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Rezolute Announces Positive Interim Data for its Phase 3 upLIFT Study of Ersodetug in Tumor Hyperinsulinism

Study now 50% enrolled

6 of 8 participants have already met the responder criterion for the study's primary endpoint

Topline results for the fully enrolled open-label study are expected in the second half of 2026

REDWOOD CITY, Calif., June 02, 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 a congenital or any acquired form of hyperinsulinism (HI), today provided an interim update on its ongoing open-label Phase 3 study (upLIFT) of ersodetug in tumor HI.

With 8 participants enrolled in upLIFT to date, comprising both insulinoma and non-islet cell tumor hypoglycemia, the Company is midway through enrollment of the planned study sample size of 16 participants.

Of the 8 participants enrolled, 6 have already met the responder criterion for the study's primary endpoint, which is the number of participants achieving at least a 50 percent reduction from baseline in intravenous glucose requirements (glucose infusion rate; GIR) within the 8-week pivotal treatment phase. Each of these 6 participants also achieved a complete discontinuation of intravenous glucose requirements with the administration of ersodetug.

One of the 8 enrolled participants withdrew study consent and discontinued ersodetug and all other non-palliative therapies prior to completion of the pivotal treatment phase. This patient had Stage 4 metastatic colon cancer and a poor Eastern Cooperative Oncology Group performance status (ECOG 4). The participant elected to be discharged from the hospital to receive hospice care at home, where they died one week later due to cancer progression. The reduction and eventual discontinuation of intravenous glucose were undertaken in the setting of hospice transition, so the participant is being counted as a non-responder for purposes of assessing the primary endpoint.

The 8th participant was recently enrolled and is still dosing in the pivotal phase of the study. All participants that have completed the 8-week pivotal treatment period have elected to continue into the open-label extension, with a cumulative treatment duration of up to 6 months. Ersodetug has been well-tolerated in the pivotal and extension phases of the study, with no drug-related adverse events or other safety findings reported to date.

"We are very excited by the interim observations from the upLIFT study as they largely

mirror what we previously observed and reported from an initial case series of patients from our expanded access program for compassionate use," said Dr. Brian Roberts, Chief Medical Officer of Rezolute. "These results reveal the clinically impactful hypoglycemia-correcting activity of ersodetug in an unbiased GIR assessment in patients with HI caused by varying tumor types. This further highlights the aberrant outcome from the recently completed randomized, placebo-controlled, Phase 3 sunRIZE study in pediatric congenital HI, where we believe that self-monitored glycemic measures were confounded by divergent caretaker behaviors stemming from functional unblinding to treatment status by real-time glucose monitoring. Importantly, these findings continue to support the potential for ersodetug to be a universal treatment option for patients with serious and refractory hypoglycemia caused by congenital and a variety of acquired forms of hyperinsulinism, including tumor HI and following bariatric and non-bariatric gastrointestinal surgeries. We look forward to announcing topline results of the fully enrolled upLIFT study in tumor HI in the second half of 2026, as well as continuing our engagement with FDA to determine the path forward for the congenital HI indication."

About upLIFT

The Phase 3 registrational study is a single-arm, open-label, pivotal trial in approximately 16 participants with insulinoma or non-islet cell tumors who have uncontrolled hypoglycemia caused by tumor hyperinsulinism (HI). Eligible participants requiring continuous intravenous (IV) glucose will receive ersodetug 9 mg/kg per week for 8 weeks, as an add-on to standard of care. Following this 8-week pivotal treatment period, all participants may receive ersodetug in long-term extension. The primary endpoint is the proportion of participants achieving at least a 50 percent reduction from baseline in IV glucose requirements (glucose infusion rate; GIR). Additional endpoints include the number of participants and time to discontinuation of GIR, time to discharge from the hospital, extent of hypoglycemia events and hypoglycemia time in the outpatient setting by self-monitored blood glucose and continuous glucose monitor, respectively, and patient reported quality of life.

About Tumor Hyperinsulinism

Tumor hyperinsulinism (HI) is a rare disease that may be caused by two distinct types of tumors: islet cell tumors (ICTs) and non-islet cell tumors (NICTs), both of which lead to hypoglycemia as a result of over-activation of the insulin receptor. Insulinomas are the most common type of ICT and cause hypoglycemia by stimulating the over production of insulin. A variety of different NICTs, particularly hepatocellular carcinoma, can cause hypoglycemia by producing and secreting insulin-like paraneoplastic substances such as variants of IGF-2 that bind to and activate the insulin receptor. With high morbidity and mortality rates within tumor HI, there remains a significant unmet need for new therapies directed at hypoglycemia treatment. Ersodetug has shown real-world benefit in patients with insulinoma and NICTs.

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 glucose absorption, gastrointestinal incretin hormones, and pancreatic insulin secretion, it has the potential to be universally effective at treating refractory hypoglycemia due to a congenital or any acquired form of HI, including tumor HI

(insulinoma, NICTH) or hypoglycemia as a complication of a variety of bariatric or non-bariatric gastrointestinal surgeries.

About Rezolute, Inc.

Rezolute is a late-stage ultra-rare disease company focused on treating refractory hypoglycemia caused by a congenital or any acquired 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 potential efficacy of ersodetug in treating hypoglycemia associated with either a congenital or any acquired form of HI or the timing of the release of topline results for upLIFT. 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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