Press Release

Göteborg March 22, 2024

IRLAB receives minutes from End-of-Phase 2 meeting confirming alignment with the FDA on the Phase III program for mesdopetam

Gothenburg, Sweden, March 22, 2024 – IRLAB Therapeutics AB (Nasdaq Stockholm: IRLAB A), a company discovering and developing novel treatments for Parkinson's disease, today announced the receipt of written minutes from a recent End-of-Phase 2 meeting for mesdopetam with the US Food and Drug Administration, FDA. The minutes confirm the previously communicated positive verbal feedback from the meeting. Based on this successful outcome, IRLAB will now move forward with the preparations of the Phase III program.

At the End-of-Phase 2 meeting with the FDA, aspects related to all parts of the development plan for mesdopetam, including the design of a Phase III program, were evaluated and commented upon, based on the briefing package submitted to the agency before the meeting.

The written minutes, which confirm the verbal positive feedback provided at the meeting, are positive for the mesdopetam program and its advancement into Phase III. The minutes cover the FDA's opinion on the robustness of four key areas of the mesdopetam program to date: i) preclinical data, ii) toxicology, iii) clinical pharmacology (Phase Ia), and iv) clinical studies (Phase Ib, IIa and IIb). Thus, the response from the agency means that the data generated in all key areas is sufficient and adequate to move the program ahead into Phase III.

Alignment with the FDA was confirmed regarding the Phase III program including the following key components:

- The patient population will be in alignment with previous clinical studies in the mesdopetam program.
- The primary endpoint will be UDysRS part 1+3+4.
- The secondary endpoints will be based on subsections of UDysRS and MDS-UPDRS, and 24-hour Motor diaries.
- The estimated total sample size for Phase III will be 200-250 patients (1:1 active or control) with a treatment duration of 3 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 1 year in the safety extension of the phase III program.

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 nominally significant and clinically meaningful anti-dyskinetic effect of mesdopetam at 7.5 mg twice daily as compared to placebo (ITT analysis, p=0.026).

"Following the successful End-of-Phase 2 meeting for mesdopetam, we are now delighted to conclude that the FDA's formal meeting minutes confirm our plans for Phase III and validate the quality of our development activities. It is gratifying to see that the extensive work carried out by Irlab's experienced team meets the requirements of the regulatory authority to move mesdopetam into a confirmatory clinical Phase III program," said Gunnar Olsson, CEO, IRLAB.

Based on the positive feedback from the FDA, IRLAB continues the preparations for the Phase III program and will now engage with European regulatory agencies in accordance with standard practice before initiation of the Phase III program.

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 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, has completed Phase IIb and is in preparation toward Phase III. 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 IRL757 (financially supported by the Michael J. Fox Foundation), IRL942, and IRL1117 towards Phase I studies. IRLAB's pipeline has been generated by the company'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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