

May 28, 2020



# Rezolute to Present Clinical Data for RZ358, Lead Candidate in Phase 2b Trial in Congenital Hyperinsulinism at Virtual Pediatric Endocrine Society 2020 Annual Meeting

REDWOOD CITY, Calif., May 28, 2020 (GLOBE NEWSWIRE) -- **Rezolute, Inc. (“Rezolute” or “the Company”)** (OTCQB:RZLT), today announced an upcoming oral presentation at this year’s Pediatric Endocrine Society meeting, which will be held virtually.

Details of the presentation are as follows:

**Title:** Single Dose Studies of RZ358 in Patients with Congenital Hyperinsulinism: Results of Population PK/PD Modeling and Simulation in Adult and Pediatric Patients

**Presenter:** Brian Roberts, M.D., Rezolute head of clinical development

**Date/Time:** Saturday, May 30, 2020, noon – 1:30 p.m. ET

## **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 the Company intends to advance into clinical trials after the IND has been filed. For more information, visit [www.rezolutebio.com](http://www.rezolutebio.com) or follow us on Twitter.

## **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.

### **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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