Press Release

Göteborg January 3, 2024

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

Gothenburg, Sweden, January 3, 2024 – IRLAB Therapeutics AB (Nasdaq Stockholm: IRLAB A), a company discovering and developing novel treatments for Parkinson's disease, today announced that the US FDA has granted IRLAB an end-of-Phase 2 meeting for the mesdopetam program on February 20, 2024.

"The end-of-Phase 2 meeting is an important milestone for the mesdopetam program. The further development activities, including the design of the Phase III program, will be discussed at the meeting and, thus, the path to a future New Drug Application (NDA) should be outlined. The outcome of the meeting is also important in IRLAB's business development activities for mesdopetam," 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 in the US, to develop the strategy for the mesdopetam Phase III program. IRLAB, PPG, and Clintrex have prepared the Briefing Book, which describes the full mesdopetam clinical and non-clinical development program and the scope and design of the planned randomized, placebo-controlled Phase III program.

The purpose of an end-of-Phase 2 meeting is to ensure alignment with the US FDA prior to the start of Phase III. As part of the end-of-Phase 2 meeting, the US FDA evaluates the Phase III plans and study protocols combined with the data generated in previously completed studies, i.e. review of the safety profile and assessment of the effectiveness of the drug candidate. The US FDA may, in addition, notify if any additional information is necessary to support a future New Drug Application (NDA).

Information on the outcome of the meeting will be shared when IRLAB has received feedback from the US FDA, which could be up to 30 days after the meeting.

For more information:

Gunnar Olsson, CEO
Phone: +46 70 576 14 02
E-mail: gunnar.olsson@irlab.se

Press Release

Göteborg January 3, 2024

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 IRL757 (financially supported by the Michael J. Fox Foundation), IRL942, and IRL1117 towards Phase I studies. IRLAB's pipeline is driven 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

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