Rexahn to Use MedAvante Centralized Ratings in MDD Phase 2b Study

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HAMILTON, N.J. and ROCKVILLE, Md., Oct. 26 /PRNewswire/ -- MedAvante, Inc., the leader in centralized expert evaluation of central nervous system (CNS) disorders, and Rexahn Pharmaceuticals, Inc. (NYSE Amex: RNN [1]) a clinical stage pharmaceutical company developing and commercializing potential best in class oncology and CNS therapeutics, announced that Rexahn will use MedAvante 's Remote Centralized Ratings™ in their randomized, double-blind, placebo-controlled Phase 2b clinical study assessing the efficacy of Serdaxin® in patients with major depressive disorder (MDD). MedAvante's centralized ratings were chosen to reduce bias and variability associated with CNS trials.

Rexahn is the latest in a growing number of pharmaceutical companies deciding to use centralized raters, who are free of study biases, for CNS trials. This approach has empirically demonstrated the ability to reduce rater variability and the placebo effect.

Centralized assessments in other therapeutic areas, including oncology, imaging and cardiovascular, are used to reduce bias and minimize variability and have been described affirmatively in regulatory guidance documents. Now centralized calibrated raters conducting real-time psychiatric assessments are achieving the same benefits for sponsors of CNS studies.

Rexahn's Serdaxin is a well characterized chemical entity tested for multiple CNS indications. Data from a Phase 2a study in MDD has shown that Serdaxin has the potential to improve symptoms of depression, without the side effects commonly associated with currently marketed antidepressants.

"As a company seeking to develop and deliver new treatments for CNS disorders, it is vital that we design and conduct clinical trials that maximize rater objectivity and standardization," said Rick Soni, President and Chief Operating Officer of Rexahn.

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SOURCE [2]

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