

Rezolute, Inc. Announces Top-line Results from Phase 1 Trial Evaluating AB101 in Patients with Diabetes

REDWOOD CITY, Calif., Dec. 18, 2019 (GLOBE NEWSWIRE) -- [Rezolute, Inc.](#) (“Rezolute” or “the Company”) (OTCQB:RZLT) today announced top-line results from its Phase 1 trial of AB101, an ultra-long acting basal insulin for potential use in patients with type 1 and type 2 diabetes. AB101 was administered subcutaneously in three ascending dosing cohorts in patients with type 1 diabetes, which resulted in slow onset and sustained insulin levels and activity for more than seven days. However, at the higher doses, the necessary drug volume was greater than anticipated, as was variability in onset time between patients. Consequently, the Company believes that additional formulation development is required before advancing the program further in the clinic.

“Observing a slow, sustained release of insulin for over one week after a single administration of AB101 is noteworthy,” said Nevan Elam, Chief Executive Officer of Rezolute. “While we will not invest further in the program, we hope to identify a pharmaceutical partner with the necessary resources and expertise to optimize AB101’s formulation and continue its clinical development.”

This single ascending dose study, AB101-01, was designed to assess the safety, tolerability, pharmacokinetics, and pharmacodynamics of AB101, in subjects with type 1 diabetes who were on background continuous, subcutaneous insulin infusion. AB101 was generally safe and well tolerated, without dose-limiting side effects or occurrence of sudden insulin release. At the mid and high dose levels, AB101 demonstrated a dose-dependent insulin time-action profile that was sustained for more than seven days. Decreased background basal insulin requirements were observed generally, and increased glucose requirements were seen during periodic hyperinsulinemic-euglycemic clamp tests, which are used to evaluate insulin pharmacology. These effects correlated with the observed concentration-time profile of AB101.

About Rezolute, Inc.

Rezolute is a clinical stage biopharmaceutical company specializing in the development of transformative therapies targeting rare and metabolic diseases. Rezolute is advancing a diversified pipeline including: RZ358 (Phase 2), an antibody for the ultra-orphan indication of Congenital Hyperinsulinism; RZ402 (PC), a plasma kallikrein inhibitor targeting Diabetic Macular Edema; and AB101 (Phase 1), a once-weekly injectable basal insulin. For more information, visit: www.rezolutebio.com.

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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