IRLAB reports top-line results from Phase IIa study with IRL752

IRLAB reports that the clinical Phase IIa study with IRL752 has been completed according to plan. The primary study objectives have been met. After full data analysis, the next development step is a larger efficacy study with longer treatment times.

The study was a Phase IIa safety- and tolerability study in patients with Parkinson's disease and dementia. The top-line results showed good tolerability of IRL752. Thus, the study met its primary objective. Adverse events in the IRL752 treated group were mainly related to the CNS and were mild to moderate and occurred mainly during the initial 14 days of dose titration. A mild and reversible elevation of liver enzymes was observed in three patients. Two serious adverse events were reported in the study, one in the placebo group and one in the IRL752 group. Both were considered unrelated to study medication by the study investigators. Importantly, IRL752 did not affect heart rate, blood pressure or electrocardiography (ECG).

The full study results will be published when analyses of all results in the study are complete.

“We have now completed a first study with IRL752 in patients with Parkinson's disease and dementia. We are pleased that IRL752 was well tolerated. The results of the study give us valuable information for the further development of IRL752” says Dr. Joakim Tedroff, CMO

“The results indicate that IRL752 targets the central nervous system and appears overall safe to use in persons with Parkinson´s disease and dementia, a common cause for nursing home placement. It will be important to proceed with larger trials with IRL752 for this patient group in the near future” Says Prof. Per Svenningsson, KI, principal investigator.

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 Parkinsons 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 Parkinsons 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.

About 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.

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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.