T cell immunity was evaluated in subjects with DMD who were either receiving the glucocorticoid steroid prednisone ($n=24$) or deflazacort ($n=29$), or who were not receiving steroids ($n=17$), as well as from normal age-matched control subjects ($n=21$). We demonstrate that increasing age correlates with an increased risk for the presence of anti-dystrophin T cell immunity, and that treatment with either corticosteroid decreases risk compared with no treatment, suggesting that steroid therapy in part may derive some of its benefit through modulation of T cell responses. The frequency of dystrophin-specific T cells detected by enzyme-linked immunospot assay was lower in subjects treated with deflazacort versus prednisone, despite similar overall corticosteroid exposure, suggesting that the effects of the two corticosteroids may not be identical in patients with DMD. T cells targeted epitopes upstream and downstream of the dystrophin gene mutation and involved the $CD4^+$ helper and/or $CD8^+$ cytotoxic subsets. Our data confirm the presence of preexisting circulating T cell immunity to dystrophin in a sizable proportion of patients with DMD, and emphasize the need to consider this in the design and interpretation of clinical gene therapy trials.

Connecting Genotype to Immune Cell Phenotype in Duchenne Muscular Dystrophy Patients

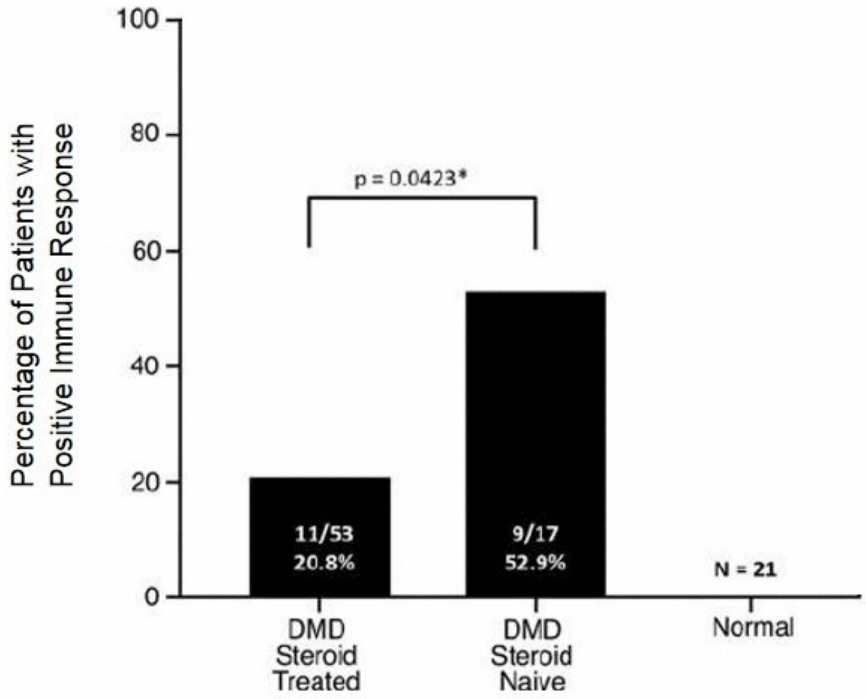
Disruption of Homeostasis
(untapped therapeutic intervention point)



Genetic Mutation	Etiology of Aberrant Protein	Localized T Cell invasion & proliferation
DMD Patients: • Splice exon 12 • Del ex 45 • Del ex 46 – 50 • Del ex 49 – 54 • Nonsense ex 59 • Nonsense ex 69	**Locations of Immune Response:** • Exons 1 – 9 • Exons 17 – 26 • Exons 42 – 50 • Exons 50 – 59 • Exons 59 – 69 • Exons 70 - 79	**T Cell Phenotype:** CD4 and/or CD8

Frisullo et al., J. Clin. Immunol., 2011 *Gallardo et al. Neurology, 2001*
Flanigan et al. Human Gene Therapy, 2013

Steroids Suppress Dystrophin Specific Peripheral T Cell Response in Duchenne Muscular Dystrophy



Flanigan et al, Human Gene Therapy, 2013

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Treatment of dysferlinopathy with deflazacort: a double-blind, placebo-controlled clinical trial

Maggie C Walter[1*†], Peter Reilich[1†], Simone Thiele[1], Joachim Schessl[1], Herbert Schreiber[2], Karlheinz Reiners[3], Wolfram Kress[4], Clemens Müller-Reible[4], Matthias Vorgerd[5], Peter Urban[6], Bertold Schrank[7], Marcus Deschauer[8], Beate Schlotter-Weigel[1], Ralf Kohnen[9] and Hanns Lochmüller[10]

Abstract

Background: Dysferlinopathies are autosomal recessive disorders caused by mutations in the dysferlin (*DYSF*) gene encoding the dysferlin protein. DYSF mutations lead to a wide range of muscular phenotypes, with the most prominent being Miyoshi myopathy (MM) and limb girdle muscular dystrophy type 2B (LGMD2B).

Methods: We assessed the one-year-natural course of dysferlinopathy, and the safety and efficacy of deflazacort treatment in a double-blind, placebo-controlled cross-over trial. After one year of natural course without intervention, 25 patients with genetically defined dysferlinopathy were randomized to receive deflazacort and placebo for six months each (1 mg/kg/day in month one, 1 mg/kg every 2nd day during months two to six) in one of two treatment sequences.

Results: During one year of natural course, muscle strength declined about 2% as measured by CIDD (Clinical Investigation of Duchenne Dystrophy) score, and 76 Newton as measured by hand-held dynamometry. Deflazacort did not improve muscle strength. In contrast, there is a trend of worsening muscle strength under deflazacort treatment, which recovers after discontinuation of the study drug. During deflazacort treatment, patients showed a broad spectrum of steroid side effects.

Conclusion: Deflazacort is not an effective therapy for dysferlinopathies, and off-label use is not warranted. This is an important finding, since steroid treatment should not be administered in patients with dysferlinopathy, who may be often misdiagnosed as polymyositis.

Trial registration: This clinical trial was registered at www.ClincalTrials.gov, identifier: NCT00527228, and was always freely accessible to the public.

Keywords: Limb girdle muscular dystrophy (LGMD), Dysferlinopathy, Therapy, Deflazacort, Muscle strength, Steroids

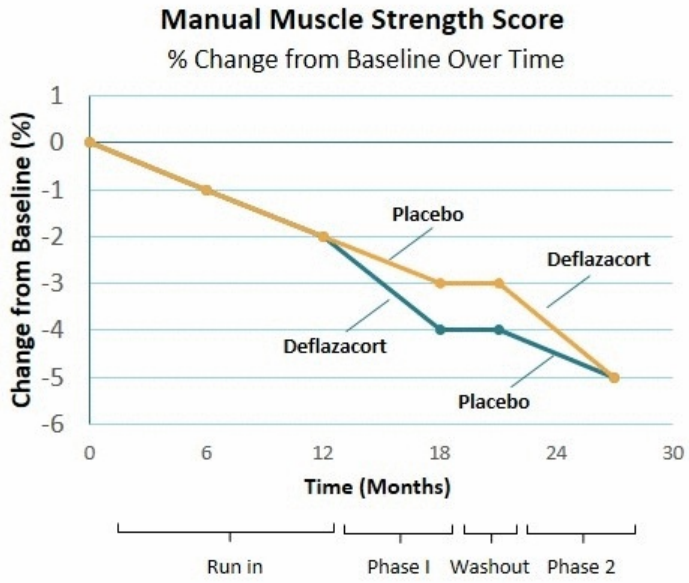
Manual Muscle Testing by CIDD

Clinical Investigation of Duchenne Dystrophy (CIDD)

- Primary outcome measures were manual muscle strength assessed bilaterally by the modified Medical Research Council Scales (MRC) CIDD (Clinical Investigation of Duchenne Dystrophy) score, graded from 0 (worst) to 10 (best)
  - http://www.researchrom.com/masterlist/view/4
- Testing was performed by two experienced neurologists after sufficient training with clinical trial procedures
- Inter-rater and intra-rater variability was assessed prior to the clinical trial, and reassessed 12-monthly during the trial period on the enrolled dysferlinopathy patients

Walter et al, Orphanet Journal of Rare Diseases, 2013

LGMD Patients Manual Muscle Strength* Decline at Double the Rate on Deflazacort vs Placebo



Treatment with Deflazacort was for 6 months in each arm
Single site, placebo controlled, cross over design (n=25)

**Manual muscle strength assessed bilaterally by the modified Medical Research Council Scales (MRC) CIDD (Clinical Investigation of Duchenne Dystrophy) score, graded from 0 (worst) to 10 (best)*

Walter et al, Orphanet Journal of Rare Diseases, 2013

Exhibit 99.3

RESOLARIS CLINICAL PROGRAM – DATA UPDATE

DECEMBER 13, 2016

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Resolaris Clinical Program Summary

Trial	Indication(s)	Patients	Highest Dose	Design	Data Timing
002	Adult FSHD	3 dose cohorts (n=20 Total)	3mg/kg weekly	Placebo controlled, Double blinded; Interpatient Dose Escalation	Announced 1Q 2016
003	Early onset FSHD	Stage 1 (n=8)	3mg/kg weekly	Open-label, Intrapatient Dose Escalation	Interim-Results Announced Today
004	Adult LGMD2B, Adult FSHD	LGMD2B (n=10) FSHD (n=8)	3mg/kg biweekly	Open-label, Intrapatient Dose Escalation	Top-line Results Announced Today
005	Adult FSHD	Rollover from 002	3mg/kg weekly	Long-term Safety Extension	Updated Today
006	LGMD2B, FSHD, Early onset FSHD	Rollover from 003 & 004	3mg/kg weekly	Long-term Safety Extension	TBD

Adult LGMD2B and FSHD (004) Trial

Objective & Rationale

Objective:

- Evaluate the safety/tolerability of total weekly exposure of 6.0mg/kg in LGMD2B and FSHD
- Assess drug activity more proximal to dosing

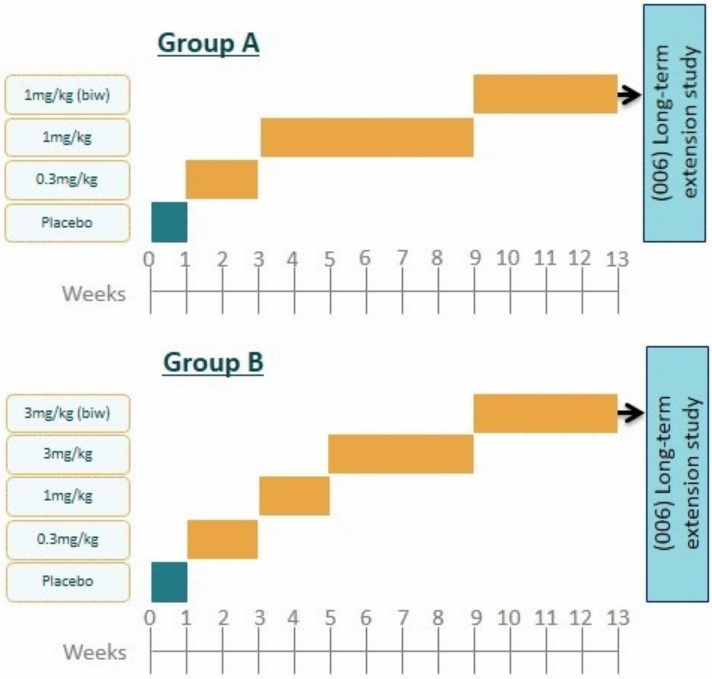
Rationale:

- To evaluate different dosing regimens

Study Design

- Open-label, intra-patient dose escalation
- Multiple sites in US & Europe
- N = 18 patients; enrollment complete
- **Group A:** 4 FSHD patients
- **Group B:** 4 FSHD patients / 10 LGMD2B patients
- 18-75 years of age
- Targeted MRI positive or circulatory markers*
  *(*in LGMD2B patients only)*

Dose Escalation



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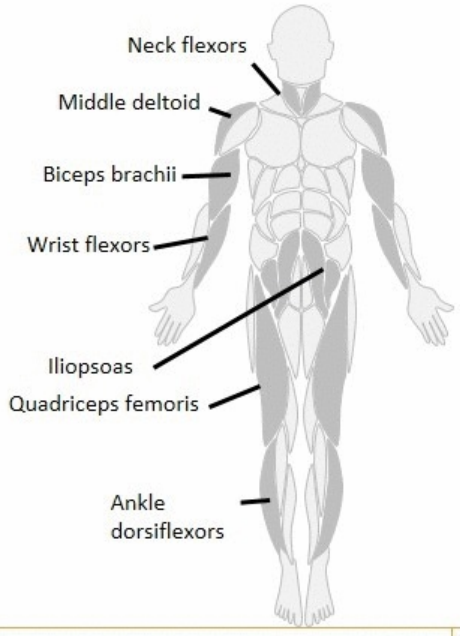
Demographics and Baseline Characteristics

Characteristic	Group A FSHD	Group B FSHD	Group B LBMD2B
Enrolled	4	4	10
Age (Mean years)	45.0	34.0	37.2
Median (Range)	45.0 (39, 51)	33.5 (33, 36)	33.5 (22, 62)
Male (number, %)	3, 75%	4, 100%	3, 30%
White (number, %)	4, 100%	4, 100%	9, 90%
BMI (kg/m^2), mean (SD)	23.38 (1.1)	24.83 (2.0)	27.67 (4.4)

Global Manual Muscle Testing

Muscle function/strength was formally assessed by investigators using Manual Muscle Testing (MMT)

- 14 muscles evaluated at different time points in studies
- Muscles scored individually
- Composite score calculated
- Progression: lower scores
  - Negative change from baseline
- Improvement: higher scores
  - Positive change from baseline



On Back (not pictured):
Neck Extensors;
Trapezius;
Gluteus medialis;
Hamstrings;
Ankle plantar flexors;
Gluteus maximus

Light grey = untested muscles Dark grey = tested muscles

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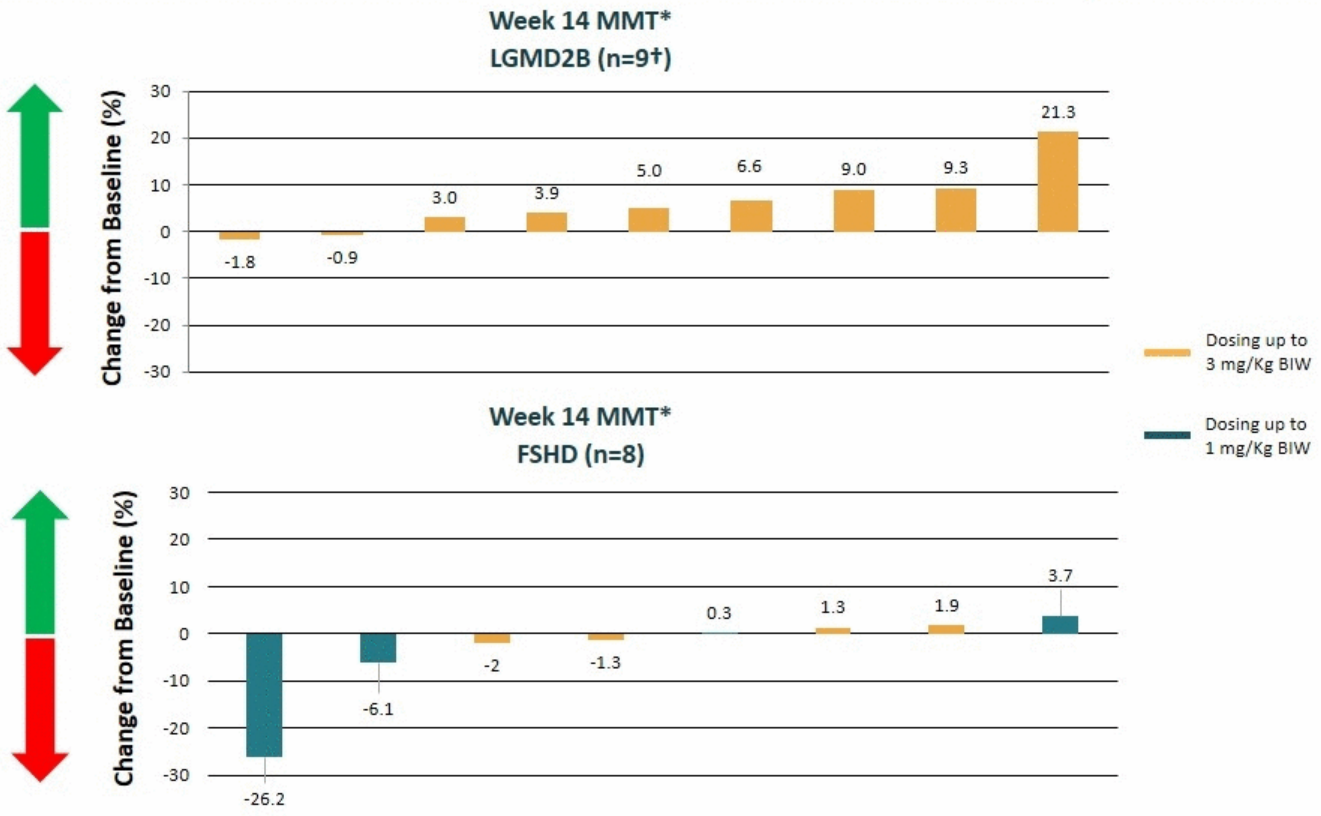
MMT Scores FSHD and LGMD2B (004 Trial)
Individual Patient Changes from Baseline (%)



**1-week follow-up is earlier than week 14 for 2 early discontinuations*

†One patient did not complete the MMT assessments due to being wheel chair bound

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Global Patient Reported Outcomes: INQoL

Individualized neuromuscular quality of life assessment

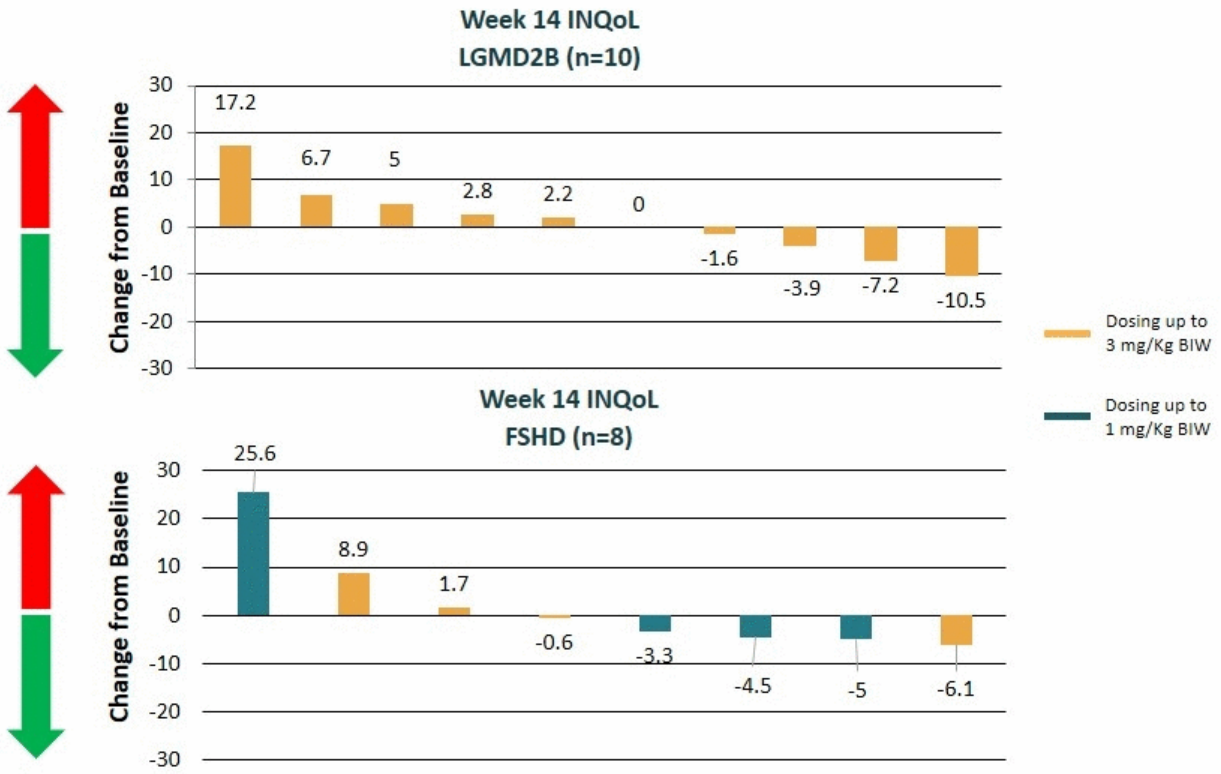
Validated Neuromuscular Assessment Tool*	• Global systematic assessment used in clinical studies and trials (to test for increased disease burden)
Self-Administered Questionnaire	• Questionnaire focuses on 4 dimensions: Symptoms, **Life Domains**, Treatment Effects, and Quality of Life • **Life Domains** comprised of 5 subsections: Activities, Independence, Social, Emotions, and Body Image
Improvement = <u>Decreased Scores</u> (Decreased Disease Burden)	• Overall INQoL score calculated from translating individual life domain scores into a 100 point scale

FDA: *"Generally, findings measured by a well-defined and reliable PRO instrument in appropriately designed investigations can be used to support a claim in medical product labeling if the claim is consistent with the instrument's documented measurement capability."***

** Vincent KA et al: Construction and Validation of a Quality of Life Questionnaire for Neuromuscular Disease (INQoL). Neurology 2007, 68:1051-1057.*

*** FDA Guidance for industry. Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims; 2009.*

Overall INQoL Score (004 Trial)
Individual Change from Baseline



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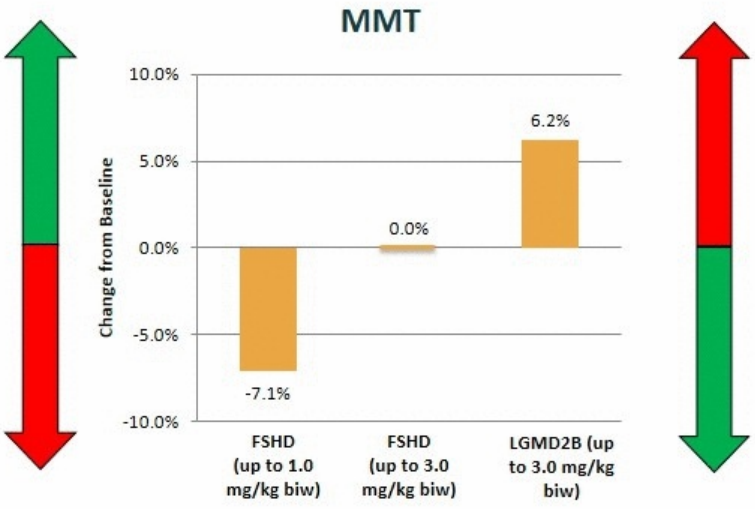
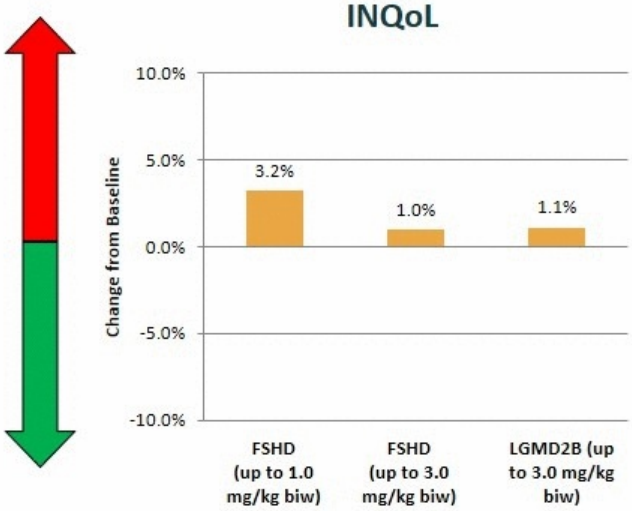
Summary 004 Trial Clinical Activity Assessments





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Biomarker Evaluation 004 Trial

- 004 Trial included various exploratory biomarkers
- Exploratory biomarkers did not generally establish sufficiently high or consistent levels or robust signals across a sufficient number of patients to determine test article effects
  - Including targeted muscle T2 and STIR MRI; and various plasma proteins
- Targeted muscle T2/STIR MRI will not be prioritized as a biomarker in the near-term
- Peripheral cell based biomarkers will be assessed at a later date

Early Onset FSHD (003) Trial

Objective & Rationale

Objective:

- Evaluate the safety/tolerability in a potentially different indication Early Onset FSHD
- Assess drug activity in new patient population and with additional endpoints

Rationale:

- Investigate an often more severe form of disease, involves additional organ systems

Status:

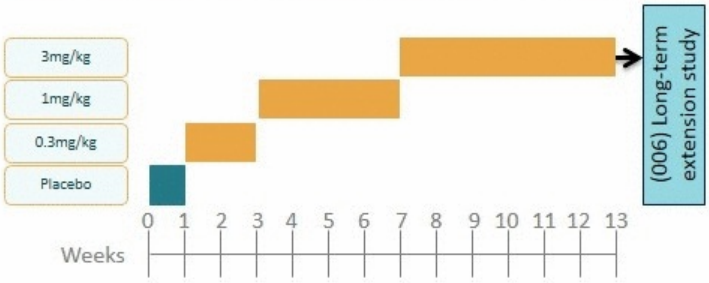
- Reported interim data analysis from the 4 patients today who completed treatment from Stage 1

Study Design

- Open-label, intra-patient dose escalation
- Multiple sites in US & Europe
- N = 16 patients
- **Stage 1:** 8 patients 16-25 years of age
- **Stage 2:** 8 patients 12-15 years of age

- Genetically confirmed diagnosis of FSHD and onset of symptoms prior to age 10

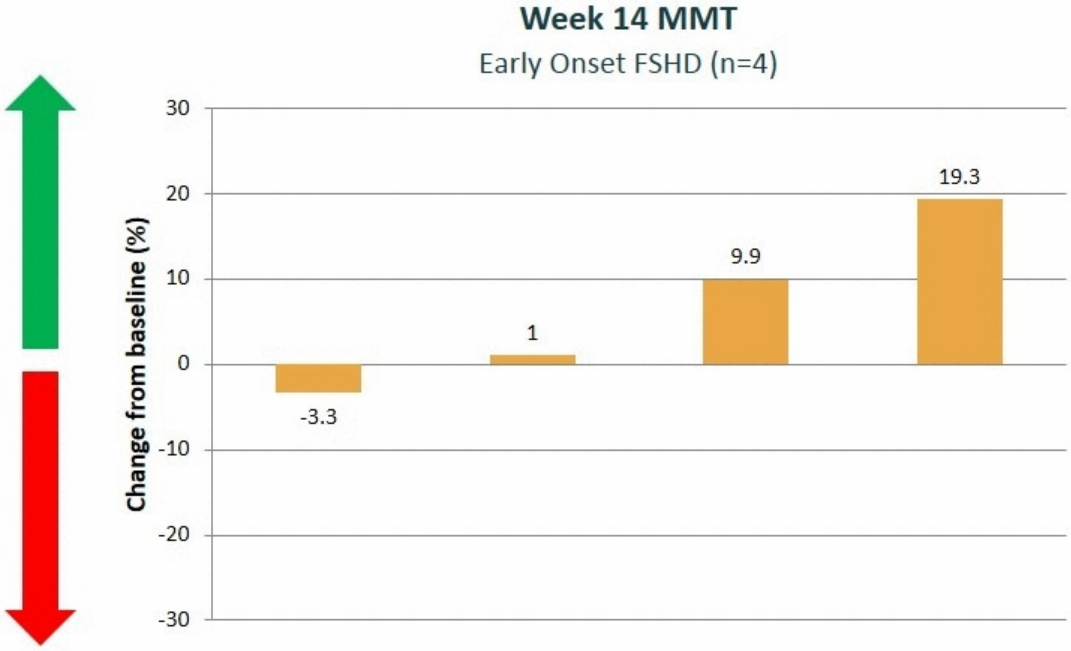
Dose Escalation



Overall MMT Score (003 Trial)

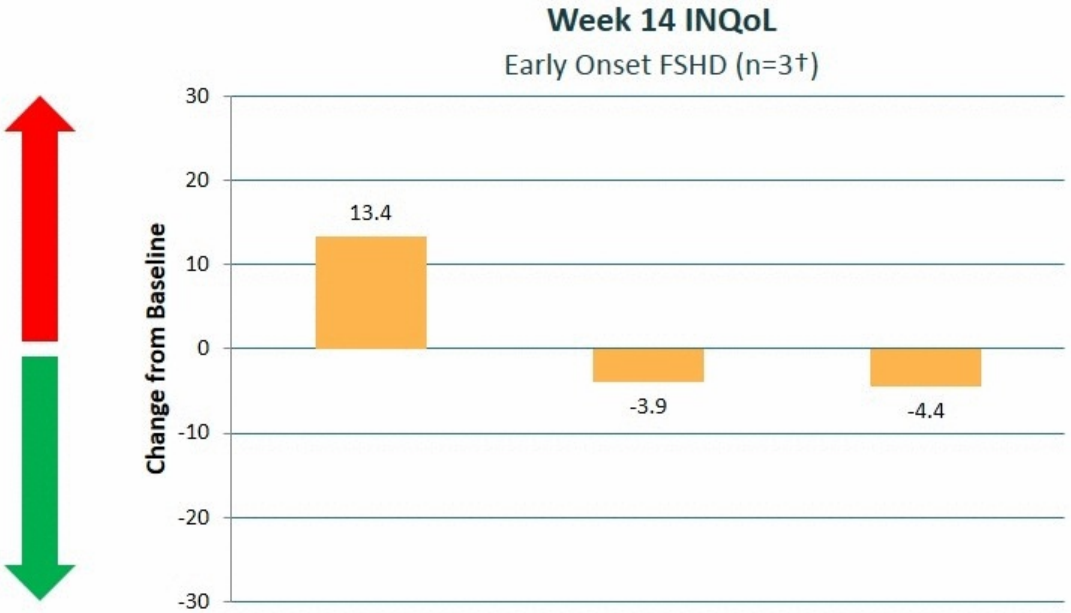
Individual Change from Baseline (%), Per Protocol Pop.

Early Onset FSHD



Overall INQoL Score (003 Trial)
Individual Change from Baseline, Per Protocol Pop.

Early Onset FSHD



† One patient did not complete INQoL at baseline

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Adult FSHD Long-Term Safety Extension (005) Trial

Study Design

- Patients receive weekly doses of 3.0 mg/kg
- Patients from Cohort 3 (3.0 mg/kg for 3 months) and Cohort 2 (1.0 mg/kg for 1 month) were eligible to roll-over to our long-term safety extension clinical trial
- Patients from Cohort 2 had greater than 12 months in between dosing (from end of 002 to initiation of 005)
- Patients from Cohort 3 were able to roll over directly into the 005 trial
- Open-label safety trial
- Initially 9 patients enrolled
- 3 sites in 3 countries

Study Objectives

Evaluate Safety and Tolerability:

- Build safety dossier for Resolaris

Evaluate Potential Activity Assessments:

1. Manual Muscle Test (MMT)
2. Individualized Neuromuscular Quality of Life (INQoL)
3. Biomarker Assessments

Clinical Findings

- 3 of the 9 patients enrolled from the adult FSHD (002) Trial are still receiving treatment
- Of the 4 patients who received at least 6 months of therapy, there were no significant trends in worsening or improvement in either MMT or INQoL scores

Safety & Tolerability Overview: 003, 004 & 005

As of December 1, 2016, 44 patients have received Resolaris, across all trials (including 002, 003, 004, and 005), for a total drug exposure of 149 patient months

Resolaris demonstrated a favorable safety profile and was generally well-tolerated across all doses tested in:

- ✓ Adult FSHD, Early onset FSHD (age range 16 to 20), and Adult LGMD2B
- ✓ Long-term exposure in adult FSHD patients (4 patients on drug ≥6 months)

No Serious Adverse Events (SAE) or deaths were reported

- ✓ All Adverse Events (AE) were in general mild or moderate in intensity
- ✓ No notable differences in AEs between adult FSHD, adult LGMD2B and early onset FSHD patients
- ✓ There were no dose limiting changes in lab parameters, vital signs or pulmonary tests

Protocol Discontinuations & Related Changes Going Forward

Protocol related discontinuations:

- Discontinued with a single IRR*(4 FSHD/1 LGMD): all IRRs mild to moderate, transient
- If Jo-1 Ab unit levels reach cut-off (5 FSHD): without associated clinical symptoms
- One LGMD patient discontinued from the 004 Trial for non-drug related reasons

- After changing the infusion protocol to a 90-minute infusion, 3 of 31 patients 9.1% experienced IRRs (previously the rate was 16.7% with an infusion rate of 30 minutes)

- Discontinuation rate in the 003/004/005 Trials under all protocols is 11 out of 35 patients (31%)

- Low level anti-drug antibody (ADA) assay signals 19/35 (54%; 13 FSHD and 6 LGMD) without associated clinical symptoms

Potential Safety & Tolerability Related Protocol Changes Going Forward:

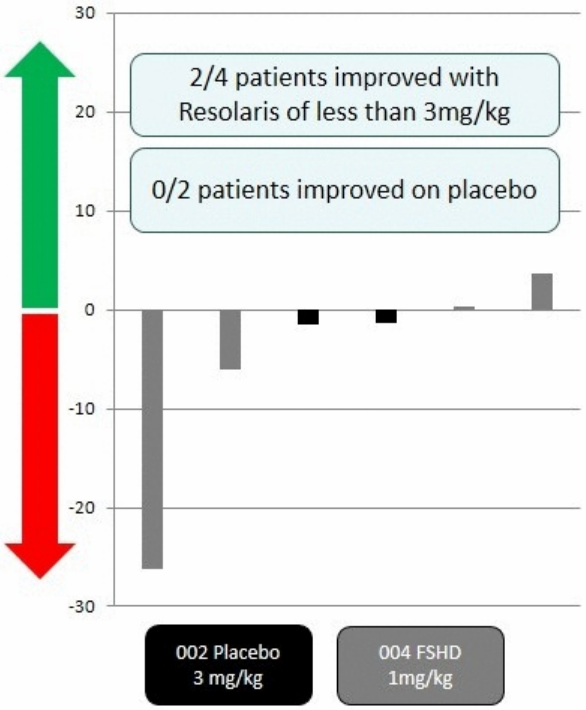
- Potential for pre-medicating patients
- Potential to continue dosing depending on the nature of the IRR
- Raising threshold for Jo-1 Levels above 1.5 U/mL (current cut off)

**Infusion Related Reaction*

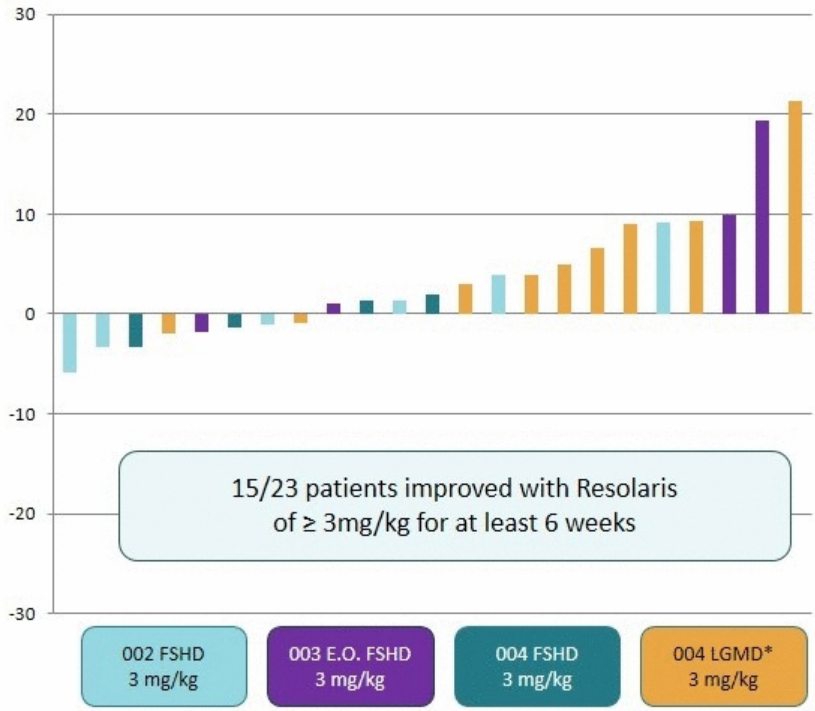
Overall MMT: FSHD, LGMD2B & Placebo

Change from baseline at week 14

Individual Patient MMT Change Week 14
FSHD & LGMD Patients Taking Placebo or Less Than 3mg/kg (002, 004 Trials)



Individual Patient MMT Change Week 14
FSHD & LGMD Patients Taking ≥ 3mg/kg for at least 6 weeks (002, 003, 004 Trials)

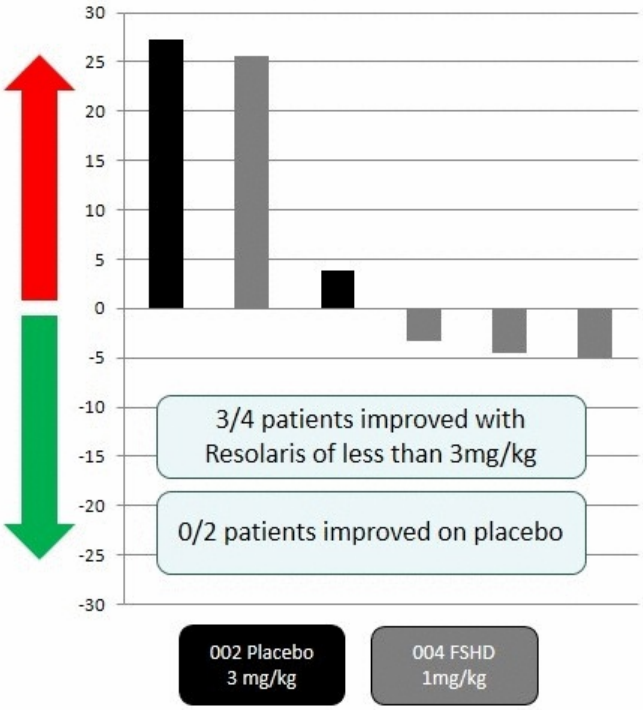


**One patient in 004 Trial did not have an MMT measurement due to being wheelchair bound*

Overall INQoL: FSHD, LGMD2B & Placebo

Change from baseline at week 14

Individual Patient INQoL Change Week 14
FSHD & LGMD Patients Taking Placebo or Less Than 3mg/kg (002, 004 Trials)



Individual Patient INQoL Change Week 14
FSHD & LGMD Patients Taking ≥ 3mg/kg for at least 6 weeks (002, 003, 004 Trials)