

Resolve Therapeutics Announces RSLV-132 Significantly Reduces Fatigue in Phase II Study of Patients with Sjögren's Syndrome

-- The Company also received confirmation of acceptance for its proposed endpoint for Phase III clinical trials from the U.S. FDA --

Madrid, Spain – June 13, 2019 – Resolve Therapeutics, an immuno-therapeutics company developing first-in-class targeted therapies for underserved autoimmune diseases, today announced positive results from the Phase II study of RSLV-132 (Study 132-04), an investigational treatment for primary Sjögren's syndrome (pSS). The study met its primary endpoint of changes in blood cell gene expression or serum protein levels indicative of reduced inflammation. Clinical efficacy measures also demonstrated that RSLV-132 improved symptoms of fatigue as compared to placebo, and was safe and well-tolerated. These data were presented at an oral session, and were also included in the Clinical Highlights Session, at the 2019 European League Against Rheumatism (EULAR) European Congress of Rheumatology in Madrid, Spain.

"Fatigue is the primary and most critical symptom contributing to poor health, diminished quality-of-life, and loss of work productivity in patients with pSS," said Dr. Fai Ng, Professor of Rheumatology, Newcastle University, UK, and principle investigator of Study 132-04. "These results are an important scientific advancement and for the first time, we see an investigational therapy making a demonstrated, positive impact on fatigue, which can be confirmed using the patient outcomes reports."

Study 132-04 was a double-blind, placebo-controlled study of 10 mg/kg RSLV-132 in patients with pSS (n=28), and was designed to explore the clinical efficacy of RSLV-132 in improving the symptoms associated with pSS, particularly fatigue. Outcomes were measured by the ESSPRI scale (EULAR Sjögren's Syndrome Patient Reported Index), which is a validated clinical outcome measure that patients use to report the fatigue, pain, and dryness associated with Sjögren's syndrome, the FACIT (Functional Assessment of Chronic Illness Therapy) fatigue measure, and the Profile of Fatigue instruments.

Specific clinical efficacy results showed that RSLV-132 brought about clinically meaningful improvements in all three instruments relative to placebo:

- Among patients receiving RSLV-132, the mental component of the PRO-F scale showed improvement of 1.53 points, compared to worsening of 0.06 points in the placebo group (p=0.046).
- The ESSPRI score at day 99 also showed a clinically meaningful improvement of 1.2 points in the RSLV-132 arm, versus 0.5 in the placebo arm.
- A clinically meaningful improvement of 6 points in the FACIT measure at day 99 was reported among patients in the RSLV-132 group, as compared to 1 point for placebo.
- Importantly, there was a significant improvement in the RSLV-132 group in their Digital Symbol Substitution Test performance, a neuropsychological measure of executive function, with a reduction of 16.4 seconds in completing the test, compared to an increase of 2.8 seconds in the placebo group (p=0.024).
- RSLV-132 was safe and well-tolerated. Adverse event reports were similar between both study arms.

End-of-Phase II meeting with U.S. FDA establishes regulatory path forward for RSLV-132

The Company also announced that it concluded a successful End-of-Phase II meeting with the U.S. Food and Drug Administration. During this discussion, the Company requested and received further guidance on its path toward registration, including designing its Phase III confirmatory studies. Importantly, the agency approved the use of the proposed outcome measure of symptoms related to primary Sjögren's syndrome.

"We are extremely pleased by the outcome of our meeting with regulatory authorities, and are confident in our development path forward for RSLV-132," said James Posada, Ph.D., CEO of Resolve Therapeutics. "Sjögren's syndrome is a significantly underserved autoimmune disease with no approved therapies, and



patients are in urgent need of new, targeted, safe therapeutic options to combat the debilitating fatigue associated with pSS. We look forward to initiating the Phase III trial and gaining deeper insights into how our compound may potentially help patients live better with primary Sjögren’s syndrome.”

About Sjögren’s Syndrome

Primary Sjögren’s syndrome is a common, systemic autoimmune disease affecting primarily women. An estimated 4 million American women suffer from the disease, which is characterized by lymphocytic infiltration of the salivary and lachrymal glands, leading to dry eyes and dry mouth. Up to 70% of patients suffering with Sjögren’s syndrome experience debilitating fatigue, which has a significant negative impact on their quality of life. Currently, there is no approved therapy for the disease.

About Resolve Therapeutics

Resolve Therapeutics is pioneering safe, targeted therapies for underserved autoimmune diseases with large unmet medical need. The Company’s lead compound is RSLV-132, a first-in-class investigational treatment in Phase II development for Sjögren’s syndrome and lupus. The drug eliminates the inflammatory material found in the blood of patients with autoimmune diseases thereby preventing the activation of numerous pro-inflammatory cascades. RSLV-132 removes just the inflammatory stimulating molecules, without shutting down the immune system or interfering with key steps in the innate immune system. For more information, visit <http://resolvebio.com/>.

Contacts:

Solebury Trout

Brad Miles

646-513-3125

bmiles@soleburytrout.com

###