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# Rezolute Announces Completion of Enrollment in Phase 3 upLIFT Study of Ersodetug in Tumor Hyperinsulinism

*Topline results expected mid-December 2026*

REDWOOD CITY, Calif., Oct. 14, 2026 (GLOBE NEWSWIRE) -- **Rezolute, Inc. (Nasdaq: RZLT)** (Rezolute or Company), a late-stage ultra-rare disease company focused on treating refractory hypoglycemia caused by any form of hyperinsulinism (HI), today announced that the open-label Phase 3 study of ersodetug in tumor HI (upLIFT) is now fully enrolled and topline data are expected mid-December 2026. The Company plans to continue its expanded access program for purposes of providing ersodetug on a compassionate use basis to individuals living with serious and refractory hypoglycemia due to tumor HI.

The upLIFT study is a single-arm, open-label, registrational study in 16 participants with insulinoma or non-islet cell tumors who have uncontrolled hypoglycemia caused by tumor HI. The study's primary endpoint is the percent of participants who require intravenous glucose for refractory hypoglycemia that achieve at least a 50 percent reduction from baseline in glucose infusion rate (GIR) within the 8-week pivotal treatment phase. For statistical significance, the lower bound of the 95% confidence interval (CI) for the percent responder rate must be ≥30%, equating to a response rate of at least 56% (95% CI of 30-80%) for 16 participants.

Earlier this year, the Company announced that 7 of the 8 participants enrolled in the first half of the study met the responder criterion for the study's primary endpoint. Furthermore, each of these participants also achieved complete discontinuation of intravenous glucose with the administration of ersodetug. Ersodetug has been well-tolerated in the study thus far, with no drug-related safety findings reported. The eighth participant in the first half of the study elected to pursue hospice care at home shortly after enrollment, where they died one week later due to cancer progression. The Company considers this participant as a non-responder, for purposes of the primary endpoint.

"Completing enrollment in the upLIFT study marks an important milestone as we advance a potentially transformative treatment option for patients living with tumor hyperinsulinism," said Dr. Brian Roberts, Chief Medical Officer at Rezolute. "Now that we have a path forward for congenital hyperinsulinism, we look forward to announcing topline data from upLIFT and to the extent the study outcomes are favorable, the potential to advance both indications in 2027. We are deeply grateful to the patients, families, investigators and advocacy groups whose dedication and partnership have enabled us to reach this point."

**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 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 able to achieve at least a 50 percent reduction from baseline in IV glucose requirements (glucose infusion rate; GIR). Additional endpoints include the number of participants achieving discontinuation of GIR and time to discontinuation, 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 because of over-activation of the insulin receptor. Insulinomas are the most common type of ICT and cause hypoglycemia by stimulating 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) and 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 potential efficacy of ersodetug in treating hypoglycemia as well as our ability to announce upLIFT topline results this year. Further, even if the upLIFT study results meet the specified endpoint and the study is a success, there can be no assurance that regulatory authorities will ever approve ersodetug for the treatment of tumor or congenital hyperinsulinism. Our ability to predict results or our plans or strategies is inherently uncertain. 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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