

Resolve Therapeutics Announces Completion of Enrollment for Phase 2a Study of RSLV-132 for the Treatment of Lupus

-- Topline data expected in Q1 2020 --

Seattle, WA – July 22, 2019 – Resolve Therapeutics, pioneering first-in-class, targeted, safe therapies for underserved autoimmune diseases, today announced completion of enrollment in its Phase 2a study of RSLV-132 for the treatment of Systemic Lupus Erythematosus (SLE; “lupus”). Study 132-03 is a double-blind, placebo-controlled trial, conducted in 64 lupus patients across 20 centers in the United States, and designed to evaluate the efficacy and safety of RSLV-132 compared to placebo.

“We are excited to move this potential new therapy one step closer to the large number of lupus patients who are in urgent need of new treatment options,” said James Posada, PhD, chief executive officer of Resolve Therapeutics. “While many development efforts have targeted specific individual cytokines with modest success, Resolve has approached the treatment of lupus by eliminating the initial critical events that trigger downstream pro-inflammatory cascades.”

Skin rash is one of the most common symptoms of lupus, and a visible proxy for systemic disease activity. Because there is an objective method to evaluate and adjudicate lupus skin disease activity that is more sensitive to detect change in disease activity than the SLEDAI (Systemic Lupus Erythematosus Disease Activity Index) scale, the primary endpoint of study 132-03 is the percent of subjects with $\geq 50\%$ improvement in Cutaneous Lupus Erythematosus Disease Area and Severity Index (CLASI) score, compared to placebo. Secondary endpoints include additional measures of disease activity according to the SLEDAI, BILAG (British Isles Lupus Assessment Group) index, PGA (Physician Global Assessment), and the FACIT Fatigue scale. Topline data from the trial are expected in the first quarter of 2020.

About Study 132-03

Study 132-03 is a double-blind, placebo-controlled trial designed to evaluate the efficacy and safety of 10mg/kg of RSLV-132, administered as 13 bi-weekly infusions over six months, compared to placebo. The study is evaluating patients with lupus who have active skin disease and elevated RNA-containing autoantibodies. Patients must have an adjudicated CLASI score of ≥ 10 , and be positive for one or more RNA-containing autoantibodies to be eligible for the study.

The CLASI score, used to measure the primary endpoint, is a validated outcomes measurement for categorizing patients into severity groups, identifying clinically significant improvements in disease activity,¹ and describing the extent of disease in terms of intensity of involvement.² The measurement instrument was developed by US-based dermatorheumatologists and the American College of Rheumatology.³ The SLEDAI and BILAG instruments are validated measurement scales used to assess disease activity over the course of 10 days and four weeks respectively. The SLEDAI scale uses 24 clinical and laboratory variables from nine organ systems, and BILAG provides an assessment of disease activity across eight organ systems, based on the physician’s intention-to-treat premise.⁴ The PGA is one of the most widely used physician reported outcomes tools, and is included in composite scores. PGA is often assessed by a single question, and relates to overall health or disease activity.⁵

About Systemic Lupus Erythematosus

1 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3282059/>

2 <https://www.sciencedirect.com/science/article/pii/S0022202X15325410>

3 <https://www.ncbi.nlm.nih.gov/pubmed/16297185>

4 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4507322/>

5 https://www.lupusresearch.org/glossary_of_terms/pga/

Systemic Lupus Erythematosus, is an autoimmune disease that primarily affects women. An estimated 500,000 American women suffer from the disease, and up to five million people are diagnosed worldwide. Lupus impacts the joints, skin, brain, lungs, kidneys, and blood vessels,⁶ and can cause widespread inflammation and tissue damage in the affected organs. There is no cure for lupus, and the standard-of-care has not significantly improved in over forty years. Current treatment approaches rely on steroids and potent immunosuppressive agents, with limited efficacy and serious side effects. Effective, safe therapy is urgently needed to address this unmet medical need.

About RSLV-132

RSLV-132 is a novel, targeted biologic drug designed to remove pro-inflammatory nucleic acids from the circulation of patients, which is one of the key triggers of multiple pro-inflammatory cascades.

About Resolve Therapeutics

Resolve Therapeutics is pioneering safe, targeted therapies for underserved autoimmune diseases with large unmet medical need. The Company's lead compound, RSLV-132, a first-in-class investigational treatment in Phase 2 development for lupus and Sjögren's syndrome. 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:

Media:

Solebury Trout

Joshua Mansbach

646-378-2964

jmansbach@troutgroup.com

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⁶ <https://www.cdc.gov/lupus/facts/detailed.html>