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Rezolute, Inc. Provides Updates in the Context of the COVID-19 Pandemic: Announces Resumption and US-Expansion of its Phase 2b Study in Congenital Hyperinsulinism

REDWOOD CITY, California, July 27, 2020 (GLOBE NEWSWIRE) -- Rezolute, Inc. ("Rezolute" or "the Company") (OTCQB:RZLT), today provided an update on the status of the Company's clinical programs in the context of the global COVID-19 pandemic ("Pandemic"), including its Phase 2b study for RZ358 ("RIZE") in congenital hyperinsulinism ("CHI") patients as well as a Phase 1 study for RZ402 in healthy volunteers.

In the Company's quarterly report filed on Form 10-Q with the US Securities and Exchange Commission in May 2020 ("10-Q"), the Company reported that, as a result of the Pandemic, it paused the RIZE study after enrollment of the first patient. The study is being conducted globally at multiple study centers and as the Pandemic abates in different regions, the Company is resuming clinical activities including trial site initiations. The Company believes that patient enrollment will recommence by the end of September 2020. Further, as reported in the 10-Q, the Company believes that it will be able to complete the RIZE study in the second half of 2021.

In addition, in the first half of 2020, the Company had positive interactions with the US Food and Drug Administration ("FDA"). In June 2020, the Company announced that FDA granted Rezolute a Rare Pediatric Disease designation for RZ358, which qualifies the Company to receive a priority review voucher upon marketing approval for the drug. Further, the Company filed a protocol for the RIZE study with FDA and is now expanding the study to include US sites. Start-up activities are now underway at select US centers of excellence in CHI and the Company believes that patient enrollment may commence in the US in the first quarter of 2021, or sooner.

With respect to its program in Diabetic Macular Edema (RZ402), the Company is prepared to file an Investigational New Drug application ("IND") with FDA. However, as a result of the present uncertainties associated with the Pandemic, the Company is deferring filing the IND until such time that the Company believes that its planned Phase 1 first in human study may be successfully and seamlessly executed. The Company anticipates initiating the clinical trial for RZ402 prior to the end of the first quarter of 2021, or sooner.

The Company's current plans and expectations regarding the timing for its clinical programs are subject to change depending upon the continued evolution of the Pandemic in the US and globally.

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 IND-ready orally available plasma kallikrein inhibitor which is staged to transition into clinical development, 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, 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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