Press Release

Göteborg March 5, 2025

IRLAB reports topline results from a Phase IIb study of pirepemat in patients with Parkinson's disease

Gothenburg, Sweden, March 5, 2025 - IRLAB Therapeutics AB (Nasdaq Stockholm: IRLAB A), a company that discovers and develops new treatments for Parkinson's disease, today announces topline results from the Phase IIb study of pirepemat (REACT-PD). The results show that treatment with pirepemat (600 mg daily) reduced the fall rate by 42 percent among individuals with Parkinson's disease; however, this effect did not reach statistical significance compared to placebo. The company will now conduct in-depth analyses of the study data ahead of a decision on the further development strategy for the drug candidate.

In the Phase IIb study, 146 patients were screened, 104 were randomized, and 90 completed the 12-week treatment period. The primary endpoint was the change in patients' fall rates during the treatment period. The fall rate decreased by 42 per cent for those treated with pirepemat at a daily dose of 600 mg, but the effect did not reach statistical significance compared to placebo. The results of the cognitive scale used in the study (Montreal Cognitive Assessment, MoCA) indicated a meaningful improvement in cognitive impairment for patients treated with pirepemat (600 mg daily). However, this effect did not reach statistical significance. The adverse event profile was consistent with previously reported clinical trial results for pirepemat. Adverse events were reported by approximately 70 percent of study participants, evenly distributed among the three treatment groups. During the study, one death was reported for a participant receiving placebo.

"The results of the Phase IIb study with pirepemat will delay our efforts to provide a treatment that reduces the frequency of falls in individuals with Parkinson's disease. Extensive further analytical work will now be conducted before we can determine the project's future direction. We remain convinced that our drug candidates have the potential to enhance the quality of life for patients and their families while helping to lower healthcare costs. Alongside the ongoing analysis of study data from the Phase IIb study of pirepemat, we are focusing on the Phase III-ready project mesdopetam, the Phase I project IRL757, and the drug candidate IRL1177 which has the potential to replace the current standard treatment for Parkinson's disease, and IRL942," says IRLAB's CEO, Kristina Torfgård.

"It is too early to draw any firm conclusions about why treatment with pirepemat did not achieve the goal of the study, a reduction in fall rate compared to placebo, despite the large reduction seen in the study. We can conclude that the placebo effect is significantly higher than in any previous study published in this field. However, it is important to point out that the reduced fall rate

in patients treated with pirepemat seems to coincide with an improvement in cognitive functions, indicating that pirepemat affects brain mechanisms common to cognition and control of balance," comments Joakim Tedroff, Chief Medical Officer at IRLAB.

IRLAB sincerely thanks the patients and their caregivers for their trust and participation in this study. The company also extends its appreciations to the investigators, the CRO and the clinical development team for their diligent and hard work with the Phase IIb trial.

Webcast for investors, analysts and media
IRLAB will host a live webcast in connection with announcing the topline results from the Phase IIb study today, March 5, 2025, at 15:30 CET.
Link to the webcast: https://youtube.com/live/T5p2OOzzNBU

For more information

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This information is information that IRLAB Therapeutics is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2025-03-05 13:40 CET.

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 the Phase IIb React-PD study with pirepemat

The randomized double-blind Phase II study (REACT-PD) was aimed to evaluate the efficacy and safety of pirepemat at two dose levels (300 mg and 600 mg per day, respectively) compared to placebo. The study screened 146 individuals with Parkinson's disease and mild cognitive impairment aged 55 to 85 years, of whom 104 were randomized and 90 completed the treatment.

Efficacy was documented through patient diaries and assessments of motor function, cognition (Montreal Cognitive Assessment, MoCA), balance, and the Clinical Global Impression Scale (CGIS). The primary outcome measure was the change in fall rate with pirepemat compared to placebo from the baseline period, four weeks prior to randomization, to the end of treatment. Patients underwent screening for six weeks, after which they were randomly assigned to one of three groups, receiving either pirepemat at 300 mg daily, 600 mg daily, or a daily placebo for 12 weeks. Study participants were subsequently followed up for 33 to 37 days.

The study was conducted at 38 trial centers across France, Germany, Poland, the Netherlands, Spain, and Sweden. Further information about the study can be found at www.clinicaltrials.gov: NCT05258071.

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.

Attachments

IRLAB reports topline results from a Phase IIb study of pirepemat in patients with Parkinson's disease