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Rezolute KOL Event Highlights Significant Unmet Medical Need in Diabetic Macular Edema

RZ402 is an oral therapy being developed as a potential alternative to anti-vascular growth factor (anti-VEGF) injections into the eye

REDWOOD CITY, Calif., March 23, 2023 (GLOBE NEWSWIRE) -- Rezolute, Inc. (Nasdaq: RZLT), a clinical-stage biopharmaceutical company dedicated to developing transformative therapies with the potential to shift the treatment paradigms of devastating metabolic diseases, yesterday hosted a virtual key opinion leader (KOL) event focused on the therapeutic landscape of Diabetic Macular Edema (DME), scientific rationale for an oral plasma kallikrein inhibitor (PKI) to target the disease, and the potential of RZ402, the company's oral PKI, to change the standard of care as a safe, effective, and less invasive treatment option.

"We were honored to have Robert Bhisitkul, MD, PhD, yesterday to share his insights for RZ402 and the current treatment landscape for DME from his perspective as a practicing physician and retina specialist," said Nevan Charles Elam, Chief Executive Officer and Founder of Rezolute. "The frequency of intravitreal therapeutic injections for diseases like DME prove to be a heavy burden on not only the patient, but the physicians who can't maintain pace with the treatment regimens. Dr. Bhisitkul's view on the unmet medical need for an oral treatment option for DME that can improve patient compliance and begin treatment earlier in the course of the disease supports development of RZ402 as a first-line monotherapy."

"The current clinical treatments of DME, especially treatment regimens utilizing anti-VEGF drugs and second-line steroid treatments, are encumbered with limitations and present an opportunity for RZ402 to truly change the standard of care," said Dr. Bhisitkul. "I am excited by the potential of RZ402 to be deployed early in disease state and prevent disease progression in patients with DME though its broad spectrum of anti-inflammation and anti-leakage mechanism of actions. An oral alternative to intravitreal injections may reduce or eliminate the need for anti-VEGF injections, expanding the treatment population while simultaneously reducing the treatment burden on the clinic."

In December 2022, Rezolute announced the initiation of a Phase 2 study of RZ402 in patients with DME. The Phase 2 study is a multi-center, randomized, double-masked, placebo-controlled, parallel-arm study to evaluate the safety, efficacy, and pharmacokinetics of RZ402 administered as a monotherapy over a 12-week treatment period in participants with DME who are naïve to or have received limited anti-VEGF injections. Top line results for the Phase 2 study are anticipated in the first quarter of 2024.

A replay of the presentation and event is accessible on the News & Events section of the company's investor relations website at ir.rezolutebio.com/news-events.

About Diabetic Macular Edema (DME)

Diabetic retinopathy (DR) affects approximately one third of adults with diabetes and can frequently lead to DME, a severe vision-threatening complication of DR characterized by swelling of the retina and thickening of the macula, the part of the eye that is responsible for high-resolution vision. More than a million people currently suffer from DME in the U.S., and this number continues to increase due to the epidemic of diabetes, making it the leading cause of blindness in adults. Anti-vascular growth factor (anti-VEGF) injections into the eye are the current standard of care for DME, requiring repeated administration over recurring periods of time to preserve vision. Due to their invasive route of administration and occasional serious side effects, there is a tendency to delay treatment until later in the disease course, and long-term compliance with eye injection regimens can be difficult for patients. Coupled with inadequate responsiveness in some patients, this leads to overall undertreatment and suboptimal vision outcomes in DME patients.

About RZ402

RZ402 is a selective and potent PKI being developed as a potential once-daily oral therapy for the chronic treatment of DME. By inhibiting the formation of kallikrein, RZ402 is designed to block downstream bradykinin production and the pro-inflammatory, pro-coagulant and fluid leaking contact-activation cascade.

Results from the Phase 1b multiple ascending dose (MAD) study showed that RZ402 was readily bioavailable with dose-dependent increases in systemic exposures. Results at both peak and 24-hour trough substantially exceeded target concentrations based on a combination of in-vitro and in-vivo profiling. RZ402 was generally safe and well-tolerated, including at higher doses than previously tested in the single ascending dose (SAD) study. There were no serious adverse events, adverse drug reactions, or identified risks.

RZ402 has been shown to improve retinal vascular leakage in animal models by up to 90%.

About the Contact Activation Kallikrein-Kinin System

The contact-activation kallikrein-kinin system promotes increased vascular permeability and inflammation via key downstream mediators, including bradykinin, and activation of the intrinsic pathway of coagulation. The pathophysiologic upregulation of this system has been linked to a variety of diseases which are characterized by vascular dysfunction, including diabetic macular edema.

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. 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.

Investor:

Kimberly Minarovich/Jillian Augustine
Argot Partners
rezolute@argotpartners.com
212-600-1902

Media:

Ingrid Mezo
Canale Communications, Inc.
ingrid.mezo@canalecomm.com
301-473-2881

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