IRLAB reports promising efficacy data from Phase IIa-study with IRL752

The overall results of the recently completed Phase IIa study indicate that IRL752 – a candidate drug developed for the treatment of Parkinson's disease dementia – improves symptoms associated with executive functions and dementia in Parkinson's disease. Effects on balance and fall tendency – so called axial symptoms – and apathy, were significant in patients treated with IRL752 but not in patients treated with placebo. Further, the study indicated a positive trend in results from cognitive tests, despite the short duration of the study. These symptoms currently lack satisfactory treatment. IRLAB has previously reported that IRL752 was well tolerated by patients in this study, which was the study's primary objective.

"It is promising that our candidate drug IRL752 seems to improve symptoms and signs characteristic to this patient group. Falls, impaired balance and apathy are difficult to treat and are associated with impaired cognitive function in Parkinson's disease. The results will facilitate the design of a longer duration Phase IIb study, which will be aimed at investigating efficacy of IRL752", says Dr Joakim Tedroff, Chief Medical Officer.

The explorative analyzes of efficacy parameters showed improvements in axial motor symptoms, reduced apathy and a trend to improve results in cognitive tests. Axial symptoms of Parkinson's disease are linked to cortical and cognitive dysfunction.

The clinical effects observed in this study are consistent with the results from the previously performed pre-clinical studies, where IRL752 enhances the neurotransmission in, and function of, the cerebral cortex, which was the starting point for the development of IRL752.

"There is a great need for treatments of the symptoms IRL752 seems to affect. It is now important to confirm these encouraging results in a larger study", says Professor Per Svenningsson, Principal Investigator, Karolinska Institute, Stockholm.

The current study was primarily intended to investigate safety and tolerability of the candidate drug. In the study, patients were given active substance or placebo for four weeks. Supplementary measurements with standardized and internationally recognized rating scales, assessing motor and mental functions. In addition, cognitive tests adapted for Parkinson's disease were administered. Previously, IRL752 was reported to be well tolerated in the study.

The full results of the study will be published in an international scientific journal.

About the study

The study, IRL752C002 (EudraCT # 2017-001673-17), was randomized, double-blind, placebo controlled and run at 9 centres in Sweden and one in Finland. Forty-three (43) patients with advanced Parkinson's disease and dementia were screened for participation in the study and 32 were randomized to four weeks of treatment, 25 with IRL752 and 7 with placebo. In the IRL752 treated group 23 of 25 completed the entire treatment period and 6 of 7 in the placebo group.

Placebo or IRL752 (300-750 mg/day) was titrated during two weeks followed by stable dosing for the remaining two weeks. Tolerability and safety were continuously monitored.

Mean age was 72 years, 28 were male and 4 female. All patients had advanced stage Parkinson's disease, 18 in Hoehn and Yahr stage 3-4. The average minimal mental state examination (MMSE) was 22.6 points on entry to the study.

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IRL752

IRL752 is developed for the treatment of Parkinson Disease Dementia (PD-D) ultimately affecting up to 80 % of all PD patients. Effective treatments are lacking and thus, the medical need is huge. IRL752 has the ability to increase synaptic availability of the neurotransmitters norepinephrine and dopamine in the frontal cortex and also activates expression of genes modulating synaptic activity and plasticity. Clinical research has shown that both norepinephrine and dopamine neurotransmitters are reduced in frontal cortical brain areas in PD-D. By counteracting this reduction, treatment with IRL752 may improve cognitive and psychiatric symptoms in these patients.

IRL752 primary targets are brain 5HT7 and cortical Alpha receptors as an antagonist leading to improvement of disturbed cognitive function, antidepressant and antipsychotic effects. These are all desired properties for the treatment of PD-D.

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.