January 23, 2024

Rezolute Receives Innovation Passport Designation from the U.K. Innovative Licensing and Access Pathway Steering Group for RZ358 in the Treatment of Hypoglycemia Due to Congenital Hyperinsulinism

REDWOOD CITY, Calif., Jan. 23, 2024 (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 U.K. Medicines and Healthcare products Regulatory Agency (MHRA) has awarded the innovative medicine designation, the Innovation Passport, to RZ358 for the treatment of hypoglycemia due to congenital hyperinsulinism (HI). The Innovation Passport designation was granted based on the substantial unmet medical need in this condition and the potential for RZ358 to benefit patients as evidenced by the Phase 2 RIZE study in congenital HI, which safely demonstrated significant improvements in hypoglycemia events.

The Innovation Passport designation in the U.K. is the entry point to the Innovative Licensing and Access Pathway (ILAP). The goal of ILAP is to accelerate the time to market and facilitate patient access to medicines. The Innovation Passport is the first step in the ILAP process, which activates the Medicines and Healthcare products Regulatory Agency (MHRA) and its partner agencies, including the National Institute for Health and Care Excellence (NICE), and the Scottish Medicines Consortium (SMC).

“Congenital hyperinsulinism is the most frequent cause of severe, persistent hypoglycemia in newborn babies, infants and children,” said Susan Stewart, J.D., Chief Regulatory Officer at Rezolute. “The Innovation Passport opens the door for Rezolute to discuss access considerations for potential future indications for RZ358. We are thrilled to receive this designation and work closely with the U.K. and other regulatory authorities to bring this meaningful therapy to patients in need.”

About Congenital Hyperinsulinism
Congenital hyperinsulinism (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 excess insulin binding and activity, thereby improving hypoglycemia. Rezolute believes that RZ358 is ideally suited as a potential therapy for congenital HI and other conditions characterized by excessive insulin activity (hyperinsulinism). 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 U.S. In the Phase 2 RIZE study, participants with congenital HI ages 2 and older nearly universally achieved significant improvements in hypoglycemia across multiple endpoints, including the primary and key secondary endpoints planned for the sunRIZE study. At doses and exposures that are planned for the Phase 3 study, RZ358 was generally safe and well-tolerated, and resulted in median improvements in hypoglycemia exceeding 80%. Based on the RIZE clinical trial outcomes and the evidence of benefit in this serious condition with substantial unmet medical need, RZ358 was subsequently granted a priority medicines (PRIME) designation by the European Medicines Agency (EMA) and an Innovation Passport designation by the U.K. Innovative Licensing and Access Pathway (ILAP) Steering Group for the treatment of congenital HI.

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. 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 statements regarding the Innovation Passport designation, the PRIME designation and the meaning of the designations on the ability of RZ358 to become an effective treatment for congenital hyperinsulinism, the effectiveness or future effectiveness of RZ358 for the treatment of congenital hyperinsulinism, 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 & Media:
Christen Baglaneas
Rezolute, Inc.
cbaglaneas@rezolutebio.com
(508)272-6717

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

Source: Rezolute, Inc.