Press Release

Göteborg July 11, 2022

IRLAB expands Phase IIb/III PD-LIDs study with mesdopetam to support Phase III program and expects completion of enrollment during the summer

IRLAB (Nasdaq Stockholm: IRLAB A) today announced that the ongoing Phase IIb/III study has been expanded to include 154 patients aiming to provide strong data supporting the design of the pivotal Phase III program and subsequent marketing authorization applications in the US, and globally, led by partner Ipsen. Patient enrollment in the Phase IIb/III study is expected to be completed during the summer, and thus, the last patient completes treatment in late fall 2022. Top-line results be communicated subsequent to database lock and data analyses, expected in Q4 2022.

"Together with our partner Ipsen, we decided to expand the number of clinical sites to support patient enrollment during the spring and early summer and to take advantage of the interest in the study. We decided to expand the study to 154 participants, from the initially planned 140. The interest from patients and clinicians has remained high and consistent, which is encouraging given the imposed restrictions due to the covid-19 pandemic across many regions during the course of the study" said Nicholas Waters, EVP and Head of R&D at IRLAB.

"I am pleased to share that observations in the blinded safety data during the study thus far is in alignment with results from the earlier completed Phase Ib and Phase IIa studies. This is a positive indication for patients as well as all involved in the development of mesdopetam. There is a major need for treatment in Parkinson's disease dyskinesia and our commitment to bring hope for a life without treatment-related complications to people living with Parkinson's and dyskinesia remains," added Joakim Tedroff, CMO at IRLAB.

To facilitate the planned increase in the number of study participants and meet the projected timeline, the study has also been expanded with additional clinical sites in the US and Poland. The study now comprises 16 sites in the US and 30 throughout Europe and Israel. Recruitment has successfully progressed during the course of the study period and enrollment is expected to be completed during the summer.

A further announcement will be made once the patient enrollment is completed and the Phase IIb /III study's final participant has been randomized into the trial. This will be followed by a three-month treatment period and subsequent database lock and data analyses before top-line results are communicated. More information can be found on clincialtrials.gov (NCT04435431).

For more information

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About mesdopetam

Mesdopetam (IRL790) is a dopamine D3-receptor antagonist being developed to prevent and treat Parkinson's disease levodopa-induced dyskinesias (PD-LIDs), a severe form of troublesome involuntary movements commonly occurring in Parkinson's disease. In clinical studies, mesdopetam reduces time spent with troublesome dyskinesia and thereby increases daily good ' ON-time' in patients with Parkinson's. Preclinical studies show that mesdopetam is a potent and efficacious antidyskinetic, and that mesdopetam also has the potential to prevent the development of dyskinesia. In addition, mesdopetam has shown antipsychotic properties in preclinical studies predictive of Parkinson's disease Psychosis (PD-P). The global specialty pharma company Ipsen obtained exclusive global rights to the development and commercialization of the mesdopetam program in 2021.

About Phase IIb study with mesdopetam

The Phase IIb study with mesdopetam is designed as a randomized, double-blinded and placebo-controlled study with the aim of evaluating the effects of mesdopetam or placebo in patients with Parkinson's disease affected by troublesome dyskinesias (LIDs). The primary outcome measure is change in daily hours of ON-time without troublesome dyskinesia as assessed with 24-hour patient home diaries. The study is now designed to randomize approximately 154 patients distributed across four groups, three dose levels of mesdopetam and a placebo group with approximately 38-39 patients in each group with a treatment period of three months. The study is conducted at clinics and sites in Europe, Israel and in the US.

About IRLAB

IRLAB discovers and develops novel treatments of Parkinson's disease and other CNS disorders. The company's most advanced drug candidates, mesdopetam (IRL790) and pirepemat (IRL752), are in Phase IIb and are designed to treat some of the most difficult complications related to Parkinson's disease. In 2021, IRLAB entered an exclusive global license agreement with Ipsen for the development and commercialization of mesdopetam.

Through the systems biology based Integrative Screening Process (ISP), its IRLABs proprietary research platform, IRLAB has discovered and generated all its drug candidates and continues to discover innovative drug candidates for the treatment of CNS disorders. In addition to IRLAB's strong clinical pipeline, IRLAB runs several preclinical programs with IRL942 and IRL757 currently in development towards Phase I studies. IRLAB is listed on Nasdaq Stockholm. More information on www.irlab.se.

Attachments

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