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Rexahn Pharmaceuticals Receives FDA Approval to Initiate Phase II Trial for Serdaxin in Patients with Major Depressive Disorders

ROCKVILLE, Md.--(BUSINESS WIRE)--

Rexahn Pharmaceuticals, Inc. (AMEX: RNN), a leader in innovative therapeutics for life-threatening and life-debilitating diseases, announced today that the Company has received FDA approval to begin Phase II trials for Serdaxin(TM), for the treatment of major depressive disorders (MDD).

This trial represents the third Phase II study currently in progress at Rexahn Pharmaceuticals. The Company's leading cancer compound, Archexin(TM), and its drug for treating erectile dysfunction, Zoraxel(TM), are already in Phase II trials at multiple locations in the U.S.

Dr. Chang H. Ahn, Chief Executive Officer of Rexahn Pharmaceuticals, noted, "We are very excited to reach this milestone with Serdaxin, which has the potential to become a new market leader for depression, with faster onset of action and broader therapeutic coverage than the present standard of care. Serdaxin also has an excellent safety profile in humans without the negative side effects of the current available treatment, which could increase patient compliance. MDD affects 45 million American adults, presenting an extremely large market opportunity for us."

Serdaxin is being developed as an orally administered, extended release tablet for the treatment of depression and anxiety. It is a dual enhancer of serotonin and dopamine neurotransmitters. Serdaxin has a well-established and excellent human safety profile, different from the current standard of care of the SSRIs and SNRIs that have been shown to cause numerous adverse side effects, including weight gain, insomnia, sexual dysfunction, dizziness, dry mouth, constipation, drowsiness, anxiety and suicidal ideation. In preclinical studies, Serdaxin was shown to significantly improve an individual's negative mood state and the loss of positive mood state, with the onset of action taking less than two days. Serdaxin has shown no serious side effects, cognitive deficit or motor impairment. It also has other CNS potential indications for utility in neuro-degenerative and behavioral diseases, including Parkinson's, Alzheimer's and ADHD.

The Serdaxin Phase II trial is a randomized, double-blind, placebo-controlled parallel study for the treatment of major depressive disorders. It is a multi-center trial with preliminary data in humans expected in the second half of 2009.

About Major Depressive Disorder (MDD)

Major depressive disorder is the leading cause of disability in the United States for ages 15 to 44, according to the World Health Organization (WHO), and is expected to become the second leading cause of disability worldwide by the year 2020. MDD is prevalent in approximately 45 million Americans. There are 154 million cases of depression reported worldwide annually, and it is nearly twice as prevalent in women than in men. Depression is characterized by a pervasive low mood and loss of interest or pleasure in normal activities, feelings of extreme sadness, hopelessness, worthlessness, an inability to concentrate, withdrawal from social situations and frequent thoughts of death or suicide. Major depression frequently coexists with other psychiatric problems. In standard treatment there are serious unmet needs for therapeutics with broader coverage and less toxic adverse events.

About Rexahn Pharmaceuticals, Inc.

Rexahn Pharmaceuticals is a biopharmaceutical company leveraging its proprietary technology platform to discover, develop and commercialize innovative treatments for cancer, central nervous system disorders, sexual dysfunction and other unmet medical needs. Rexahn's compounds are designed to uniquely treat various disease states while significantly minimizing side effects in order to allow patients to regain their quality of life. For Additional information about Rexahn visit www.rexahn.com

Safe Harbor

This press release contains statements (including projections and business trends) that are forward-looking statements. Rexahn's actual results may differ materially from the anticipated results and expectations expressed in these forward-looking statements as a result of certain risks and uncertainties, including, Rexahn's lack of profitability, its auditor's going concern qualification and the need for additional capital to operate its business to develop its product candidates; the risk that Rexahn's development efforts relating to its product candidates may not be successful; the possibility of being unable to obtain regulatory approval of Rexahn's product candidates; the risk that the results of clinical trials may not be completed on time or support Rexahn's claims; demand for and market acceptance of Rexahn's drug candidates; Rexahn's reliance on third party researchers and manufacturers to develop its product candidates; Rexahn's ability to develop and obtain protection of its intellectual property; and other risk factors set forth from time to time in our filings with the Securities and Exchange Commission. These forward-looking statements are made as of the date hereof; Rexahn assumes no obligation to update these forward-looking statements.

Source: Rexahn Pharmaceuticals, Inc.