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## **Rexahn Pharmaceuticals Submits Serdaxin(R) Phase II Protocol to FDA for Parkinson's Disease**

ROCKVILLE, Md.--(BUSINESS WIRE)-- Rexahn Pharmaceuticals, Inc. (NYSE Amex: RNN), a clinical stage pharmaceutical company commercializing potential best in class oncology and CNS therapeutics, today announced that it has submitted a Phase II protocol to the U.S. Food and Drug Administration (FDA) for the clinical study of Serdaxin<sup>(R)</sup> for the treatment of Parkinson's disease (PD).

"Serdaxin has demonstrated an ability to prevent neuronal deaths in PD models, and the drug's positive Phase IIa results in depression further enhance its promise as a treatment for PD," said Rexahn Chief Executive Officer, Dr. Chang Ahn. "Although there are currently various treatment options for PD, a meaningful cure is overdue. Based on Serdaxin's novel action as a dual serotonin and dopamine enhancer, we believe it has the potential to be the first drug of its kind to target both the classic symptoms of PD and treat the depression so often associated with this disease."

The Phase II study will assess Serdaxin's efficacy as a treatment for Parkinson's disease in approximately 300 subjects. The planned double blind, randomized, placebo-controlled trial will include the Unified Parkinson's Disease Rating Scale (UPDRS) and quality of life instruments as study endpoints and will be conducted at multiple sites.

Rexahn also has formed a Parkinson's Scientific Advisory Board (SAB) composed of leading medical researchers in the field of neurology who will advise on the design and development of the Serdaxin clinical trials. Commenting on the protocol submission, Dr. William Weiner, Chairman of the SAB, and head of the Maryland Parkinson's Disease and Movement Disorders Center, and Professor and Chair of the Department of Neurology at the University of Maryland School of Medicine, said, "We believe that Serdaxin's properties in animal models open exciting possibilities as a new treatment for patients with PD. All the members of the SAB will be actively engaged in Serdaxin's clinical development, which we hope will further establish the drug's efficacy in treating PD."

### **About Serdaxin<sup>(R)</sup>**

Serdaxin<sup>(R)</sup> is a potential market-leading CNS neuroprotective agent and antidepressant. Rexahn is currently investigating Serdaxin as a treatment for depression in Phase II clinical trials. Serdaxin may achieve greater and broader therapeutic coverage and appears to have no serious side effects such as nausea, vomiting, insomnia, weight gain, sexual dysfunction, cognitive deficit or motor impairment that are linked to existing antidepressant drugs. Serdaxin has a well-established, excellent human safety profile. In preclinical studies, Serdaxin had onset of action in less than two days. Based on its novel mechanism as a dual

serotonin and dopamine enhancer, it is a potential treatment for multiple CNS disorders where these neurotransmitters are depleted or implicated in CNS-based illnesses, such as Parkinson's disease (PD). Serdaxin has the potential to address both non-motor and motor events of PD by serving as a neuroprotective agent and addressing loss of dopaminergic neurons that lead to loss of control of movements; and further, enhancing serotonin and dopamine levels that are involved in depression and mood disorders. Rexahn has multiple clinical programs planned for investigating Serdaxin in the treatment of anxiety disorders, Parkinson's disease, Alzheimer's disease and neurodegenerative illnesses, neuroprotection and biodefense uses.

## About Parkinson's Disease

Parkinson's disease (PD) is the most common movement disorder, affecting more than 5 million patients worldwide. Age is the most important risk factor for PD, and the aging world population is expected to push the number of the afflicted to over 10 million by 2030. In addition, its chronic and debilitating nature warrants high socio-economic impacts. PD is characterized by the progressive loss of dopaminergic neurons in the brain. The resulting dopamine depletion leads to its cardinal motor symptoms, such as rigidity (muscle stiffness), bradykinesia (slowing of movement), postural instability and resting tremor. These impairments are accompanied by non-motor disabilities, including dementia, depression, and sleep disturbance. The current standard treatment options target the dopaminergic pathway, either by supplementing the molecule or stimulating dopamine receptors (binding partners of dopamine). While these strategies ameliorate symptoms in early stages, they become less effective over the course of the disease. In addition, dopamine therapies fail to tackle the underlying causes of the disease, and therefore, do not slow the progression of PD or extend the life expectancy of patients. Serdaxin is a new class of CNS disorder therapeutics that has prevented neuronal deaths in PD models. In contrast to other PD drugs, Serdaxin directly targets the disease mechanism by slowing or halting the progression of the disease, fulfilling unmet needs in Parkinson's disease treatment.

## About Rexahn Pharmaceuticals, Inc.

Rexahn Pharmaceuticals is a clinical stage pharmaceutical company dedicated to commercializing first in class and market leading therapeutics for cancer, CNS disorders, sexual dysfunction and other unmet medical needs. Rexahn currently has three drug candidates in Phase II clinical trials, Archexin<sup>(R)</sup>, Serdaxin<sup>(R)</sup>, and Zoraxel(TM) - all potential best in class therapeutics - and a robust pipeline of preclinical compounds to treat multiple cancers and CNS disorders. Rexahn also operates key R&D programs of nano-medicines, 3D-GOLD, and TIMES drug discovery platforms. For more information, please visit [www.rexahn.com](http://www.rexahn.com).

## Safe Harbor

This press release contains forward-looking statements. Rexahn's actual results may differ materially from anticipated results, and expectations expressed in these forward-looking statements, as a result of certain risks and uncertainties, including Rexahn's lack of profitability, 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. Rexahn assumes no obligation to update these forward-looking statements.

Source: Rexahn Pharmaceuticals, Inc.