October 5, 2026

Rezolute Announces FDA Recommendation to Hold a Pre-BLA Meeting as a Precursor to Submitting a Biologics License Application (BLA) for Congenital Hyperinsulinism

The Agency reiterated its commitment to addressing the unmet need for treatment of congenital and tumor-related hyperinsulinism and to serving these patient communities

On track to report topline results for the Phase 3 upLIFT study in tumor HI this quarter

REDWOOD CITY, Calif., Oct. 05, 2026 (GLOBE NEWSWIRE) -- **Rezolute, Inc. (Nasdaq: RZLT) ("Rezolute" or the "Company"),** a late-stage ultra-rare disease company focused on treating refractory hypoglycemia caused by any form of hyperinsulinism ("HI"), today announced that following a preliminary review of detailed data from the Phase 3 sunRIZE study of ersodetug for the treatment of hypoglycemia due to congenital HI, the U.S. Food and Drug Administration ("FDA" or "Agency") recommended a pre-BLA meeting with the Company as a precursor to submitting a BLA.

As previously reported, sunRIZE, a Phase 3, multicenter, double-blind, randomized, placebo-controlled safety and efficacy study of ersodetug for the treatment of congenital HI, demonstrated glycemic improvements, but did not meet the primary endpoint because the reductions in hypoglycemia events by finger-stick self-monitored blood glucose (SMBG) were not statistically significant compared to placebo. Although the key secondary endpoint of time in hypoglycemia by continuous glucose monitoring (CGM) was not met in the Week 24 End-of-Treatment evaluable window, consistent and clinically relevant improvements in hypoglycemia were observed for this and multiple other CGM-based hypoglycemia endpoints in both treatment arms.

At a March 2026 Type B meeting with FDA, the Agency acknowledged the challenges posed by behavioral factors in clinical trials in this patient population, including limitations associated with SMBG based measures of hypoglycemia. At the meeting, the Agency requested that the Company provide the continuous CGM data for its independent review. In June 2026, the Company submitted source and analysis datasets, and summary results from a substantial number of pre-specified, post-hoc, and sensitivity analyses.

The Agency has reviewed the data and, despite the trial's failure to meet the prespecified primary and key secondary endpoints, as a next step, encouraged the Company to request a Type B pre-BLA meeting as a precursor to submitting a BLA for congenital HI. The Agency explicitly did not opine on the approvability of ersodetug for congenital HI and noted that any such determination would only be made as a part of an in-depth evaluation of the supporting

data during a formal BLA review, as is customary during a BLA process.

In light of expected topline results this quarter from the Company's upLIFT study in tumor HI and the potential for an additional pre-BLA meeting for that indication should the study results support a submission, the Company will evaluate its overall BLA submission strategy for potentially both programs following the announcement of upLIFT study results.

"We appreciate FDA's thorough review of the extensive body of data generated in sunRIZE and are encouraged by the Agency's recognition that this data will require in-depth evaluation during a formal BLA review," said Nevan Charles Elam, Chief Executive Officer and Founder of Rezolute. "We share FDA's commitment to addressing the significant unmet needs of individuals living with rare diseases like congenital HI, where traditional drug development can present unique challenges. We believe this unusual process of preliminary review of detailed data demonstrates what can be achieved when regulators, companies, clinicians, and advocacy organizations work collaboratively to evaluate the totality of evidence for promising rare disease therapies."

"For many people living with congenital hyperinsulinism, the threat of severe and unpredictable hypoglycemia remains a daily reality, and existing treatments are not enough," said Julie Raskin, Chief Executive Officer of Congenital Hyperinsulinism International (CHI). "We are encouraged by the progress toward potential new therapies and grateful to the patients, families, researchers, clinicians, regulators, and biotechnology companies working together to bring better options to our community."

The open-label extension (OLE) phase of the study is ongoing, with a continued high retention rate, equating to an ersodetug treatment duration in sunRIZE ranging from approximately nine months to well over two years. This, along with continued glycemic control and a notable reduction in the use of background standard of care therapies, potentially indicate continued glycemic and clinical benefit with ersodetug in longer-term use.

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 pancreatic insulin or paraneoplastic IGF-2 secretion and from entero-incretin pathways, it has the potential to be universally effective at treating refractory hypoglycemia due to any form of hyperinsulinism (HI), including congenital HI, tumor HI (insulinoma, non-islet cell tumors) or bariatric/non-bariatric gastrointestinal surgery hypoglycemia. Ersodetug for the treatment of HI is investigational. Statements about safety and efficacy have not been approved by any health authority.

About Rezolute, Inc.

Rezolute is a late-stage ultra-rare disease company focused on treating refractory hypoglycemia caused by any form of hyperinsulinism (HI). The Company's antibody therapy, ersodetug, has been studied in clinical trials and used in real-world cases for the treatment of refractory hypoglycemia due to a variety of causes of 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 overall BLA process, the potential efficacy of ersodetug in treating hypoglycemia as well as our ability to complete enrollment of the upLIFT study this year and announce topline results. Our ability to predict results or our plans or strategies is inherently uncertain. Notably, despite the FDA encouraging us to request a pre-BLA meeting for congenital HI, there can be no assurance that FDA will agree with the Company that the totality of evidence from the sunRIZE program demonstrates a clinically meaningful benefit or is sufficient to support the approval for ersodetug in congenital HI. Accordingly, FDA may determine that additional clinical data, including data from a new randomized controlled trial similar to sunRIZE, are required to support approval. Should the Agency make such a determination, it would adversely impact the timing and feasibility of approval for the congenital HI indication as well as the the commercial potential for ersodetug. 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.

Contacts:

Christen Baglaneas
Rezolute, Inc.
1411 Broadway, 16th Floor
New York, NY 10018
cbaglaneas@rezolutebio.com
508-272-6717

Carrie McKim
Rezolute, Inc.
1411 Broadway, 16th Floor

New York, NY 10018
cmkim@rezolutebio.com
336-608-9706

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