Press Release

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IRLAB submits request for an end-of-Phase 2 meeting with the FDA for the Phase III-ready mesdopetam program

Gothenburg, Sweden, December 18, 2023 – IRLAB Therapeutics AB (Nasdaq Stockholm: IRLAB A), a company discovering and developing novel treatments for Parkinson's disease, today announced that the company has submitted a request for an end-of-Phase 2 meeting with the US FDA for the Phase III-ready mesdopetam program. This is an important milestone in the preparation for initiating a Phase III program.

The purpose of an end-of-Phase 2 meeting with the US FDA, is to ensure alignment with the regulatory agency and determine the pathway to Phase III. As part of the end-of-Phase 2 meeting, the US FDA reviews the adequacy of safety and efficacy, in previous non-clinical and clinical studies, and evaluates the plans for proceeding to Phase III. The US FDA may, in addition, note if any additional information is necessary to support a future marketing application. According to guidelines, the US FDA will respond to a request within 14 calendar days and schedule an end-of-Phase 2 meeting within 70 calendar days from receipt of the meeting request. IRLAB will communicate the meeting date once set by the US FDA.

"I am impressed that IRLAB, in close collaboration with international expert advisors, has been able to put together the Briefing Book based on the comprehensive data, including the important studies performed by Ipsen, in less than four months. I am pleased that this achievement has now led to this important milestone – submission of a request for an end-of-phase 2 meeting," said Gunnar Olsson, CEO, IRLAB.

IRLAB is working together with the US advisory groups Clintrex, a clinical and regulatory strategy advisor; and ProPharma Group (PPG), IRLAB's regulatory agent, to develop the strategy for the Phase III program and the Briefing Book for the end-of-Phase 2 meeting.

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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[NW1] 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 very 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 recently completed Phase IIb study with 156 patients 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.

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 IRL942, IRL757, and IRL1117 towards Phase I studies. The pipeline is driven by IRLAB'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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