April 23, 2025

Rezolute Announces Positive Recommendation After Independent Interim Analysis of Phase 3 sunRIZE Study of Ersodetug in Congenital Hyperinsulinism ("HI")

Independent Data Monitoring Committee (the "DMC") recommends continuation of sunRIZE trial as planned with no need to increase sample size

Enrollment on track and expected to be completed in May 2025; topline data anticipated in December 2025

U.S. sites activated and enrolling patients

REDWOOD CITY, Calif., April 23, 2025 (GLOBE NEWSWIRE) -- Rezolute, Inc. (Nasdaq: RZLT) (the "Company or "Rezolute"), a late-stage biopharmaceutical company dedicated to developing transformative therapies for rare diseases with serious unmet needs, today announced the DMC's recommendation to continue the Phase 3 sunRIZE study as planned in patients with congenital HI, without an increase in the study sample size.

"We are thrilled with the DMC's favorable recommendation, which appears to validate our initial assumptions for the design and powering of the Phase 3 sunRIZE study," said Brian Roberts, M.D., Chief Medical Officer at Rezolute. "While we remain blinded to the partial study data and are not privy to any of the statistical outputs from the DMC, we are nevertheless encouraged by this recommendation considering past outcomes from the Phase 2 RIZE study with the same objectively measured glycemic primary endpoint, real-world observations from our Expanded Access Program, and previously announced pharmacokinetic data from the open-label arm of the sunRIZE study. With U.S. clinical sites now also enrolling patients as part of our global study, and the Company tracking to complete enrollment next month, we look forward to announcing topline results, anticipated in December of this year, and remain confident in the potential of ersodetug to be a best-in-class treatment option for people living with hyperinsulinism."

The interim analysis of the Phase 3 sunRIZE study was performed by an unblinded DMC and was based on a pre-specified analysis of the primary study endpoint (hypoglycemia events), after approximately half of enrolled patients completed the primary assessments. The analysis was intended to evaluate for study futility or otherwise to inform a potential sample size increase, for purposes of optimizing the study power and statistical confidence in the final analysis outcomes. The Company has remained blinded throughout the interim analysis and has not seen the information made available to the DMC to inform its decision making, nor received any other information from the DMC after their meeting, other than its

recommendation to continue the study as planned.

About sunRIZE
The Phase 3 sunRIZE study 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 HI who are experiencing poorly controlled hypoglycemia. Participants between the ages of 3 months to 45 years old are eligible to participate. The study is enrolling up to 56 participants in more than a dozen countries around the world.

About Ersodetug
Ersodetug is a fully human 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 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 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 significantly improving outcomes for individuals with 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 congenital HI 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 its authorized officers, may contain certain forward-looking statements regarding our prospective performance and strategies within the meaning of Section 27A of the Securities Act of 1933, as amended, 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 ability of ersodetug to become an effective treatment for congenital HI, statements regarding the potential regulatory approval and commercialization

of ersodetug, the efficacy of the Phase 3 sunRIZE study, statements related to the Phase 3 sunRIZE study sample size, and statements regarding the timing of the completion of enrollment and release of topline data. 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 Rezolute's Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, which are available on the SEC's website at www.sec.gov. You are urged to consider these factors carefully by 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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