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Rezolute Provides Update on its Congenital Hyperinsulinism Program Following FDA Meeting

FDA encourages the Company to submit comprehensive data from sunRIZE and the ongoing open-label extension to inform next steps for the program

REDWOOD CITY, Calif., March 24, 2026 (GLOBE NEWSWIRE) --**Rezolute, Inc. (Nasdaq: RZLT) ("Rezolute" or the "Company"),** a late-stage rare disease company focused on treating hypoglycemia caused by all forms of hyperinsulinism (HI), today announced outcomes from an in-person Type B meeting with the U.S. Food and Drug Administration (FDA) held on March 17, 2026, related to sunRIZE, a Phase 3, multicenter, double-blind, randomized, placebo-controlled safety and efficacy study of ersodetug for the treatment of congenital HI.

In December 2025, the Company reported that sunRIZE demonstrated reductions from baseline in hypoglycemia events, but the study did not meet its primary endpoint because the reductions were not statistically significant compared to placebo, which the Company believes was a result of a pronounced study effect.

Although consistent and clinically significant improvements in time in hypoglycemia by continuous glucose monitoring (CGM) were observed compared to placebo over the course of the entire pivotal treatment period, nominal statistical significance was not achieved in this key secondary endpoint at the pre-specified Week 24 end-of-treatment period.

During the meeting with FDA, the Company presented summary results from sunRIZE including: (i) information to support the Company's belief that the primary endpoint was confounded as a result of behavioral factors; (ii) evidence of pharmacologic activity, as target therapeutic drug concentrations were achieved in both treatment groups with highly sensitive biomarker responses of decreased insulin cell signaling; (iii) consistent improvements compared to placebo in time in hypoglycemia and a variety of other CGM-based glycemic endpoints; and (iv) preliminary favorable observations from the ongoing open-label extension portion of the study (OLE), which indicate continued improvement in glycemic parameters in the ersodetug treatment arms and placebo roll-over, concurrent with a notable reduction of other background standard-of-care therapies.

FDA acknowledged the challenges posed by the potential impact of varied behavioral factors on clinical trials in this heterogeneous patient population, including the associated limitations of self-monitored blood glucose (SMBG) based metrics in measuring hypoglycemia in congenital HI.

The Company believes that the unblinded nature of self-monitored glucose necessary for patient standard of care, together with perceptions of treatment assignment, may have led to divergent behaviors between treatment groups during the study, which may have impacted the measurement of hypoglycemia by SMBG.

While acknowledging these challenges, the agency reiterated the expectation for adequate and well-controlled studies and outcomes as the standard for evaluating substantial evidence of efficacy criteria as the basis for approving new therapies.

The agency and the Company then discussed summary outcomes from various CGM-based glycemic endpoints and preliminary observations from the OLE. These and other outcomes from the pivotal portion of the sunRIZE trial will be shared by oral presentation at an upcoming scientific conference.

As a next step for the program, FDA encouraged the Company to submit study reports and analysis datasets for the agency's independent evaluation. Following that review, the Company believes that a determination may be made whether there is sufficient evidence to support the submission of a marketing application for sunRIZE or if additional information is required. The Company expects to have an update on the program in the second half of 2026.

"We are extremely encouraged by the outcome of our meeting with FDA including the fact that, while acknowledging their feedback was preliminary, the agency did not dismiss sunRIZE outright on the basis of not meeting its primary endpoint," said Nevan Charles Elam, Chief Executive Officer and Founder of Rezolute. "FDA was engaged with the content we presented, asked astute questions necessary to fully understand the results, and expressed a desire to conduct a thorough review that would assist in decision making regarding advancement of the program."

Mr. Elam continued, "We are grateful for FDA's hands-on approach and look forward to continuing to work with them to hopefully find a timely path forward to make ersodetug available to patients and families in need."

"As an attendee of the meeting, I was extremely impressed observing FDA and Rezolute working together with a common understanding of the profound burden congenital hyperinsulinism places on patients and caregivers, and for their commitment to advance meaningful improvements in care," said Julie Raskin, Chief Executive Officer of Congenital Hyperinsulinism International, an international advocacy organization. "Our community has long awaited new treatment options, and this open dialogue reflects important progress toward potentially safely bringing more effective and better-tolerated therapies."

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 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 been studied in clinical trials and used in real-world cases 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, the potential efficacy of ersodetug in treating hypoglycemia, the timing and ability of the Company to provide study reports and analysis datasets for the FDA's independent evaluation, the persuasiveness of the study reports and analysis datasets and the possibility of FDA agreeing to advance the congenital HI program based on those study reports and analysis datasets notwithstanding the lack of statistical significance in the sunRIZE study, the timing of any FDA response to the study reports and analysis datasets, the timing of any update on the sunRIZE program and the timing and content of any future presentations and market updates related the sunRIZE program. 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 at the U.S. Securities and Exchange Commission'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.

Rezolute Contacts:

Christen Baglaneas
cbaglaneas@rezolutebio.com
508-272-6717

Carrie McKim

cmckim@rezolutebio.com
336-608-9706



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