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Rezolute Initiates Phase 2b Clinical Trial of Lead Candidate RZ358 in Congenital Hyperinsulinism

REDWOOD CITY, Calif., Feb. 10, 2020 (GLOBE NEWSWIRE) -- **Rezolute, Inc. (“Rezolute” or “the Company”)** (OTCQB:RZLT), today announced the initiation of the RIZE study (RZ358-606), a Phase 2b clinical trial of its lead candidate, RZ358, in patients with congenital hyperinsulinism (CHI). The Company has screened the first patient and expects to make significant enrollment progress to enable attainment of mid-study results over the coming year.

“Congenital hyperinsulinism is the most common cause of persistent low blood sugars in infants and children and often leads to serious neurologic complications,” said Brian Roberts, M.D., head of clinical development at Rezolute. “Given that existing medical or surgical therapies are often ineffective or have significant side effects or long term risks, the availability of a safe and effective treatment option could have a profound impact for patients and families living with CHI, by relieving the fear of dangerously low blood sugars. This study will provide additional insights and build on the favorable results already demonstrated in earlier clinical trials evaluating RZ358 in patients with this rare disease.”

This multi-center, open-label, repeat-dose study will assess the safety, tolerability and efficacy of RZ358 in patients who are at least two years old with CHI and who have residual hypoglycemia that is inadequately controlled on existing therapies. In addition to safety and pharmacokinetic evaluations, continuous glucose monitoring and self-monitored blood glucose will be utilized to evaluate several glycemic efficacy endpoints.

About Congenital Hyperinsulinism
Congenital hyperinsulinism is a rare, genetic, pediatric endocrine disorder that leads to the inappropriate secretion of the hormone insulin by the pancreas. High levels of insulin in the blood result in episodes of low blood sugar or hypoglycemia with associated suppression of ketone bodies, the only other potential source of fuel to the glucose-dependent brain. Repeat episodes and/or dangerously low blood sugars increase the risk of neurological and developmental complications, including persistent feeding problems, learning disabilities, recurrent seizures, and/or brain damage, or even death. Existing medical options were not developed for CHI and are often either ineffective since certain groups of patients do not respond to these therapies, or are associated with substantial side effects that discourage compliance and lead to suboptimal treatment outcomes. Surgical removal of the pancreas is also an option, but this approach is invasive, may require repeat surgery, and ultimately leads to the development of lifelong insulin-dependent diabetes.

About RZ358
RZ358 is an intravenously administered human monoclonal antibody that binds with high potency and selectivity to an allosteric site on the insulin receptor. RZ358 counteracts the effects of elevated insulin at its target tissues by diminishing the binding and downstream signaling of insulin at its receptor. This unique mechanism of action gives properties of reversibility and graded activity, which are dependent on the extent of insulin elevation. Therefore, RZ358 is ideally suited as a potential therapy for hyperinsulinism, and it is being developed to treat the hypoglycemia associated with diseases such as CHI.

RZ358 received Orphan Drug Designation in the United States and European Union. Rezolute is currently evaluating RZ358 in the RIZE trial, a Phase 2b clinical trial in patients with CHI.

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 CHI inadequately controlled on existing therapies. The Company intends to enroll four sequential dosing cohorts, each with six to eight patients, starting at a dose of 3 mg/kg and increasing to as high as 12 mg/kg in the final cohort, as needed and tolerated. RZ358 will be administered weekly for the first month and then bi-weekly for the second month, for a total treatment duration of 8 weeks. The study is being conducted at leading CHI centers by Rezolute and its global study partners.

For more information, please visit: https://www.clinicaltrialsregister.eu/ctr-search/search?query=RZ358-606.

About Rezolute, Inc.
Rezolute is advancing targeted therapies for rare, metabolic, and life-threatening diseases. Its lead clinical asset,

RZ358, is in Phase 2b development as a potential treatment for CHI, a rare pediatric endocrine disorder. Its pipeline also includes RZ402, an orally-available plasma kallikrein inhibitor in late-stage preclinical development for the treatment of diabetic macular edema, which is expected to enter clinical trials in 2H, 2020 . 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 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 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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