RSLV-132 Demonstrates Clinically Meaningful Improvement in Patients With Systemic Lupus Erythematosus in Phase 2a Clinical Trial

St. Petersburg, FL – December 9, 2020 – Resolve Therapeutics, pioneering first-in-class, targeted, safe therapies for underserved autoimmune diseases, today announced results from its Phase 2a study of RSLV-132 in patients with Systemic lupus erythematosus (SLE). Sixty-six patients diagnosed with SLE and a CLASI score of ≥ 10 at screening were enrolled into the study at 19 clinical centers in the United States. The study was conducted in a segment of SLE patients with moderately active systemic disease and severe skin manifestations.

Baseline Patient Characteristics	**Placebo (N=22)**	**RSLV-132 (N=42)**
Mean SLEDAI (SD)	8.6 (3.3)	8.2 (3.7)
Mean CLASI (SD)	22.4 (7.9)	24.1 (9.9)
BILAG Scores (organ systems ≥ 5% A or B)		
Mucocutaneous (A/B)	50%/50%	64%/31%
Musculoskeletal (A/B)	5%/55%	10%/38%
Renal (A/B)	0%/14%	2%/12%
SS-A Positive	68%	57%
SS-B Positive	9%	10%
RNP Positive	50%	36%
ds-DNA Positive	32%	24%

On the primary endpoint, change in CLASI score between the two groups at day 169; 23% of patients in the placebo group had a 50% reduction in CLASI score, and 33% of RSLV-132 treated subjects had a CLASI 50 response. Secondary endpoints included the BICLA and SRI-4 composite endpoints. Patients with more severe systemic disease, evidenced by higher SLEDAI scores, experienced greater clinical benefit from treatment with RSLV-132 than did patients with less active systemic disease.

	All Subjects		**Severe SLEDAI Subgroup (≥9)**	
Endpoint	Placebo (N=22)	RSLV-132 (N=42)	Placebo (N=11)	RSLV-132 (N=15)
CLASI50	23%	33%	9%	27%
SRI-4	23%	21%	18%	47%
BICLA	18%	24%	9%	20%

"This phase 2a study demonstrated the ability of RSLV-132 to reduce SLE disease activity relative to placebo by several different clinical indices." said James Posada, PhD, chief executive officer of Resolve Therapeutics. "The study identified the segment of SLE patients for whom RSLV-132 will have the most clinical benefit, Resolve will confirm this finding in a larger Phase 2 study planned for 2021."

About SLE

Systemic lupus erythematosus is an autoimmune disease involving chronic inflammation in which the immune system develops antibodies (autoantibodies) which may damage the patients' skin, joints, or kidneys. Many of the autoantibodies recognize nuclear antigens which contain RNA, a molecule that has potent inflammatory activity. The disease is very heterogenous and patients with SLE may have different clinical manifestations. The mainstay of current therapy for SLE includes steroids and potent immunosuppressive drugs both of which may have serious adverse effects. Therefore, new, safe, targeted therapies are desperately needed.

About RSLV-132
RSLV-132 is a safe, 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. The compound consists of a catalytically active human RNase moiety fused to a human IgG1 Fc domain which digests RNA circulating in the blood and thereby decreases inflammation.

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 development for lupus and Sjogren'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://resolvetherapeutics.com/.

Contacts:
James Posada
Resolve Therapeutics
208-727-7010
jp@resolvebio.com
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