Press Release

Göteborg February 20, 2025

IRLAB receives positive feedback from EMA confirming alignment with FDA on Phase III program for Mesdopetam

Gothenburg, Sweden, 20 February, 2025 – IRLAB Therapeutics AB (Nasdaq Stockholm: IRLAB a company discovering and developing novel treatments for Parkinson's disease, today announces that the European Medicines Agency (EMA) has provided positive feedback on the company's proposed design for the Phase III program of mesdopetam. Based on EMA's guidance, IRLAB can now proceed with preparations for the registration studies of the drug candidate, which has demonstrated efficacy in a phase Ib and in two Phase II studies against levodopa-induced dyskinesia in patients with Parkinson's disease.

"With the positive feedback from EMA, we can now plan the design of the Phase III program for mesdopetam to meet regulatory requirements in both the U.S. and Europe. This significantly enhances the value of the project and is a crucial part in our discussions with potential collaborators for the final development stages and a possible commercialization of our unique drug candidate," said IRLAB's CEO, Kristina Torfgård.

Following the successful dialogue with EMA and the company's prior End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA), IRLAB has reached a consensus with both European and US regulatory authorities on the remaining clinical development plan for mesdopetam. This agreement includes the program required for the approval of mesdopetam as a treatment for levodopa-induced dyskinesia (LIDs) in patients with Parkinson's disease.

EMA has reviewed the comprehensive data package provided by IRLAB and has given feedback on all aspects of the mesdopetam development plan, including the design of the Phase III studies.

The agency has responded positively and accepts the setup of the Phase III program, including the following key components:

- The patient population will be the same as in previous clinical studies within the mesdopetam program.
- The primary efficacy endpoint will be UDysRS parts 1+3+4.
- Secondary efficacy endpoints will be based on elements of UDysRS, MDS-UPDRS, and 24-hour diaries.
- The estimated number of participants required to demonstrate efficacy in Phase III is approximately 250–270 patients, distributed across two parallel studies (both with a 1:1 randomization between active treatment and placebo) with a treatment duration of three months.

- The dose to be evaluated in the Phase III program will be 7.5 mg twice daily.
- The required safety documentation will include a population of at least 100 patients treated with a clinically relevant dose of mesdopetam during one year in the safety extension of the phase III program. The safety population in the program will be adjusted to ensure sufficient overall exposure to mesdopetam required for registration across different markets.

Importantly, efficacy on the planned primary endpoint in the Phase III program, UDysRS part 1+3+4, was prespecified and evaluated in the Phase IIb study of mesdopetam. Using this specific assessment scale for dyskinesia, the Phase IIb study demonstrated a clinically meaningful and nominally significant and anti-dyskinetic effect of mesdopetam at 7.5 mg twice daily as compared to placebo (ITT analysis, p=0.026).

For more information

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About mesdopetam

The investigational drug mesdopetam (IRL790), a dopamine D3 receptor antagonist, is being developed as a treatment for Parkinson's disease levodopa-induced dyskinesias (PD-LIDs). The objective is to improve the quality of life for people living with Parkinson's and having a severe form of involuntary movements commonly occurring after chronic levodopa treatment. Around 25-40 percent of all people being treated for Parkinson's develop LIDs, which equates to approximately 1.4-2.3 million people in the eight major markets globally (China, EU5, Japan and the US). Mesdopetam has also potential as a treatment for Parkinson's disease Psychosis (PD-P), and other neurological conditions such as tardive dyskinesia, representing an even larger market. The Phase Ib and Phase IIa studies showed a good safety and tolerability profile as well as proof-of-concept with potential for a better anti-dyskinetic effect compared with current treatment options. A Phase IIb study, completed in 2023, showed that mesdopetam has a dose-dependent anti-dyskinetic and anti-parkinsonian effect in combination with a tolerability and safety profile on par with placebo. The mesdopetam program is now undergoing preparations for Phase III.

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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

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