May 28, 2025

Rezolute Announces Completion of Enrollment in the Phase 3 sunRIZE Study of Ersodetug in Patients with Congenital Hyperinsulinism

Target enrollment exceeded with 62 participants enrolled, including approximately 15 percent from U.S. sites

Topline data is anticipated in December of 2025

REDWOOD CITY, Calif., May 28, 2025 (GLOBE NEWSWIRE) -- Rezolute, Inc. (Nasdaq: RZLT) (“Rezolute” or the “Company”), a late-stage rare disease company focused on treating hypoglycemia caused by hyperinsulinism (HI), today announced that enrollment is complete in the sunRIZE study, a global, Phase 3 multicenter, double-blind, randomized, placebo-controlled, parallel arm study designed to evaluate the efficacy and safety of ersodetug for the treatment of hypoglycemia in patients with congenital HI.

“The completion of enrollment in the sunRIZE study is a significant milestone for Rezolute and those affected by congenital hyperinsulinism,” said Brian Roberts, M.D., Chief Medical Officer at Rezolute. “This achievement brings us one step closer to potentially offering a new therapeutic option in a space where few exist. We are deeply grateful to the patients, families, and investigators who are helping to advance care in an area that has long been underserved, and we look forward to announcing topline data later this year.”

Assuming supportive data from sunRIZE, the Company anticipates a clear path to submit a Biologics License Application to the U.S. Food and Drug Administration for ersodetug in 2026.

About sunRIZE

The Phase 3 sunRIZE study (RZ358-301) is a multi-center, randomized, double-blind, placebo-controlled, parallel arm study designed to evaluate the efficacy and safety of ersodetug in patients with congenital hyperinsulinism (HI), ages 3 months to 45 years old, who are experiencing continued hypoglycemia on currently available standard of care (SOC). Eligible participants are randomized to one of three treatment arms to receive either ersodetug (5 or 10 mg/kg) or matched placebo-control as add on to existing SOC. Study drug is administered every other week during an initial loading phase, and then every 4 weeks during the 6-month controlled pivotal treatment period. Following the pivotal treatment phase of the study, participants may roll-over into an optional open-label extension phase to continue to receive ersodetug, which has had a high rate of continuation thus far.

The study was to enroll approximately 56 participants in more than a dozen countries around

the world, inclusive of U.S. patients, and has been exceeded. The primary and key secondary efficacy endpoints in the study are the change from baseline in the average number of hypoglycemia events per week and the average percent time in hypoglycemia, respectively, over six months of treatment. Based on preliminary information and other than lower ages intended by the eligibility criteria, the demographics and baseline characteristics of the enrolled population in sunRIZE appear generally comparable to the Phase 2 RIZE study of ersodetug, which successfully evaluated the same primary and key secondary efficacy endpoints in the same target population.

About Ersodetug

Ersodetug is a fully human IgG2 monoclonal antibody that binds allosterically to the insulin receptor to decrease receptor over-activation by insulin and related substances (such as IGF-2) in the setting of hyperinsulinism (HI), thereby improving hypoglycemia. Because ersodetug acts downstream from the pancreas, it has the potential to be universally effective at treating hypoglycemia due to any congenital or acquired form of HI.

About Rezolute, Inc.

Rezolute is a late-stage rare disease company focused on treating hypoglycemia caused by hyperinsulinism (HI). The Company's antibody therapy, ersodetug, is designed to treat all forms of HI and has shown substantial benefit in clinical trials and real-world use for the treatment of both congenital and tumor HI. For more information, visit www.rezolutebio.com.

Forward-Looking Statements

This release, like many written and oral communications presented by Rezolute and our authorized officers, may contain certain forward-looking statements regarding our prospective performance and strategies within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995 and are including this statement for purposes of said safe harbor provisions. Forward-looking statements, which are based on certain assumptions and describe future plans, strategies, and expectations of Rezolute, are generally identified by use of words such as "anticipate," "believe," "estimate," "expect," "intend," "plan," "project," "seek," "strive," "try," or future or conditional verbs such as "could," "may," "should," "will," "would," or similar expressions. These forward-looking statements include, but are not limited to, statements regarding the potential efficacy of ersodetug in the congenital HI patient population, the timeline for achieving results in the Phase 3 study and the potential approval and commercialization of ersodetug. Our ability to predict results or the actual effects of our plans or strategies is inherently uncertain. Accordingly, actual results may differ materially from anticipated results. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this release. Except as required by applicable law or regulation, Rezolute undertakes no obligation to update these forward-looking statements to reflect events or circumstances that occur after the date on which such statements were made. Important factors that may cause such a difference include any other factors discussed in our filings with the SEC, including the Risk Factors contained in the Rezolute's Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, which are available at the SEC's website at www.sec.gov. You are urged to consider these factors

carefully in evaluating the forward-looking statements in this release and are cautioned not to place undue reliance on such forward-looking statements, which are qualified in their entirety by this cautionary statement.

Contacts:

Rezolute, Inc.
Christen Baglaneas
cbaglaneas@rezolutebio.com
508-272-6717

Media
Sarah Lima
Sarah@galvinPR.com
(774) 766-0200

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