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Rezolute Provides Update on its Phase 3 sunRIZE Study of Ersodetug for the Treatment of Hypoglycemia Due to Congenital Hyperinsulinism

Open-label arm (infant participants < 1 year old) has been recently reviewed by a Data Monitoring Committee (DMC) and target drug concentrations were safely reached at tested doses

DMC approved enrollment of infants into the double-blind portion of the study

sunRIZE enrollment completion expected in Q2 2025, subject to outcomes from upcoming interim analysis

REDWOOD CITY, Calif., Feb. 04, 2025 (GLOBE NEWSWIRE) -- **Rezolute, Inc. (Nasdaq: RZLT)** (“**Rezolute**” or the “**Company**”), a late-stage biopharmaceutical company dedicated to developing transformative therapies for rare diseases with serious unmet needs, today announced outcomes from an independent Data Monitoring Committee (DMC) review of the open label arm (OLA) portion of the sunRIZE Phase 3 study of ersodetug for the treatment of hypoglycemia due to congenital hyperinsulinism (HI) and provided additional study updates including guidance on its upcoming interim analysis (IA) by the DMC. This IA will assess the adequacy of the sample size for the primary endpoint and may recommend adjustments if necessary.

The open label arm of 8 infant participants ages 3 months to 1 year has been fully enrolled and accrued sufficient data for the DMC to review the safety and pharmacokinetics (PK) of ersodetug, which was administered at doses of 5 or 10 mg/kg over a bi-weekly loading phase followed by a monthly maintenance phase. The task of the DMC was to independently review the safety and PK data in infants for purposes of dose confirmation, continued benefit-risk determinations, and the appropriateness of opening enrollment of the double-blind portion of the study to infant participants at the dose regimen under study. The DMC did not review glycemic efficacy and the Company remains blinded to glucose results and efficacy outcomes.

Findings from the DMC include the following:

- Ersodetug was generally safe and well-tolerated in participants 3 months to 1 year of age.
- Observed ersodetug drug levels at peak and trough were comparable to exposures in older pediatric participants in the Phase 2b RIZE study, which were demonstrated to be effective.

- Safety and exposures validate the chosen dose regimen of 5 and 10 mg/kg administered bi-weekly and monthly.
- Subsequent infant participants may now be enrolled into the double-blind, placebo-controlled study.

“We are encouraged by these preliminary outcomes from the open label arm of the sunRIZE study, particularly as it is a strong indication of the safety profile of ersodetug and provides additional validation of the selected doses in very young participants,” said Brian Roberts, M.D., Chief Medical Officer at Rezolute. “Having recently received Breakthrough Therapy Designation from the FDA, 2025 has already been an exciting year for Rezolute and we look forward to additional milestones over the course of this year as we progress in our mission to provide a safe and effective therapy for people living with hyperinsulinism.”

Study start up activities in the U.S. have progressed and sites are expected to be activated and enrolling this quarter. Study enrollment completion is anticipated in the second quarter of 2025 and topline results are expected in the fourth quarter of 2025, pending recommendations from the DMC based on an upcoming IA.

An IA of the study primary hypoglycemia endpoint is being conducted following the accumulation of sufficient patient data and is designed to optimize the study sample size and statistical confidence in the final analysis outcomes. The IA will be conducted at the end of this quarter and the Company plans to announce the conclusions of the DMC early in the second quarter of 2025 while also providing additional overall study updates. There are three possible outcomes from the analysis: (i) futility and the study should be stopped, (ii) continue the study as is or (iii) continue the study as is but increase the sample size by 33% (18 additional patients) to enhance statistical confidence in the final outcome.

If the study sample size is increased, the Company estimates completion of enrollment would shift to the fourth quarter of 2025 and that top line results would be available in mid-2026. Other than for futility, the outcomes of the IA should not be viewed as a read-through to end of study efficacy, either favorably or unfavorably.

For more information on our pipeline and the sunRIZE study, please visit www.rezolutebio.com/for-patients/.

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 Ersodetug

Ersodetug is a fully human monoclonal antibody that binds allosterically to the insulin receptor to counteract the effects of insulin receptor over-activation by insulin and related substances (such as IGF-2), thereby shifting over-signaling back into a more normalized range and improving hypoglycemia in the setting of hyperinsulinism (HI). 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 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 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 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," "potential," 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 efficacy of ersodetug in patient populations of 3 months to 1 year of age, the DMC approval of enrollment of infants into a double-blind control study of ersodetug, the FDA's grant of the Breakthrough Therapy Designation for ersodetug, the ability of ersodetug to become an effective treatment for congenital hyperinsulinism, the effectiveness or future effectiveness of ersodetug for the treatment of congenital hyperinsulinism, statements regarding clinical trial timelines for ersodetug, the timing of the Phase 3 sunRIZE study. 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 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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