Press Release

Göteborg January 14, 2025

The last patient has now completed the full treatment period in IRLAB's Phase IIb study with pirepemat

Gothenburg, Sweden, January 14, 2025 - IRLAB Therapeutics AB (Nasdaq Stockholm: IRLAB A), a company that discovers and develops new treatments for Parkinson's disease, today announces that all patients enrolled in the Phase IIb study with the drug candidate pirepemat (REACT-PD) have completed their final follow-up visit. Topline data from the study are expected in the first quarter of 2025.

"The completion of the final follow-up visit for patients in the Phase IIb study marks an important milestone in our clinical development program for pirepemat. We are delighted that as many as 87% of the enrolled patients completed the study indicating a low drop-out rate and that the participants enrolled in the current study are reported to be very satisfied during the treatment period. We now look forward to present topline results in the first quarter of 2025," says Kristina Torfgård, CEO of IRLAB.

Pirepemat has the potential to significantly improve the treatment of Parkinson's disease by addressing one of the most challenging complications of the disease: patients' tendency to fall. Falls are a major concern as they greatly impact quality of life and may ultimately result in serious complications such as fall-related injuries and increased mortality. Currently, there is no approved medication aimed at reducing falls, making the development program for pirepemat unique. Thus, pirepemat could potentially become the first treatment to prevent and reduce falls and associated injuries.

"As previously communicated, blinded data from the REACT-PD study indicate that the number of falls has decreased by approximately one-third compared to observations during the baseline period. Since the study is double-blind, it is not yet possible to determine the difference in effect between patients treated with pirepemat and those receiving placebo and it is therefore not possible to draw any conclusions about the effect of pirepemat on the fall rate. However, it can be concluded that participation in this study leads to a reduction in fallrates," says Joakim Tedroff, Chief Medical Officer at IRLAB.

The Phase IIb study with pirepemat (IRL752C003 - REACT-PD) is a randomized, double-blind, placebo-controlled trial designed to evaluate the efficacy, safety, and tolerability of two different doses of pirepemat or placebo, in individuals with Parkinson's disease, aiming to establish the optimal dose for a Phase III program. In addition to assessing safety and tolerability, the study also investigates the impact of pirepemat on fall rate, postural dysfunction, cognitive function, and

motor and neuropsychiatric symptoms associated with Parkinson's disease. The study is conducted at clinics throughout France, Poland, the Netherlands, Spain, Sweden, and Germany. Patients were monitored during a month-long baseline period, and then treated for three-months with either a placebo, 300 mg of pirepemat daily, or 600 mg of pirepemat daily, allocated in a 1:1:1 ratio. After treatment, follow-up visits were conducted. As all patients now have completed the study, data management, database locking, and analysis will be carried out in accordance with a predefined analysis plan. Topline results are anticipated to be reported in the first quarter of 2025. More information can be found at EudraCT: 2019-002627-16 and www.clinicaltrials.gov: NCT05258071.

For more information

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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.

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 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.

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Attachments

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