RESOLVE ANNOUNCES POSITIVE CLINICAL DATA FROM RSLV-132 LUPUS STUDY

Seattle, WA- (February 10, 2016) Resolve Therapeutics, LLC, a clinical stage biopharmaceutical company developing potentially transformative new approaches to the treatment of lupus and Sjogrens syndrome, today announced the successful completion of a multiple ascending dose study in patients with systemic lupus erythematosus (SLE) with its lead compound RSLV-132.

Data from a multicenter double-blind, placebo-controlled multiple ascending dose study of RSLV-132 in 32 subjects with SLE demonstrate the safety and tolerability of the compound. The study investigated three to five doses of RSLV-132 in four dose cohorts ranging from 0.3 mg/kg to 10 mg/kg given either weekly or bi-weekly in patients with mild SLE. The frequency of adverse events (AEs) was similar between the placebo and drug-treated groups, with the majority of AEs being mild and not related to the dose of RSLV-132. Most AEs were judged as not drug related. There were no deaths in the study and only one discontinuation due to a severe adverse event (SAE) which was not drug related.

The serum half-life of RSLV-132 was approximately 19 days, potentially supporting monthly dosing. Additionally, there were no subjects in the study that tested positive for anti-RSLV-132 antibodies.

While the study was conducted in subjects with primarily mild or inactive disease, changes in disease activity were monitored throughout the study using the systemic lupus erythematosus disease activity index (SLEDAI). Of the evaluable subjects with a
SLEDAI >0 (N=22), a greater proportion of RSLV-132 treated subjects (44%) had an improvement in disease activity as compared to placebo treated subjects (33%). SLEDAI improvements in the RSLV-132 treated subjects were accompanied in some cases by decreases in RNA autoantibodies or interferon signature.

“These data provide evidence of the safety and tolerability of RSLV-132, while the improvements in disease activity and decreases in RNA autoantibody levels in this short one-month study are very encouraging support for this new mechanistic approach to lupus. We believe RSLV-132 holds great promise for the large number of patients suffering from lupus who are poorly controlled on the currently available therapies” commented James Posada, Ph.D. chief executive officer of Resolve Therapeutics.

SLE is an autoimmune disease affecting an estimated 400,000 patients in the United States and up to 5 million worldwide, 90% of whom are women. The standard of care in lupus has not significantly improved in over forty years and relies on steroids and potent immunosuppressive agents with limited effectiveness and serious side effects. Effective, safe therapy for SLE is urgently needed to address the unmet medical need. A large and growing body of scientific data point to the central role of RNA bound to autoantibody immune complexes in the activation of the interferon pathway. RSLV-132 is a novel Fc fusion protein consisting of human RNase attached to the Fc portion of human IgG which is designed to enzymatically digest the RNA contained in immune complexes thereby preventing the chronic activation of interferon and inflammation characteristic of SLE.

About Resolve Therapeutics
Resolve Therapeutics is a privately held biotechnology company that is dedicated to helping patients with lupus and Sjogrens syndrome through the development of its platform of targeted nuclease therapeutics. In addition to the lead molecule, RSLV-132, the company is developing additional molecules that contain both RNase and DNase activities, which may also be useful in the treatment of lupus, Sjogrens syndrome and other autoimmune diseases. Resolve is funded by a syndicate of venture capital firms
including, New Science Ventures, WRF Capital, and Easton Capital. For more information on the company please visit:  http://www.resolvebio.com.

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