Press Release

Göteborg July 2, 2024

IRLAB's Phase IIb study of pirepemat can proceed as planned after positive opinion from external safety committee

Gothenburg, Sweden, July 2, 2024 – IRLAB Therapeutics AB (Nasdaq Stockholm: IRLAB A), a company discovering and developing novel treatments for Parkinson's disease, today announced that the independent Data Safety Monitoring Board (DSMB) has completed the last of two pre-determined safety and data integrity reviews of the ongoing Phase IIb study of pirepemat. The DSMB unanimously recommends that the study should continue without any changes. In accordance with the previously communicated plan, IRLAB will complete patient recruitment in the third quarter of 2024.

Reviews by the independent safety committee, DSMB, are part of the study protocol for the Phase IIb study of pirepemat, IRL752C003 - React PD. This is the second and final safety and data integrity review of the study and, as on the first occasion in July 2023, the DSMB unanimously recommends that ReactPD can proceed under the approved study protocol without modifications.

"Following the positive opinion from the independent safety committee, DSMB, we can now complete the study in full accordance with the study protocol. Our aim is to always maintain the highest possible patient safety and a rigorous scientific approach, where DSMB reviews are an important part," says Gunnar Olsson, CEO of IRLAB.

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

The Phase IIb study of pirepemat (IRL752C003 - React PD) is a randomized, double-blind, placebo-controlled study to evaluate the efficacy, safety and tolerability of different doses of pirepemat in people living with Parkinson's disease to determine the optimal dose for Phase III. In addition to safety and tolerability, the study aims to evaluate the effect of pirepemat on fall frequency, postural dysfunction, cognitive function, and symptoms of Parkinson's disease in people living with Parkinson's disease. The study is being conducted in clinics in France, Poland, the Netherlands, Spain, Sweden and Germany. Recruitment of patients is expected to be completed in the third quarter of 2024, followed by a three-month treatment period, follow-up visits, data management and database lock before top-line results can be presented.

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About pirepemat (IRL752)

Drug candidate pirepemat (IRL752) has the potential to be the first treatment in a new class of drugs designed to improve balance and reduce falls and fall injuries in people living with Parkinson's disease. Pirepemat is designed to strengthen nerve cell signaling in the prefrontal cortex via antagonism at 5HT7 and alpha-2 receptors leading to increased dopamine and noradrenaline levels. 45 percent of all people living with Parkinson's fall recurrently, which approximates 2.6 million people suffering from a significantly reduced quality of life also due to fear of falling. There are no available treatments at present, despite the great medical need. Pirepemat is currently in a Phase IIb study to evaluate the efficacy, safety, and tolerability of different doses of pirepemat in people living with Parkinson's disease to identify the optimal dose for Phase III. The study is active at 38 study sites across France, Germany, Poland, the Netherlands, Spain, and Sweden.

About IRLAB

IRLAB discovers and develops a portfolio of transformative treatments for all stages of Parkinson's disease. The company originates from Nobel Laureate Prof Arvid Carlsson's research group and the discovery of a link between brain neurotransmitter disorders and brain diseases. Mesdopetam (IRL790), under development for treating levodopa-induced dyskinesias, has completed Phase IIb and is in preparation for Phase III. Pirepemat (IRL752), currently in Phase IIb, is being evaluated for its effect on balance and fall frequency in Parkinson's disease. IRL757, a compound being developed for the treatment of apathy in neurodegenerative disorders, is in Phase I. In addition, the company is also developing two preclinical programs, IRL942 and IRL1117, towards Phase I studies. IRLAB's pipeline has been generated by the company's proprietary systems biology-based research platform Integrative Screening Process (ISP). Headquartered in Sweden, IRLAB is listed on Nasdaq Stockholm (IRLAB A). For more information, please visit www.irlab.se.

Attachments

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