IRLAB provides update on drug candidate IRL790's clinical program

IRLAB today provided an update on the clinical program for the drug candidate IRL790 in development for the treatment of dyskinesia and psychosis in Parkinson's disease, with the following highlights:

- **Based on advice in a recent FDA pre-IND meeting, the company received confirmation that performed and planned pre-clinical studies and CMC-program in the development of IRL790 are sufficient to apply for an IND.**
- **Currently, IRL790 is undergoing a clinical Phase IIa trial in Parkinson's disease patients with dyskinesias. The study's independent Data Safety Monitoring Board (DSMB) has reported that there were no safety concerns in the study.**
- **Furthermore, the recruitment rate in the Phase IIa trial has tripled in recent months.**

A pre-Investigational New Drug (pre-IND) meeting was recently held with the U.S. Food and Drug Administration (FDA) regarding IRLAB's drug candidate IRL790. The meeting discussed the regulatory pathway for the development of the drug candidate IRL790. The FDA indicated that the concluded preclinical studies, Phase I studies and the chemistry, manufacturing and controls (CMC) package, form a sufficient foundation for an IND application. An approved IND application is necessary to conduct clinical studies in the US.

Furthermore, IRLAB's planned pre-clinical studies and CMC-program were deemed sufficient by the authority, who also provided clear guidance on the design of the planned Phase II study for the treatment of psychosis in Parkinson's disease. As an outcome of the meeting, IRLAB will proceed with the development of the candidate as planned.

"We are pleased with the informative meeting with the FDA, and can now confirm that an IND-application for IRL790 will not require any additional non-clinical data or CMC work to support the next Phase II clinical study," said Joakim Tedroff, Chief Medical Officer (CMO) at IRLAB. "This is one of many important milestones that we have methodically ticked off advancing IRL790's clinical development program."

During the autumn, the independent committee of experts the ongoing Phase IIa clinical study with IRL790, Data Safety Monitoring Board (DSMB), has reviewed safety data from the first set of patients that has completed the study. The DSMB concluded that there were no safety concerns and recommended continuation of the Phase IIa study according to the previously approved study protocol.

An upcoming key milestone in the clinical program for IRL790 is the completion of study recruitment in the ongoing phase IIa study of LIDs in Parkinson's disease. As a result of actions taken by the company in the last few months, the recruitment pace in the study has tripled. To date, 66 patients suitable for treatment, fulfilling initial criteria for participation in the trial, have been identified whereof a majority have been randomized to, or have finalized, treatment. The recruitment will continue throughout December 2018 and early 2019 to reach the planned 74 patients. Top-line results are expected within 10 weeks after last patient have entered the study.

"The independent Data and Safety Monitoring Board's stated after their first review, that there were no safety concerns in the ongoing Phase IIa study with IRL790, indicating that we have chosen to study the right dose range. Furthermore, we are also pleased to see the increase in recruitment pace in the study. As we are closing the year, we can conclude that we have made significant progress across both our clinical programs and the preclinical R&D work. With these achievements, we look forward to continue the advancement of our project portfolio during 2019," said Nicholas Waters, CEO at IRLAB.

For further information

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About IRLAB

IRLAB is a research and development company, listed on Nasdaq First North Premier, focused on development of novel therapies for the treatment of neurodegenerative diseases, in particular Parkinson's disease.

IRLAB has two clinical candidate drugs, IRL752 and IRL790, focused on medical needs in Parkinson's disease. IRLAB also has additional programs in pre-clinical stages.

IRLAB's research is aimed at discovery and development of new candidate drugs addressing unmet medical need in diseases of the central nervous system, using the unique and proprietary integrative screening process, ISP.

IRLAB is based in Gothenburg, Sweden. The operations are mainly carried out through the subsidiary Integrative Research Laboratories Sweden AB.

For more information, please visit www.irlab.se.