

June 27, 2023



Rezolute to Initiate a Pivotal Phase 3 Study of RZ358 in Participants 3 Months of Age and Older with Congenital Hyperinsulinism

Study to be initiated in Europe and other ex-US geographies in Q4 2023, with topline results expected 1H 2025

Conference call scheduled today at 4:30 p.m. ET

REDWOOD CITY, Calif., June 27, 2023 (GLOBE NEWSWIRE) -- [Rezolute, Inc.](#) (Nasdaq: RZLT), a clinical-stage biopharmaceutical company dedicated to developing transformative therapies with the potential to disrupt current treatment paradigms for devastating metabolic diseases, today provided an update on its clinical development plans for RZ358, the Company's product candidate for congenital hyperinsulinism (congenital HI). Rezolute plans to initiate sunRIZE, a pivotal Phase 3 clinical study of RZ358, in Europe and other geographies outside the US in Q4 2023, with topline results anticipated in the first half of 2025. The sunRIZE study is a randomized, double-blind, placebo-controlled, parallel arm evaluation of RZ358 in participants with congenital HI who are not adequately responding to standard of care medical therapies. The Phase 3 study follows the Company's successful Phase 2b RIZE study which demonstrated that RZ358 was generally safe and well-tolerated, as well as effective in improving hypoglycemia in participants who were failing available medical therapies.

The Company has concluded its pre-Phase 3 regulatory and scientific advice meetings with European health authorities and has reached agreement on the sunRIZE study design, that will include participants 3 months of age and older. In the US, the Company has had similar interactions with the US Food and Drug Administration (FDA) culminating in a meeting held with the agency on May 24, 2023, and FDA has maintained an existing age restriction of 12 years and older on RZ358 clinical studies and implemented dose level restrictions for RZ358 based on historical rat toxicology findings. The FDA restrictions make it infeasible to include the US in the sunRIZE study at this time, particularly given that the pediatric population with congenital HI has the greatest therapeutic need. The Company is evaluating potential nonclinical studies to address FDA's concerns in parallel with the initiation and advancement of sunRIZE outside of the US.

Nevan Charles Elam, Rezolute's Founder and Chief Executive Officer, stated, "We believe that RZ358 has tremendous potential to fulfill a significant unmet need for patients and families living with congenital HI around the world and we are delighted to have alignment for sunRIZE with regulators outside of the US. We believe that there may be a path forward to address FDA's nonclinical concerns and ensure that patients in the US have access to RZ358 should the therapy continue to demonstrate good safety and efficacy and be eligible for regulatory approval."

More information on sunRIZE and related regulatory interactions can be found in a filing made today on Form 8-K filed with the US Securities and Exchange Commission.

Conference Call Information

Rezolute will host a conference call today, June 27, 2023, at 4:30 p.m. EDT. To access the conference call, dial 1-877-270-2148 from the U.S. and Canada or 1-412-902-6510 internationally and ask to be joined into the Rezolute call. The live audio webcast of the call will be available under "Events" in the Investor section of the Company's website at <https://ir.rezolutebio.com/news-events/ir-calendar>.

About Congenital Hyperinsulinism (HI)

Congenital HI is the most common cause of recurrent and persistent hypoglycemia in children. Patients with congenital HI typically present with signs or symptoms of hypoglycemia within the first month of life. These episodes can result in significant brain injury and death if not recognized and managed appropriately. Additionally, recurrent, or cumulative, hypoglycemia can lead to progressive and irreversible damage over time, including serious and devastating brain injury, seizures, neuro-developmental problems, feeding difficulties, and significant impact on patient and family quality of life. The two most commonly used long-term medications, diazoxide and somatostatin analogs, are not Food and Drug Administration (FDA) approved for all forms of this condition and often are ineffective or have intolerable side effects. In cases of congenital HI that are unresponsive to medical management, surgical removal of the pancreas may be required. In those with diffuse congenital HI where the whole pancreas is affected, a near-total pancreatectomy can be undertaken, although about half of these children will continue to have hypoglycemia and require medical treatment for congenital HI.

About RZ358

RZ358 is a human monoclonal antibody that binds to a unique allosteric site on insulin receptors in the liver, fat, and muscle. The antibody counteracts the effects of elevated insulin in the body by modifying insulin's binding, signaling, and activity to maintain glucose levels in a normal range. Rezolute believes that RZ358 is ideally suited as a potential therapy for congenital hyperinsulinism (HI) and other conditions characterized by excessive insulin levels. As RZ358 acts downstream from the beta cells, it has the potential to be universally effective at treating congenital HI, regardless of the causative genetic defect. RZ358 received Orphan Drug Designation in the United States and European Union as well as Pediatric Rare Disease Designation in the US.

About Rezolute, Inc.

Rezolute strives to disrupt current treatment paradigms by developing transformative therapies for devastating rare and chronic metabolic diseases. Its novel therapies hold the potential to both significantly improve outcomes and reduce the treatment burden for patients, the treating physician, and the healthcare system. Patient, clinician, and advocate voices are integrated in the Company's drug development process, enabling Rezolute to boldly address a range of severe conditions. Rezolute is steadfast in its mission to create profound, positive, and lasting impact on patients' lives. The Company's lead clinical asset, RZ358, is in late-stage development for the treatment of congenital hyperinsulinism, a rare pediatric endocrine disorder. Rezolute 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 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 Rezolute, 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. These forward-looking statements include, but are not limited to, statements regarding future events and results, clinical study plans and the locations of such clinical studies, the timing of the release of Phase 3 clinical study results, our ability to address FDA's concerns through additional nonclinical studies, our ability to conduct the Phase 3 study in Europe and throughout the world, the effectiveness or future effectiveness of RZ358. 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. Important factors that may cause such a difference include any other factors discussed in Rezolute's filings with the SEC, including the Risk Factors contained in the Rezolute's Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, which are available at the SEC's website at www.sec.gov. You are urged to consider these factors carefully in evaluating the forward-looking statements in this release and are cautioned not to place undue reliance on such forward-looking statements, which are qualified in their entirety by this cautionary statement.

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