Rezera Announces Ruvonoflast Met its Primary Inflammation Endpoint and Demonstrated Favorable Safety Profile in RESOLVE-1 Phase 2 Clinical Trial

Rezera has aligned with regulators on trial design of Phase 3 study of ruvonoflast in peripheral artery disease (PAD), expected to initiate in 1H of 2027

Presentation of full RESOLVE-1 results expected in Q4 of 2026

Boston, MA, September 9, 2026 – Rezera Inc. (the "Company"), a clinical-stage biotechnology company developing a portfolio of internally-invented and wholly-owned oral inhibitors of NLRP3 to address inflammatory drivers of cardiovascular and neurologic diseases, today announced positive topline results from RESOLVE-1, a Phase 2 randomized, double-blind, placebo-controlled clinical trial evaluating the clinical effects and safety of ruvonoflast in participants with and without type 2 diabetes.

The study met its primary inflammation endpoint of change from baseline in high-sensitivity C-reactive protein (hsCRP) up to week 24. The 150 mg daily and twice daily doses of ruvonoflast tested in the trial each reduced hsCRP compared with placebo, despite lack of enrichment in the trial for participants with elevated baseline hsCRP. Reductions were observed in participants with and without type 2 diabetes, reflecting the therapeutic potential across the cardiometabolic spectrum.

These results are consistent with the previously published anti-inflammatory activity of ruvonoflast in participants with elevated cardiovascular risk and high inflammatory burden in which hsCRP was reduced by 82% at 4 weeks.[1] The combined findings demonstrate a clear dose-response for ruvonoflast, and provide a strong foundation for Phase 3 trials with doses of up to 450 mg/day.

"The RESOLVE-1 results are a key milestone in the development of ruvonoflast, establishing dose-dependent clinical effects in a broad cardiometabolic patient population and demonstrating a favourable safety profile that supports advancement of this unique NLRP3 inhibitor into Phase 3. I would like to thank the participants and investigators who partnered with us in one of the longest and largest NLRP3 inhibitor trials to date," said Dr. Jyothis George, MBBS, Ph.D., Chief Medical Officer at Rezera. "These data are consistent with our recent peer-reviewed publication in study participants with elevated cardiovascular risk. We look forward to advancing ruvonoflast into a Phase 3 study in participants with PAD, where the unmet need is high."

In addition to lowering hsCRP, treatment with ruvonoflast resulted in concordant reductions across multiple thrombo-inflammatory biomarkers. These findings represent broad, dose-dependent pathway engagement across the NLRP3 inflammatory axis, supporting the potential for NLRP3 inhibition as an upstream mechanism modulating chronic inflammation in atherosclerotic cardiovascular disease. There was no impact on body weight.

Ruvonoflast was generally well tolerated across all treatment groups. Analysis of safety data revealed no evidence of liver toxicity caused by ruvonoflast, and no increase in infections or serious infections. There were no drug-related serious adverse events.

Data from RESOLVE-1 complement previously published Rezera data in participants with elevated cardiovascular risk and high inflammatory burden[1], and in participants with neuroinflammation[2]. The Company's plans to progress ruvonoflast into Phase 3 are underpinned by a clinical dataset comprising more than 400 participants enrolled across five ruvonoflast

clinical trials, with trial durations of up to 9 months, studying doses ranging from 150 mg/day to 450 mg/day.

Rezera has aligned with regulators on core elements of the Phase 3 PAD trial design, including endpoints, sample size, duration, and safety, and the Company plans to initiate a Phase 3 study in PAD in the first half of 2027.

“Ruvonoflast has demonstrated significant reductions in multiple measures of inflammation, a core driver of disease in PAD, giving us a potential novel therapeutic approach for a disease with great unmet need,” said Marc Bonaca, M.D., M.P.H., Executive Director of the Colorado Prevention Center (CPC), Professor of Medicine at the University of Colorado Anschutz, and Chair of the American Heart Association’s PAD Collaborative. “Peripheral artery disease affects more than 230 million people worldwide, yet the treatments we have still don't adequately address one of the core axes of risk and drivers of the disease. I’m excited about the prospect of a new treatment for patients in a field that has lagged in innovation relative to other areas of cardiovascular medicine. The upstream targeting of the NLRP3 pathway with ruvonoflast, a highly tissue penetrant molecule, could address PAD in a way that the current standard of care simply doesn't reach.”

The Company plans to present detailed findings from RESOLVE-1 at an upcoming medical conference and submit them for publication in a peer-reviewed medical journal.

About RESOLVE-1

RESOLVE-1 was a multi-center, randomized, double-blind, placebo-controlled, Phase 2 clinical trial (NCT07055516) evaluating the efficacy, safety, and pharmacodynamic effects of ruvonoflast in participants with and without type 2 diabetes. The study was designed to assess the impact of NLRP3 inhibition on clinically relevant inflammatory biomarkers and safety. RESOLVE-1 enrolled 176 participants with and without type 2 diabetes, randomized to receive ruvonoflast at 150 mg/day or 300 mg/day or placebo in addition to standard of care for a treatment duration of 24 weeks. The study evaluated the effect of NLRP3 inhibition with ruvonoflast on a hierarchy of endpoints, with change from baseline in hsCRP up to week 24 as a primary endpoint to assess impact on residual inflammatory risk. Baseline hsCRP was not an inclusion criterion.

About Rezera

Rezera is a clinical-stage biotechnology company developing a portfolio of internally-invented and wholly-owned oral inhibitors of NLRP3 to address inflammatory drivers of cardiovascular and neurologic diseases driven by the NLRP3 inflammation pathway. The Company’s lead program, ruvonoflast (f/k/a NT-0796), recently completed its Phase 2 RESOLVE-1 and RESOLVE-2 trials. The Company expects to commence a Phase 3 registrational study of ruvonoflast in H1 of 2027. The Company is also advancing trabzanoflast (f/k/a NT-0150) for treatment of neurologic diseases and expects to communicate Phase 1 topline results in Q4 of 2026.

Rezera is headquartered in Boston, Massachusetts, with an R&D base in Cambridge, UK.

Learn more at www.Rezera.com or follow the Company on LinkedIn.

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