May 1, 2026

Rezolute Announces Oral Presentation of Results From its Phase 3 sunRIZE Study of Ersodetug in Patients with Congenital Hyperinsulinism at the Pediatric Endocrine Society Annual Meeting

Includes results from additional continuous glucose monitoring (CGM)-based outcomes which demonstrate significant and consistent improvements in glycemic control in ersodetug treatment arms compared to placebo, across multiple pre-specified and post-hoc endpoints

Participation, retention, and treatment duration in the open-label extension (OLE) phase of the study is high and has resulted in continued glycemic benefit, concurrent with the reduction and/or discontinuation of background standard of care (SOC) therapies

REDWOOD CITY, Calif., May 01, 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 that expanded analyses from the Phase 3 sunRIZE study of ersodetug in patients with congenital HI were presented at the Pediatric Endocrine Society (PES) 2026 Annual Meeting. The oral presentation was made by Diva D. De León-Crutchlow, M.D., M.S.C.E., Chief of the Division of Endocrinology and Diabetes, Director of the Congenital Hyperinsulinism Center at Children's Hospital of Philadelphia, and Principal Investigator of the sunRIZE study. In addition to the previously reported topline results, the presentation included additional results from pre-specified and post-hoc sunRIZE analyses, which the Company believes reiterates evidence of target engagement and highlights the potential therapeutic benefit of ersodetug.

As discussed in today's presentation, although statistical significance for the secondary endpoint (% time in hypoglycemia by CGM) was not achieved at the Week 24/End of Treatment evaluation window, larger and often nominally statistically significant glycemic improvements were consistently observed throughout the maintenance dosing phase of the study, across time and numerous pre-specified and post-hoc CGM-based endpoints. These outcomes are summarized below and depicted by the Forest Plot in Figure 1.

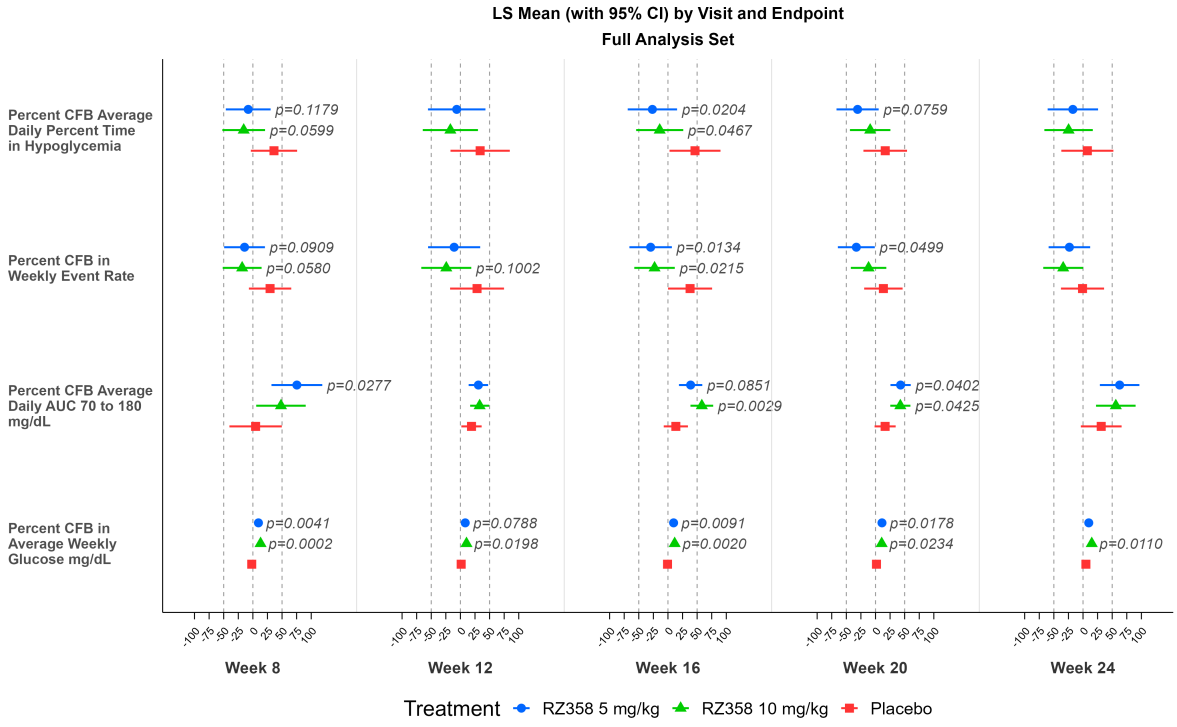
Summary of Key Additional Data Presented

- **Average daily percent time in hypoglycemia by CGM**: clinically relevant and nominally statistically significant reductions of >50% (Full Analysis Set [FAS]) and ~60-80% (Per Protocol Set [PPS]), compared to placebo across multiple timepoints
- **Average weekly hypoglycemia events by CGM**: clinically relevant and nominally

statistically significant reductions of ~50-65% (FAS) and ~50-80% (PPS), compared to placebo across multiple timepoints

- **Average daily AUC 70 to 180 mg/dL (Exposure to Normoglycemia) by CGM** clinically relevant and nominally statistically significant increases of ~25-50% (FAS and PPS), compared to placebo across multiple timepoints
- **Average blood glucose (mg/dL) by CGM**: clinically relevant and nominally statistically significant increases of ~10-15% (~10-15 mg/dL) in both the FAS and PPS, compared to placebo across multiple timepoints

Figure 1: Consistent and Clinically Relevant Glycemic Improvements in Ersodetug Treatment Groups Compared to Placebo Across Time & Multiple CGM Outcomes (LS-Mean [95% CI] Percent Change from Baseline; FAS Population)



The Company is also assessing the longer-term efficacy and safety of ersodetug in a real-world setting in an ongoing OLE phase of the study, including the roll-over of placebo participants. Following the conclusion of the randomized and placebo-controlled phase of sunRIZE, all 59 study completers elected to enter the OLE, as previously reported by the Company. Reflecting no change since last reported, 57 participants continue to attend regular study visits at sunRIZE study centers to receive ersodetug in the OLE, now representing a cumulative ersodetug exposure duration in the study ranging from approximately 6 to 24 months. Preliminary OLE observations demonstrate continued glycemic benefit, including a clinically significant change in glycemic control in the rolled-over placebo participants compared to the controlled period of the study. These glycemic benefits have enabled a concurrent significant overall reduction in background SOC therapies (e.g. diazoxide, somatostatin analogs, and/or regular tube feeds), with a significant number of patients now receiving ersodetug as monotherapy.

Notably, a summary of these same CGM-based study outcomes and preliminary observations from the OLE phase of the study were recently discussed with the U.S. Food and Drug Administration (FDA) as part of the Company's Type B meeting held on March 17, 2026. The meeting resulted in the agency acknowledging challenges associated with the study primary endpoint (events by finger-stick self-monitored blood glucose [SMBG]), and concluded with the agency requesting that the Company submit the broader study data for the agency's comprehensive evaluation to inform next steps for the program.

"We are pleased to highlight that deeper analyses of the sunRIZE outcomes and ongoing observations from the extension phase of the study consistently indicate evidence of target engagement, drug activity, and the potential for meaningful therapeutic benefit from ersodetug," said Brian Roberts, M.D., Chief Medical Officer of Rezolute. "These results underscore our confidence in the potential of ersodetug to transform the HI treatment landscape and embolden our mission to achieve alignment with FDA on an acceptable path to approval in this indication, so that we can keep delivering ersodetug to patients and families living with congenital HI."

The Company's full data presentation from PES can be found on the Publications and Presentations page of the Rezolute website here.

About sunRIZE

The Phase 3 sunRIZE study (RZ358-301) was 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 were experiencing continued hypoglycemia on currently available standard of care (SOC). Eligible participants were 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 was 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 could roll-over into an optional open-label extension phase to continue to receive ersodetug.

The study enrolled 63 participants in more than a dozen countries around the world, inclusive of U.S. patients. The primary and key secondary efficacy endpoints in the study were 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.

Although sunRIZE demonstrated reductions from baseline in hypoglycemia events, the study did not meet its primary endpoint, which assessed change in average weekly hypoglycemia events by self-monitored blood glucose (SMBG) compared to placebo. The reductions observed were not statistically significant, which the Company believes was a result of functional unblinding of the SMBG endpoint, leading to divergent and confounding glucose-modifying behaviors between treatment groups, and a pronounced study effect in the placebo arm.

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 sufficiency of CGM data to support a potential path forward in the congenital HI program with FDA, the predictive nature of the CGM data as it relates to the potential efficacy of ersodetug in treating hypoglycemia, the 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. 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.

Diva D. De León-Crutchlow, M.D., M.S.C.E., is a paid consultant to Rezolute Inc., and served as the site Principal Investigator for the Phase 3 sunRIZE study at Children's Hospital of Philadelphia.

Rezolute Contacts:

Christen Baglaneas

cbaglaneas@rezolutebio.com

508-272-6717

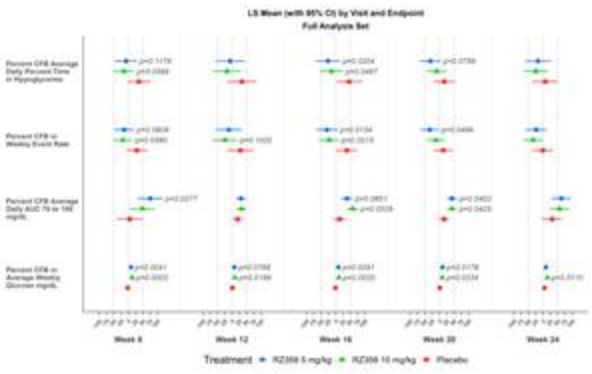
Carrie McKim

cmckim@rezolutebio.com

336-608-9706

A photo accompanying this announcement is available at https://www.globenewswire.com/NewsRoom/AttachmentNg/d26d1af6-0969-4bba-b973-6d2294367aae

Figure 1



Consistent and Clinically Relevant Glycemic Improvements in Ersodetug Treatment Groups Compared to Placebo Across Time & Multiple CGM Outcomes (LS-Mean [95% CI] Percent Change from Baseline; FAS Population)

Source: Rezolute, Inc.