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Rezolute Receives Rare Pediatric Disease Designation for RZ358, Phase 2b Candidate for the Treatment of Congenital Hyperinsulinism, Enabling Eligibility for Priority Review Voucher

REDWOOD CITY, Calif., June 10, 2020 (GLOBE NEWSWIRE) -- **Rezolute, Inc. ("Rezolute" or "the Company")** (OCTQB:RZLT), today announced that the company has received rare pediatric disease designation (RPD) from the Food and Drug Administration (FDA) for RZ358, a potential treatment for congenital hyperinsulinism (HI) that is currently being evaluated in a global Phase 2b study.

According to an FDA Guidance for Industry document (July 2019) concerning the incentive program for rare pediatric diseases, Rezolute now qualifies to be eligible for a Rare Pediatric Disease Priority Review Voucher as the sponsor of RZ358. Following an approval of RZ358 for congenital HI in pediatrics, such a voucher could be redeemed to receive a priority review of a subsequent marketing application.

"If we are successful at obtaining final approval for RZ358, we may obtain a valuable and transferable priority review designation for any subsequent marketing application that Rezolute could choose to utilize in the best interest of its shareholders," said Nevan Elam, J.D., chief executive officer of Rezolute. "As there is currently no approved therapy with a label indication specifically for congenital hyperinsulinism, patients typically rely on treatments that are not optimal for the disorder. As a result, patients often experience serious side effects or limited drug efficacy. RZ358 is designed to restore healthy levels of insulin action in congenital HI for patients of any age – including children."

RZ358 is a monoclonal antibody designed specifically to address congenital HI, an ultra-rare genetic endocrine disorder that appears in 1 in 25,000 to 1 in 50,000 live births in many populations. Congenital HI is characterized by excess insulin secretion, which causes repeated episodes of low blood sugar, or hypoglycemia. The condition often goes unnoticed in infants, putting them at risk of complications of recurring hypoglycemic events, including developmental delays, seizures, coma and death.

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 congenital hyperinsulinism, 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 the Company intends to advance into

clinical trials after the IND has been filed. For more information, visit www.rezolutebio.com or follow us on Twitter.

About Congenital Hyperinsulinism
Congenital hyperinsulinism (HI) 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 congenital HI 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 congenital HI.

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 congenital HI.

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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