IRLAB's Phase IIb/III study in Parkinson's disease to target Good ON

IRLAB's clinical Phase IIb/III study with the drug candidate mesdopetam (IRL790) in development for the treatment of levodopa induced dyskinesia (LIDs) in Parkinson's disease, will have a study design with the following main points:

- **Approximately 140 patients evenly distributed across four groups: three dose levels of mesdopetam and one placebo group and a three-month study duration.**
- **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 planned to be conducted at centers in Europe and USA.**

In-depth explorative analysis of data from the Phase IIa study with mesdopetam in Parkinson's patients with LIDs (Levodopa Induced Dyskinesia) indicates that the daily time without troublesome dyskinesias, called "Good ON", increases dose dependently. In the study, the best performing dose was 7.5 mg twice daily with Good ON increasing by 5.6 hours daily, compared with 1 hour ($p<0.002$) in the placebo group. This represents a significant improvement of Good ON for these patients who, prior to treatment, had approximately 6.3 hours Good ON per day. Higher dosing did not show additional benefit to the patient.

"When mesdopetam was given in addition to standard Parkinson medication, patients experienced considerably longer periods of good daily motor function without aggravated involuntary movements. This is highly relevant since involuntary, levodopa-induced dyskinesia is a major problem in the treatment of Parkinson's disease preventing optimal treatment.", says Joakim Tedroff, CMO at IRLAB. "Mesdopetam represents a new approach that, by inhibiting the mechanisms in the brain that has the most impact on levodopa dependent development of troublesome dyskinesias, and thus, can prevent these, improving the daily function in these severely affected patients."

"The treatment effects seen in our Phase IIa study exceeds the results published for other treatment strategies in troublesome dyskinesias. We believe that mesdopetam has a very good chance to offer a completely new and better treatment strategy for the large group of Parkinson's patients with levodopa induced dyskinesia", said Nicholas Waters, CEO at IRLAB.

The strategy for the Phase IIb/III study has been developed in collaboration with international regulatory and clinical experts. The strategy is based on the results from IRLAB's 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 pharmaceutical drugs in the treatment of Parkinson's disease.

"The strategy planning for the Phase IIb/III-study with mesdopetam in Parkinson's disease is now completed. We have recently also secured financing for the study and initiated a collaboration with a highly reputable CRO", said Nicholas Waters.

The study preparations are progressing according to plan. As a part of the work with the Phase IIb/III study with mesdopetam, preparations are now underway for the applications to regulatory agencies and ethics committees in selected countries for permission to start the study in the second half of 2020.

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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. 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 ($p<0,002$). 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 that occurs after treatment with levodopa. 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 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 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's Certified Adviser on Nasdaq First North Premier Growth Market is FNCA Sweden AB, info@fnca.se, +46 (0)8528 00 399. More information on www.irlab.se.