August 5, 2024

Rezolute Announces FDA Clearance of IND Application for Phase 3 Registrational Study of RZ358 for Treatment of Hypoglycemia Due to Tumor Hyperinsulinism

Second rare disease program with RZ358 in Phase 3 development

Follows successful treatment of multiple patients with tumor hyperinsulinism under the Company's Expanded Access Program

REDWOOD CITY, Calif., Aug. 05, 2024 (GLOBE NEWSWIRE) -- Rezolute, Inc. (Nasdaq: RZLT) ("Rezolute" or the "Company"), a late-stage biopharmaceutical company committed to developing novel, transformative therapies for serious rare diseases, today announced that it received U.S. Food and Drug Administration (FDA) clearance for its Investigational New Drug (IND) application for RZ358 (ersodetug) to treat hypoglycemia in patients with tumor hyperinsulinism (HI). The Company is initiating start-up activities for the study which will be primarily conducted in the U.S. and patient enrollment is planned to commence in the first half of 2025. Ersodetug is also being studied in an ongoing global, pivotal, Phase 3 clinical trial in patients with congenital HI. Topline data from that study is expected in mid-2025.

"Hypoglycemia associated with tumor HI requires treatment to prevent serious adverse outcomes and to improve patients' daily function and quality of life, including enabling them to receive tumor directed therapies," said Brian Roberts, M.D., Chief Medical Officer at Rezolute. "We are encouraged by the substantial real-world benefit we've witnessed in tumor HI patients who have previously received ersodetug in our Expanded Access Program, coupled with the safety and efficacy demonstrated in clinical studies in patients with congenital HI, a similar condition. We believe that the clearance of our IND for this Phase 3 study reflects FDA's recognition of the potential for ersodetug to address this serious unmet need and we are excited to be moving one step closer to a potential universal treatment for hypoglycemia caused by all forms of HI."

The Phase 3 registrational study is a double-blind, randomized, placebo-controlled trial of 24 participants who have inadequately controlled hypoglycemia because of tumor HI. Eligible participants will be randomized in 1:1 fashion (12 per treatment arm) to receive ersodetug 9 mg/kg per week or matched placebo, as an add-on to standard of care. Up to 24 additional participants may be enrolled into an open-label arm, in participants whose hypoglycemia is being managed by IV glucose in a hospital setting. Following a 6-week pivotal treatment period, all participants may receive ersodetug in open-label extension. The primary endpoint is the change in Level 2 (moderate) and Level 3 (severe) hypoglycemia events by self-

monitored blood glucose. Additional endpoints include overall hypoglycemia events, time in hypoglycemia by continuous glucose monitor, patient reported quality of life, hospitalizations, and change in glucose requirements (for open-label hospitalized participants).

Ersodetug is a fully human monoclonal antibody that binds to an allosteric site on the insulin receptor at target tissues such as liver, fat and muscle. Ersodetug counteracts excess insulin receptor activation caused by insulin and related hormones thereby correcting hypoglycemia. Ersodetug has the potential to be universally effective at treating hypoglycemia caused by any form of HI, including congenital or acquired forms.

About Tumor Hyperinsulinism (HI)

Tumor 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 Rezolute, Inc.

Rezolute is a late-stage rare disease company focused on significantly improving outcomes for individuals with hypoglycemia caused by 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.

Forward-Looking Statements

Any statements in this press release about the Company's future expectations, plans and prospects, including statements regarding the public offering, constitute forward-looking statements for purposes of the safe harbor provisions under the Private Securities Litigation Reform Act of 1995. Forward-looking statements include any statements about the Company's strategy, future operations and future expectations and plans and prospects for the Company, and any other statements containing the words "anticipate," "believe," "estimate," "expect," "intend", "goal," "may", "might," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions. These forward-looking statements include statements about the RZ358 Expanded Access Program, the Investigational New Drug (IND) application for RZ358, the ability of the U.S. Ersodetug to become an effective treatment for congenital hyperinsulinism, the effectiveness or future effectiveness of the U.S. Ersodetug to become an effective treatment for congenital hyperinsulinism, and statements regarding clinical trial timelines for RZ358. These forward-looking statements are based on information currently available to the Company and its current plans or expectations, and are subject to a number of uncertainties and risks that could significantly affect current plans. Such forward-looking statements involve substantial risks and uncertainties that could cause the Company's development programs, future

results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, those related to market and other financial conditions, the potential completion of the public offering, satisfaction of customary closing conditions related to the public offering and other factors discussed in the “Risk Factors” section contained in the preliminary prospectus supplement and the reports that the Company files with the SEC. Any forward-looking statements represent the Company’s views only as of the date of this press release. The Company anticipates that subsequent events and developments will cause its views to change. While the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so except as required by law.

Contacts:

Rezolute, Inc.
Christen Baglaneas
cbaglaneas@rezolutebio.com
508-272-6717

LHA Investor Relations
Tirth T. Patel
tpatel@lhai.com
212-201-6614

Source: Rezolute, Inc.