Press release
Gothenburg, 09 May 2019

IRLAB completes recruitment for its Phase II study with IRL790 in Parkinson's disease patients with dyskinesia

IRLAB announced today that the patient recruitment for the Phase II study with drug candidate IRL790 in Parkinson's disease patients with dyskinesia has been concluded. The study recruitment target of 74 randomized patients has been achieved with the last patient now having entered the study and begun treatment. Following the last patient's five-week study participation, the study data will be analyzed, and top-line results are thus expected within 10 weeks from this announcement.

The clinical Phase II study (IRL790C003) is randomized, double-blind and placebo-controlled and is conducted at clinical sites both in the UK and in Sweden. The aim of the study is to evaluate the efficacy of IRL790 on dyskinesia (involuntary movements) in patients with Parkinson's disease using the Unified Dyskinesia Rating Scale (UDysRS). The secondary endpoints are to evaluate the effects of IRL790 on core symptoms of Parkinson's disease, using the Unified Parkinson's Disease Rating Scale (MDS-UPDRS), and to evaluate the pharmacokinetics, safety and tolerability of IRL790 in these patients. In the study, patients either receive IRL790 or placebo with 1:1 randomization.

Joakim Tedroff, CMO at IRLAB, commented "This is the company's second successfully completed patient recruitment in a clinical Phase II trial in Parkinson's disease. After intensified efforts of supporting patient recruitment during the past months, it is rewarding to see the effects of the work. We are now looking forward to completing the treatment phase of this study and receive the results."

"We are currently working to reach our main objective of completing the clinical proof of concept for IRL790. This Phase II study is the first step. The next study for IRL790, a Phase II study in Parkinson's disease patients with psychosis, is planned to be initiated later this year," said Nicholas Waters, CEO at IRLAB.

The steps following the last patient's completed treatment and a follow-up visit includes a final quality control of the data, by the assigned study monitors, before the database can be locked and unblinded. Statisticians will then analyze the data and produce the top-line results. The top-line results are expected within 10 weeks from this announcement.

More information about the study can be found on Clinicaltrial.gov, identifier: NCT03368170.

About IRL790

IRL790 is under development for the treatment of PD-LIDs, dyskinesia (involuntary movements) that often follows treatment with levodopa, and PD-P, psychosis in Parkinson's disease. In pre-clinical studies, IRL790 reduces involuntary movements that occurs after a period of treatment with L-dopa. Additionally, in pre-clinical studies, IRL790 has shown antipsychotic properties. The company believes that IRL790 thus has the potential to simultaneously treat both dyskinesias and psychosis in Parkinson's disease.

For more information

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About IRLAB

IRLAB is a Swedish biotech company focused on Parkinson's disease. The company's clinical Phase 2 candidates, IRL752 and IRL790, intend to treat some of the most difficult symptoms related to Parkinson's disease: involuntary movements (LIDs), psychosis and dementia. Through the proprietary ISP (Integrative Screening Process) research platform, IRLAB discovers and develops drug candidates for central nervous system (CNS) related diseases where big growing medical needs 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 is FNCA Sweden AB, info@fnca.se, +46 (0)8-528 00 399. More information on www.irlab.se.