Press Release

Göteborg July 17, 2023

IRLAB's Phase IIb study with pirepemat passes DSMB safety review with unanimous recommendation to continue the ongoing Phase IIb study

Gothenburg, Sweden, July 17, 2023 – IRLAB Therapeutics AB (Nasdaq Stockholm: IRLAB A), a company discovering and developing novel treatments for Parkinson's disease, today announced that the independent Data and Safety Monitoring Board (DSMB) for the ongoing Phase IIb study with pirepemat, after review of safety and the integrity of data, unanimously recommends that the Phase IIb study continues.

The DSMB review is part of the Phase IIb study of pirepemat's, IRL752C003 – React PD, study protocol. The DSMB has evaluated data from the initial 25 patients participating in the study and completing the study. After this review, the DSMB unanimously recommend that the Phase IIb study continues according to the approved study protocol without modifications.

"This achievement – the outcome of the DSMB review – supports our commitment to patient safety and our rigorous scientific approach. It gives confidence in our efforts to develop safe and effective therapies that can improve lives," said Gunnar Olsson, CEO of IRLAB.

A DSMB is an independent committee of experts responsible for reviewing clinical trial data on an ongoing basis during an ongoing study to ensure the safety of study subjects and the validity and integrity of the data. The DSMB makes recommendations concerning the continuation, modification, or termination of the clinical trial based on the findings in the pre-specified review of the data.

The Phase IIb study of pirepemat (IRL752C003 – React PD) is a randomized, double-blind, and placebo-controlled study with the aim to evaluate the efficacy, safety, and tolerability of different doses of pirepemat in people living with Parkinson's disease in order to identify the optimal dose for Phase III. Besides safety and tolerability, the study objectives are to evaluate the effect of pirepemat on falls frequency, postural dysfunction, cognitive function, and symptoms of Parkinson's disease in people living with Parkinson's disease. The study is active at 38 study sites across France, Germany, Poland, the Netherlands, Spain, and Sweden. Patient recruitment and randomization are expected to be completed by the year-end of 2023, followed by a three-month treatment period, follow-up visits, data management, and database lock. Top-line results are expected during H1 2024.

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About IRLAB

IRLAB is discovering and developing a portfolio of transformative therapies targeting all stages of Parkinson's disease. The company has its origin in Nobel Laureate Prof. Arvid Carlsson's research group and the discovery of a connection between the brain's neurotransmitters and CNS disorders. Mesdopetam (IRL790), in development for the treatment of levodopa-induced dyskinesias, is the company's most advanced program and was licensed to Ipsen in 2021. A second candidate, pirepemat (IRL752), is currently in Phase IIb, being evaluated for its effect on balance and fall frequency in Parkinson's disease. In addition, the company is also progressing the three preclinical programs IRL942, IRL757, and IRL1117 towards Phase I studies. The pipeline is driven by IRLAB's proprietary systems biology-based Integrative Screening Process (ISP) research platform. Headquartered in Sweden, IRLAB is listed on Nasdaq Stockholm (IRLAB A). For more information, please visit www.irlab.se.

Attachments

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