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Rezolute Announces Initiation of Dosing in the Second Cohort of its Phase 2b Trial of RZ358 for Congenital Hyperinsulinism

Tracking to Announce Top line data in Q1 2022

REDWOOD CITY, Calif., Sept. 09, 2021 (GLOBE NEWSWIRE) -- **Rezolute, Inc.** (Nasdaq: RZLT), a clinical-stage biopharmaceutical company developing transformative therapies for metabolic diseases associated with chronic glucose imbalance, today announced that it has begun dosing patients in the second cohort of its Phase 2b clinical trial of RZ358 (RIZE). RZ358 is a monoclonal antibody targeting the treatment of hypoglycemia caused by excessive insulin levels and is currently in clinical development for congenital hyperinsulinism (HI), a rare pediatric endocrine disorder.

Rezolute reported that a dose escalation review committee, comprised of HI expert investigators, voted to approve dose escalation and initiation of cohort 2 (6 mg/kg), based on their interim review of safety data from Cohort 1 (3 mg/kg). Following completion of the second cohort, the company plans to initiate a third and likely final cohort at 9 mg/kg.

“We are making great strides with the RIZE study and based on our recent clinical trial activity, we are tracking toward the original timeline we laid out prior to the COVID-19 pandemic. In that regard, we are expecting to substantially complete enrollment by the end of 2021 and have top-line data in Q1 of 2022,” said Brian Roberts, MD, Senior Vice President and Head of Clinical Development at Rezolute. “We will continue to monitor the evolution of the pandemic, including the impact of the Delta variant, which could alter our ability to screen and enroll patients in a timely fashion.”

Rezolute also announced the addition of Adrian Vella, MD, Professor of Medicine in the Endocrinology Division at the Mayo Clinic College of Medicine, to the Company’s Scientific Advisory Board. Dr. Vella is a leading expert in hypoglycemic disorders and will provide guidance on the development of RZ358.

Dr. Roberts noted, “We are pleased to welcome Dr. Vella to our Scientific Advisory Board. Given his background and knowledge of RZ358, he will be extremely valuable to Rezolute as we advance the development of RZ358 for HI and evaluate the possibility of expanding into other related and applicable indications.”

Dr. Vella is a Professor of Medicine in the Mayo Clinic College of Medicine and has published over 160 peer reviewed articles related to endocrinology, metabolic disorders, and diabetes. He is regularly the lead author or editor on evidence-based reviews of hyperinsulinism and hypoglycemia.

About RIZE (RZ358-606)

The open-label, repeat-dose Phase 2b study is designed to assess the safety and tolerability of intravenously administered RZ358 in patients with congenital hyperinsulinism inadequately controlled on existing therapies. The Company intends to enroll up to four sequential dosing cohorts, each with up to six to eight patients, starting at a dose of 3 mg/kg and increasing to as high as 9 mg/kg in the final cohort, as needed and tolerated. RZ358 will be administered bi-weekly for a total treatment duration of 8 weeks. The study is being conducted at leading HI centers by Rezolute and its global study partners.

About RZ358

RZ358 is an intravenously administered human monoclonal antibody that binds to a unique site (allosteric) on the insulin receptor throughout the body, such as in the liver, fat, and muscle. The antibody modifies insulin's binding and signaling to maintain glucose levels in a normal range which counteracts the effects of elevated insulin in the body. Therefore, the company believes that RZ358 is ideally suited as a potential therapy for conditions characterized by excessive insulin levels, and it is being developed to treat the hyperinsulinism and low blood sugar characteristic of diseases such as congenital HI. As RZ358 acts downstream from the beta cells, it has the potential to be universally effective at treating congenital HI caused by any of the underlying genetic defects.

RZ358 received Orphan Drug Designation in the United States and European Union as well as Pediatric Rare Disease Designation in the US. Rezolute is currently evaluating RZ358 in the RIZE trial, a Phase 2b clinical trial in patients with congenital hyperinsulinism.

About Rezolute, Inc.

Rezolute is developing transformative therapies for metabolic diseases related to chronic glucose imbalance. The Company’s lead clinical asset, RZ358, is in Phase 2b development for treatment of congenital hyperinsulinism (HI), a rare pediatric endocrine disorder. The Company is also developing RZ402, an orally available plasma kallikrein inhibitor, for the treatment of diabetic macular edema. For more information, visit www.rezolutebio.com or follow us on Twitter.

Forward-Looking Statements

This release, like many written and oral communications presented by Rezolute, Inc. 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 the Company, 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. 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.

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