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Rezolute Receives Priority Medicines (PRIME) Eligibility from European Medicines Agency for Enhanced Regulatory Support of RZ358 in Congenital Hyperinsulinism

PRIME eligibility granted based on key positive data from the Phase 2b (RIZE) study and current unmet medical need in congenital hyperinsulinism

REDWOOD CITY, Calif., Oct. 17, 2023 (GLOBE NEWSWIRE) -- Rezolute, Inc. (Nasdaq: RZLT), a clinical-stage biopharmaceutical company committed to developing novel, transformative therapies for serious metabolic and rare diseases, today announced that the European Medicines Agency (EMA) has granted Priority Medicines (PRIME) eligibility to RZ358 for the treatment of congenital hyperinsulinism (HI).

PRIME eligibility is granted by EMA to drug candidates that target an unmet medical need and show potential benefit for patients based on clinical trial results. The PRIME initiative was created to provide proactive and enhanced support to developers of promising medicines to optimize development plans and accelerate evaluation with the goal of having new therapies reach patients faster. With respect to congenital HI, EMA has stated that there is an unmet medical need with no specifically authorized therapeutics available for the condition and that there are significant short-term and long-term risks, which are consequences of severe hypoglycemia.

“We are excited to receive PRIME eligibility for RZ358, especially as we plan to initiate our Phase 3 study for RZ358 this quarter,” remarked Susan Stewart, JD, Chief Regulatory Officer at Rezolute. “We are appreciative that the EMA recognizes the devastating nature of the disease and the potential for RZ358 to have a significant positive impact on clinical outcomes for patients and their families.”

PRIME eligibility was granted based on data from the RIZE study in congenital HI, which safely demonstrated significant improvements in hypoglycemia events and time, with average improvements of approximately 75% at the intended Phase 3 doses. Glucose improvements were independent of age, with a similar magnitude in the patient age groups of 2-6 years old, 6-12 years old, and > 12 years old.

About Congenital HI
Congenital HI is the most common cause of recurrent and persistent hypoglycemia in children. Patients with congenital HI typically present with signs or symptoms of

hypoglycemia within the first month of life. These episodes can result in significant brain injury and death if not recognized and managed appropriately. Additionally, recurrent, or cumulative, hypoglycemia can lead to progressive and irreversible damage over time, including serious and devastating brain injury, seizures, neuro-developmental problems, feeding difficulties, and significant impact on patient and family quality of life. In cases of congenital HI that are unresponsive to medical management, surgical removal of the pancreas may be required. In those with diffuse congenital HI where the whole pancreas is affected, a near-total pancreatectomy can be undertaken, although about half of these children will continue to have hypoglycemia and require medical treatment for congenital HI.

About RZ358

RZ358 is a fully human monoclonal antibody that works downstream from the pancreas and instead binds to a unique allosteric site on insulin receptors in the liver, fat, and muscle. The antibody counteracts the effects of elevated insulin in the body by modulating insulin's binding, signaling, and activity to restore glucose levels to a normal range. Rezolute believes that RZ358 is ideally suited as a potential therapy for congenital HI and other conditions characterized by excessive insulin levels. Because RZ358 acts downstream from the pancreas, it has the potential to be universally effective at treating congenital HI, regardless of the causative genetic defect, as well as acquired forms of HI such as those mediated by insulinomas and other tumor types. RZ358 received Orphan Drug Designation in the United States and European Union for the treatment of congenital HI, as well as Pediatric Rare Disease Designation in the US.

About Rezolute, Inc.

Rezolute strives to disrupt current treatment paradigms by developing transformative therapies for devastating rare and chronic metabolic diseases. Its novel therapies hold the potential to both significantly improve outcomes and reduce the treatment burden for patients, treating physicians, and the healthcare system. Rezolute is steadfast in its mission to create profound, positive, and lasting impacts on patients' lives. Patient, clinician, and advocate voices are integrated in the Company's drug development process. Rezolute places an emphasis on understanding the patient's lived experiences, enabling the Company to boldly address a range of severe conditions. In addition to RZ358 for the treatment of congenital HI, Rezolute is also developing RZ402, an orally available plasma kallikrein inhibitor, for the treatment of diabetic macular edema. 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 and statements regarding

PRIME designation and the designation's meaning on the ability of RZ358 to become an effective treatment to congenital HI, the effectiveness or future effectiveness of RZ358 for the treatment of congenital HI, and statements regarding clinical trial timelines for RZ358. 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 the Rezolute's Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, which are available at the SEC'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.

Investors:
Stephanie Carrington
ICR Westwicke
RezoluteIR@westwicke.com
(646)277-1282

Media:
media-relations@rezolutebio.com

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