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Rezolute Announces Publication of RZ402 Data in Diabetic Macular Edema (DME) in Investigative Ophthalmology & Visual Science

REDWOOD CITY, Calif., June 15, 2020 (GLOBE NEWSWIRE) -- **Rezolute, Inc. ("Rezolute" or "the Company")** (OCTQB:RZLT), announced that the company's abstract accepted to the virtual Association for Research in Vision and Ophthalmology (ARVO) 2020 meeting, titled "Nonclinical safety and pharmacology of RZ402, a plasma kallikrein inhibitor, for the treatment of diabetic macular edema as a daily oral therapy," was published in the peer-reviewed journal *Investigative Ophthalmology & Visual Science.*

"In people with diabetes, localized activation of the kallikrein/kinin pathway in the eye may increase vascular permeability and fluid leakage. That leakage may lead to swelling, or edema, of the macula, which in turn may cause vision loss or even total blindness," said Sankaram Mantripragada, Ph.D., Rezolute's chief scientific officer. "Small molecule RZ402 inhibits the action of that kallikrein pathway, potentially offering the means to clinical treatment objectives including edema reduction and improved visual acuity in people with DME. We have found in relevant animal models that RZ402 demonstrates an excellent safety profile in both single- and repeat-dosing settings at a range of doses. Importantly, exposure-dependent plasma levels of the drug are consistent with once-daily oral dosing, an encouraging signal as we plan clinical trials."

Highlighted results of RZ402 single and repeat oral dosing studies in rats and cynomolgus monkeys include the following:

- RZ402 demonstrated an excellent ADME (absorption, distribution, metabolism and excretion) profile, with moderate renal clearance
- Plasma levels of RZ402 remained above EC_{50} for 24 hours after dosing, consistent with a daily oral dose regimen
- No adverse effects were seen in rat models after repeat-dose administration at over 500-fold excess dosing (up to 1,000 mg/kg) for 7 days
- No adverse effects were seen in respiratory or central nervous system safety pharmacology studies (up to 1,000 mg/kg) in rats or in cardiovascular safety studies (up to 400 mg/kg) in monkeys
- Dose-proportional exposure up to 800 mg/kg in monkeys

"As a prevalent complication of diabetes, DME threatens vision in 1 to 2 million patients in the United States alone," said Nevan Elam, CEO of Rezolute. "Up to half of those patients respond sub-optimally to standard-of-care anti-VEGF therapy, which requires direct injections into the eye. A plasma kallikrein therapy, by targeting a different mechanism of

DME, may improve outcomes for patients whose inadequate responses are rooted in physiology. For patients who struggle with reliance on frequent injections, an oral therapy stands to improve comfort and convenience. RZ402 potentially offers both of those features, which could meaningfully change patient experience in their aim to protect their vision."

The abstract is available here.

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.

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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