Prexton announces initiation of phase II clinical testing in Parkinson's disease

Study will evaluate first-in class treatment in six European countries

Geneva, Switzerland and Amsterdam, The Netherlands, July 10, 2017 - Prexton Therapeutics (Prexton), a biopharmaceutical company developing novel therapeutic compounds for the treatment of Central Nervous System (CNS) conditions, today announces the launch of phase II clinical testing of its investigational drug candidate, Foliglurax, in Parkinson's disease (PD). The clinical study will evaluate 165 patients in sites across six European countries (UK, Germany, France, Austria, Spain and Italy), starting in July 2017.

The study is double-blind, randomised, placebo-controlled parallel-arm phase II in subjects who are experiencing the two major issues associated with PD, namely the wearing-off of Levodopa and Levodopa-Induced Dyskinesia (LID). The trial will assess the safety and tolerability of Foliglurax and the change from baseline to end of treatment period in the daily awake off-time.

Current PD treatments primarily aim to replace dopamine or to mimic its effects. This approach only provides initial symptomatic relief, but loses efficacy as the disease progresses. Foliglurax works by stimulating a novel compensatory neuronal system that activates a specific glutamatergic system target (mGluR4) that is unaffected by PD. The aim is to treat the motor symptoms of PD, such as resting tremor, muscle rigidity ('off-time') and uncontrolled movements ('Dyskinesia').

A phase I trial with Foliglurax was successfully completed in September 2016. The results showed that Foliglurax was safe and well-tolerated with an excellent pharmacokinetic profile.

"The start of this phase II trial is another significant milestone for Prexton and for Parkinson's patients desperately in need of novel and innovative therapeutic solutions," said Francois Conquet, CEO of Prexton Therapeutics. "We are excited about the potential of Foliglurax in addressing these needs."

About the phase II trial (AMBLED)
The trial will enroll a total of 165 patients. Two groups will receive oral doses (10mg and 30mg) of the treatment over a period of 28 days. A third group will receive a placebo. The trial will assess the efficacy, safety and tolerability of the compound in reducing the motor complications of levodopa therapy. The primary outcome measured will be the change from baseline to end of treatment period in the daily awake off-time based on patient diary entries (Hauser). Data is expected in 2019.
clinicaltrials.gov/show/NCT03162874

About Parkinson's disease

Parkinson's disease is a chronic and progressive neurological disorder affecting around 6.3 million people worldwide, characterized by a number of symptoms including tremors, limb stiffness, slowness of movements and difficulties with posture and balance.

Parkinson's disease is more prevalent in people over 60 and the incidence of the disease is expected to increase as the average age of the population increases. It is estimated that more than one million people in the United States live with the disease.

Today, the worldwide market for Parkinson's disease is around $3bn (€2.65bn). It is dominated by matured Dopaminergic treatments, which frequently induce negative side effects. There is an overall consensus in the field supporting the development of more efficient approaches, while limiting or even abolishing the occurrence of adverse effects.

About Prexton Therapeutics

Prexton Therapeutics is a biopharmaceutical company founded in 2012 by Francois Conquet and Merck Ventures. It is part of a Merck Ventures entrepreneurial partnership program, which supports the creation of spin-offs from Merck. Prexton Therapeutics applies a new scientific approach that fully integrates molecular, behavioral and chemistry technologies to address Parkinson's disease and other brain disorders. Prexton Therapeutics uses its powerful discovery platform to target specific novel compounds focused on the treatment of Parkinson's disease. Prexton Therapeutics is based in Geneva (Switzerland) and in Amsterdam (The Netherlands).

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