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Rezolute Receives Breakthrough Therapy Designation from FDA for Ersodetug in the Treatment of Hypoglycemia Due to Tumor Hyperinsulinism

Registrational study in patients with tumor hyperinsulinism (HI) expected to commence mid-year

Designation underscores need for therapies to treat severe hypoglycemia in the oncology setting

REDWOOD CITY, Calif., May 05, 2025 (GLOBE NEWSWIRE) -- Rezolute, Inc. (Nasdaq: RZLT) ("Rezolute" or the "Company"), a late-stage rare disease company focused on treating hypoglycemia caused by HI, today announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation (BTD) to its investigational therapy, ersodetug, for the treatment of hypoglycemia caused by tumor HI.

BTD for ersodetug was granted based on clinical trial data across the overall program and a recognition of the mechanistic applicability to tumor HI, further validated by real-world experience in tumor HI patients who have been successfully treated with ersodetug throughout the U.S. in the Company's Expanded Access Program. BTD is intended to expedite the development and regulatory review of therapies for serious or life-threatening conditions where preliminary clinical evidence indicates the potential for substantial improvement over existing treatment options.

"This designation highlights FDA's recognition of ersodetug's potential therapeutic benefit in this life-threatening condition where the current standard of care is often insufficient to manage persistent hypoglycemia, particularly when it is refractory or an impediment to surgery or other tumor-directed therapies," said Nevan Charles Elam, Chief Executive Officer and Founder of Rezolute. "We believe that this is a validation of ersodetug's unique mechanism that enables the treatment of various forms of hyperinsulinism and the success that we have observed in treating patients with tumor HI over the last two years."

Rezolute plans to initiate a registrational study of ersodetug in patients with tumor HI in the middle of 2025, with topline results anticipated in the second half of 2026. In parallel and utilizing its BTD, the Company plans to engage further with FDA to discuss the registrational trial, including the necessary data package to support a BLA filing and potential approval for the tumor HI indication, as an expansion of the congenital HI indication.

Earlier this year, the Company announced that BTD was granted to ersodetug for the treatment of hypoglycemia caused by congenital HI, a separate late-stage program currently progressing in an ongoing Pase 3 clinical study.

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 excessive activation of the insulin receptor. Insulinomas are the most common type of ICT and may 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 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 preclinical studies have shown that ersodetug can similarly blunt IGF-2 and insulin-mediated insulin-receptor signaling.

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 shown substantial benefit in clinical trials and real-world use for the treatment of congenital HI 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 its authorized officers, may contain certain forward-looking statements regarding our prospective performance and within the meaning of Section 27A of the Securities Act of 1933, as amended, 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, statements regarding the ability of ersodetug to be an effective treatment for tumor HI as well as statements regarding the timing of the registrational study of ersodetug and the timing of topline results. 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 on the SEC's website at www.sec.gov. You are urged to consider these factors carefully by 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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