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Rezolute Announces Positive Results from the Phase 3 upLIFT Study in Tumor Hyperinsulinism

Primary efficacy endpoint achieved based on preliminary results from a November 5th data evaluation

Topline results for the completed study, along with additional study details including statistical analysis of the primary endpoint, are expected by mid-December 2026

REDWOOD CITY, Calif., Nov. 13, 2026 (GLOBE NEWSWIRE) -- **Rezolute, Inc. (Nasdaq: RZLT) (Rezolute or the Company),** a late-stage ultra-rare, metabolic disease company focused on treating refractory hypoglycemia caused by any form of hyperinsulinism (HI), today announced positive results from the ongoing open-label Phase 3 upLIFT study of ersodetug in tumor HI, in which the primary efficacy endpoint has been achieved, based on preliminary results from a November 5th data evaluation.

The primary efficacy endpoint in the upLIFT study is the proportion of patients able to achieve at least a 50% reduction from baseline in glucose infusion rate (GIR), a measure of intravenous glucose dependency for underlying hypoglycemia. To achieve statistical significance for the endpoint, the lower bound of the 95% confidence interval for percent of patients responding must exceed 30%, which equates to at least 9 responders (≥56%), based on enrollment of 16 participants. To date, 13 participants have met the responder criterion, including 12 who also achieved a complete discontinuation of IV glucose. Three participants are still in the pivotal period of the study, including two who have not yet met the responder criterion. As previously reported, one participant discontinued the study early and chose to enter home hospice care, and died one week later due to cancer progression. This participant has been classified as a non-responder for purposes of the primary endpoint. Results for the completed study, including statistical analysis of the primary endpoint, are expected by mid-December 2026.

“We are thrilled with this outcome and what it means for individuals living with tumor hyperinsulinism,” said Nevan Charles Elam, Founder and Chief Executive Officer of Rezolute. “Notably, these results substantially mirror the powerful outcomes that we have observed over the last few years in our expanded access program. We believe that we are well positioned to advance both congenital HI and tumor HI into the approval process next year and we look forward to discussions with FDA in the first quarter of 2027.”

The 16 enrolled participants include four with non-islet cell tumors and 12 with insulin-secreting malignant islet cell tumors (insulinomas). Ersodetug has been well-tolerated to date in the pivotal and extension phases of the study, with no drug-related safety findings attributed to ersodetug.

About upLIFT

The upLIFT 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 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 at a reduced dosing frequency in long-term extension. The primary endpoint is the proportion of participants able to achieve at least a 50 percent reduction from baseline in GIR, a measure of intravenous glucose dependency for underlying hypoglycemia. Additional endpoints include the number of participants achieving complete discontinuation of GIR and time to discontinuation, time to discharge from the hospital as applicable, 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 because of over-activation of the insulin receptor. Insulinomas are the most common type of ICT and cause hypoglycemia via the overproduction of insulin. A variety of different NICTs, including hepatocellular carcinoma and soft tissue malignancies (e.g. sarcomas), 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 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 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, metabolic 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 potential safety, efficacy and therapeutic and commercial potential of ersodetug for the treatment of hypoglycemia caused by hyperinsulinism; the timing and final results of the Phase 3 upLIFT study of ersodetug in tumor HI, including our expectation to announce full topline results by mid-December 2026; the Company's plans and expectations regarding a pre-BLA meeting and the potential submission of one or two Biologics License Applications (BLA) for ersodetug for both of tumor HI and congenital HI in 2027; the potential safety, efficacy and therapeutic potential of ersodetug for treating refractory hypoglycemia caused by any form of HI. Our ability to predict results or the actual effects of our plans or strategies is inherently uncertain. With respect to congenital hyperinsulinism, although FDA has recommended that the Company file a BLA for review for congenital HI after holding a pre-BLA meeting, there can be no assurance that FDA will agree that the totality of evidence from the sunRIZE program demonstrates a clinically meaningful benefit or is sufficient to support approval of ersodetug for congenital HI. 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.

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