July 9, 2025

Rezolute Announces Presentation of Participant Baseline Data from its Fully Enrolled Phase 3 Study of Ersodetug in Congenital Hyperinsulinism at the Upcoming Annual Meeting of the Endocrine Society (ENDO 2025)

REDWOOD CITY, Calif., July 09, 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 the abstract titled "Preliminary Patient Demographics And Baseline Characteristics From A Phase 3 Study (sunRIZE) Of Ersodetug For Hypoglycemia Due To Congenital Hyperinsulinism: Trial In Progress" has been selected for a late-breaking presentation at ENDO 2025 taking place July 12-15, 2025 in San Francisco, CA, USA.

"We are excited to share baseline data from the sunRIZE study, which will offer important insights into this population and its comparability to the Phase 2 RIZE study, further highlighting the persistent unmet medical need," said Brian Roberts, M.D., Chief Medical Officer at Rezolute. "With enrollment now complete and topline data expected in December, we are one step closer to potentially delivering a much-needed therapy to patients who currently have limited options."

Presentation details are as follows:

Title: Preliminary Patient Demographics And Baseline Characteristics From A Phase 3 Study (sunRIZE) Of Ersodetug For Hypoglycemia Due To Congenital Hyperinsulinism: Trial In Progress
Format: Poster presentation
Session: Pediatric and Adolescent Endocrinology
Presentation Number: MON-213
Date/Time: Monday, July 14, 2025, 12:00 – 01:30 PM Pacific time
Presenters: Gopal Saha, MBBS and Brian Roberts, MD

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, which has been completed and 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.

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 Congenital Hyperinsulinism

Congenital Hyperinsulinism (HI) is the most common cause of recurrent and persistent hypoglycemia in children. Patients with congenital HI typically present with signs or symptoms of hypoglycemia within the first month of life. These episodes can result in significant brain injury and death if not recognized and managed appropriately. Additionally, recurrent, or cumulative, hypoglycemia can lead to progressive and irreversible damage over time, including serious and devastating brain injury, seizures, neuro-developmental problems, feeding difficulties, and significant impact on patient and family quality of life. In cases of congenital HI that are unresponsive to medical management, surgical removal of the pancreas may be required. More than half of children with congenital HI require long-term medical treatment for hypoglycemia that is not addressed by available therapies.

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 data presented at ENDO 2025 and subsequent conferences, 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.

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