IRLAB's mesdopetam IND accepted by the US FDA

IRLAB (Nasdaq Stockholm: IRLAB A) announced today that the U.S. Food and Drug Administration (FDA) has accepted IRLAB's investigational new drug application (IND) for the drug candidate mesdopetam (IRL790). The acceptance of the IND will allow IRLAB to include US patients in the upcoming clinical trial in Parkinson's disease in accordance with the study protocol submitted with the IND application. The planned Phase IIb/III study for mesdopetam will thus include hospitals and enrol patients in the US and Europe. Mesdopetam is in development for the treatment of levodopa-induced dyskinesias in Parkinson's disease, PD-LIDs, with the objective to increase daily good ON-time.

"We are pleased to receive acceptance of the IND. The FDA clearance of the IND is a quality stamp on the mesdopetam project and validates mesdopetam as a safe and tolerable drug candidate. It also means that we now expand our clinical development operations to the US, an important strategic goal for the company, " said Nicholas Waters, CEO at IRLAB. "We believe that mesdopetam has a very good chance to offer a completely new and better treatment for the large group of Parkinson's patients experiencing daily complications and reduced quality of life due to levodopa-induced dyskinesia."

"The treatment effects seen in the previous Phase IIa study exceeds the results for other treatment strategies in troublesome dyskinesias. When mesdopetam was given in addition to standard Parkinson medication, patients experienced considerably longer periods of good daily motor function without aggravated involuntary movements improving the daily function in these severely affected patients. This is highly relevant since involuntary, levodopa-induced dyskinesia is a major problem In Parkinson's disease today preventing optimal individual treatment", says Joakim Tedroff, CMO at IRLAB.

The strategy for the Phase IIb/III study has been developed in collaboration with regulatory and clinical experts. The strategy is based on the results from IRLAB's successful Phase I, Phase Ib and Phase II studies with mesdopetam as well as the common use of patient diaries in previous marketing authorizations granted by regulatory authorities for treatments in Parkinson's disease.

The Phase IIb/III study preparations are progressing according to plan with parallel application processes to regulatory authorities and ethics committees ongoing in selected European countries. The objective is to start patient recruitment during Q4 2020.

This disclosure contains information that IRLAB Therapeutics AB is obliged to make public pursuant to the EU Market Abuse Regulation (EU nr 596/2014). The information was submitted for publication, through the agency of the contact person, on October 1, 2020 at 08:20 CET.

For more information

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About Phase IIb/III study in PD-LIDs

The upcoming Phase IIb/III study with mesdopetam is designed as a randomized, double-blinded and placebo-controlled study with the aim of evaluating the effect of mesdopetam in patients with Parkinson's disease affected by troublesome dyskinesias. The planned primary outcome measure is change in daily hours of ON-time without troublesome dyskinesia as assessed with 24-hour patient home diaries. The study is designed to randomize approximately 140 patients distributed across four groups, three dose levels of mesdopetam and a placebo group with approximately 35 patients in each group. The study is planned to be conducted at clinics in Europe and the US. IRLAB collaborates with a CRO that has longstanding expertise and experience in running studies in Parkinson's disease.

About mesdopetam

Mesdopetam (IRL790) is a dopamine D3 receptor antagonist in development for the treatment of PD-LIDs, troublesome dyskinesias commonly occurring after treatment with levodopa, and psychosis in Parkinson's disease. In preclinical and initial clinical studies, mesdopetam reduces troublesome dyskinesia by increasing "Good ON" that occurs after treatment with levodopa. Analysis of the data from the recently completed Phase IIa study showed a dose dependent improvement of this measure. Patients treated with mesdopetam 7,5 mg twice daily had, on average, 5.6 hours longer Good ON compared with 1 hour in the placebo group ($p<0,002$). Additionally, in preclinical studies, mesdopetam has also shown antipsychotic properties. IRLAB believes that mesdopetam thus has the potential to simultaneously treat both troublesome dyskinesias and psychosis in Parkinson's disease.

About IRLAB

IRLAB is a Swedish research and development company that focuses on developing novel treatments in Parkinson's disease. The company's most advanced candidates, mesdopetam (IRL790) and pirepemat (IRL752), both of which completed Phase IIa-studies, intends to treat some of the most difficult symptoms related to Parkinson's disease: involuntary movements (PD-LIDs), psychosis (PD-P) and symptoms linked to cognitive decline such as impaired balance and increased risk of falls (PD-Falls). Through the proprietary research platform, ISP (The Integrative Screening Process), IRLAB discovers and develops unique drug candidates for central nervous system (CNS) related disorders where large and growing medical need exist. In addition to the clinical candidates, the ISP platform has also generated several CNS programs that are now in preclinical phase. IRLAB is listed on Nasdaq Stockholm Main Market. More information on www.irlab.se.