Press release
Gothenburg, 14 March 2019

IRLAB adds sites to Phase II study with IRL790 and passes DSMB's second safety review

IRLAB announced today that the independent Data Safety Monitoring Board, DSMB, reported no safety concerns in their second review of the ongoing Phase IIa study with the drug candidate IRL790. IRL790 is in development for the treatment of dyskinesias and psychosis in Parkinson's disease. The outcome illustrates that the study's dose range and design are appropriate and treatment with IRL790 is safe in this patient population. To complete the ongoing study, four Swedish clinical sites have joined the 16 UK sites in the study and are now treating patients in the study.

The independent committee of medical experts, the DSMB, has made its second, and last, planned review of safety data from patients who have completed treatment in the Phase IIa study. In December 2018, IRLAB reported that the DSMB after their first safety review concluded that there were no safety concerns. The DSMB's conclusion remains after this second review. Their recommendation is therefore to complete the Phase IIa study according to the approved study protocol.

"It is a significant milestone to receive the DSMB's opinion at this point in the ongoing study. Additional patients have completed treatment without safety issues, which is key in a successful study," said Nicholas Waters, CEO at IRLAB.

While retaining the study's high quality of conduct, IRLAB has continued to work with the UK clinical sites to increase patient recruitment. In addition, activities targeting expansion of the eligible patient population has been executed. As a result, the first Swedish patients were randomized shortly after the study was granted approval by the Swedish Medical Products Agency, Ethics committee and Biobank Sverige, in February 2019.

"We maintain a strong focus on recruitment and have introduced measures to speed up recruitment, both in the UK and by adding Swedish sites to the program. We note that these measures while being prudent, are having a positive effect," said Joakim Tedroff, CMO at IRLAB.

Four Swedish clinical sites are currently recruiting patients into the study, in addition to the already active 16 UK clinical sites. At present, the outcome of all these activities indicates a continued steady pace of recruitment. The study's patient recruitment will be concluded once 74 patients have been randomized.

The company will inform once the patient recruitment has been completed. Top-line results are expected within 10 weeks after the last patient have entered the study.

About IRL790

IRL790 is under development for the treatment of PD-LIDs, 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.

About the study IRL790C003

IRL790C003 is a randomized, double-blind, placebo-controlled, Phase IIa study. The primary endpoint is to evaluate the efficacy of IRL790 in Parkinson's disease dyskinesia, using the Unified Dyskinesia Rating Scale

(UDysRS). The secondary objectives 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. The study is conducted at clinical sites in the UK and in Sweden and will randomize 74 patients to IRL790 or placebo (1:1 randomization).

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.