Press Release

Göteborg February 22, 2024

IRLAB has completed a successful End-of-Phase 2 meeting with the FDA on the design of the Phase III program for mesdopetam

Gothenburg, Sweden, 22 February 2024 – IRLAB Therapeutics AB (Nasdaq Stockholm: IRLAB A), a company discovering and developing novel treatments for Parkinson's disease, today announced that the company's recent End-of-Phase 2 meeting with the US Food and Drug administration, FDA, was held in a constructive and engaging spirit. The discussions during the meeting indicate alignment between the FDA and IRLAB on the design of the Phase III program.

At the End-of-Phase 2 meeting with the FDA, aspects related to the Phase III program with mesdopetam were discussed. Prior to the meeting, IRLAB had provided the FDA with comprehensive information on mesdopetam generated through preclinical studies, toxicology, clinical pharmacology, and the outcomes of the clinical Phase Ib, Phase IIa and Phase IIb studies conducted in people living with Parkinson's and levodopa-induced dyskinesias. A proposal for the further development of mesdopetam was included in the information package.

Based on this information, the FDA provided clear guidance that is substantially consistent with the proposed design of the Phase III-program for mesdopetam. Alignment with the FDA was reached on the key components of the Phase III program, including the primary and secondary endpoints, key inclusion and exclusion criteria and safety monitoring during the study period.

"We had a very good meeting with the FDA where we reached alignment on the final design of the Phase III program for mesdopetam. It is gratifying to see that the extensive work with exploratory as well as mandatory regulatory studies that has been carried out meets requirements to move mesdopetam into a confirmatory clinical Phase III program," said Gunnar Olsson, CEO, IRLAB.

More information about the study program will be communicated once the FDA has provided its formal feedback in the form of the official meeting minutes. IRLAB will receive the meeting minutes no later than 30 days after the meeting.

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 2024-02-22 08:30 CET.

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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.

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 recently completed Phase IIb study 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.

Attachments

IRLAB has completed a successful End-of-Phase 2 meeting with the FDA on the design of the Phase III program for mesdopetam