

IRLAB secures full ownership of the mesdopetam project and continues product development

Gothenburg, Sweden, August 21, 2023 – IRLAB Therapeutics AB (Nasdaq Stockholm: IRLAB A), a company discovering and developing novel treatments for Parkinson's disease, today announced the transfer of rights for the now Phase III-ready mesdopetam project to IRLAB. IRLAB now has secured full ownership of the mesdopetam project including, inter alia, all technology, rights, know-how, intellectual properties, and materials, and will control the further clinical development and future commercialization. As compensation, IRLAB will pay Ipsen a low single-digit royalty based on future product sales. IRLAB and its advisors, with Ipsen's support, are now preparing for an end-of-Phase 2 meeting with the FDA as part of the detailed planning for Phase III.

All technical aspects in the preparation of mesdopetam for Phase III were completed during the IRLAB/Ipsen collaboration. These include all data generated in preclinical studies, all necessary Phase I, Phase Ib, Phase IIa and IIb studies, an expanded IPR portfolio, and CMC development including production of study drug for Phase III. Recently, Ipsen successfully completed three Phase I studies: a pharmacokinetic, a drug-to-drug interaction, and a mass balance study.

"We and our independent advisors have a strong belief in the clinical utility and commercial potential of mesdopetam and we are committed to pursuing the development of mesdopetam through Phase III for patient benefit and commercial success. The full analysis of the mesdopetam Phase IIb study demonstrates that mesdopetam has great potential as a first-in-class efficacious and well-tolerated anti-dyskinetic treatment for people with PD-LIDs," said Gunnar Olsson, CEO, IRLAB.

"The collaboration with Ipsen has been highly professional and productive. During the collaboration, Ipsen has conducted a number of important DMPK and safety studies and developed drug product to complete the Phase III preparations. We are working closely with Ipsen in the transfer of the project with the aim of securing the best possible prospects for mesdopetam to continue through Phase III and to ensure that mesdopetam can be made available to the benefit of people living with Parkinson's," said Nicholas Waters, EVP and Head of R&D, IRLAB.

IRLAB will pursue the regulatory path towards Phase III and will approach the FDA for an end-of-Phase 2 meeting to define the design of a Phase III program. Ipsen is supporting IRLAB with the preparation for such end-of-Phase 2 meeting.

For more information

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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 2023-08-21 14:30 CEST.

About mesdopetam

The investigational drug mesdopetam (IRL790) is a dopamine D₃ receptor antagonist in development as a treatment of Parkinson's disease levodopa-induced dyskinesias (PD-LIDs). The primary objective of mesdopetam is to improve the quality of life of individuals with Parkinson's disease by reducing PD-LIDs, a debilitating condition characterized by involuntary movements that frequently develop in patients who receive prolonged/chronic levodopa treatment. The results of the completed clinical studies in the Phase I and Phase II programs demonstrate a consistent anti-dyskinetic effect of mesdopetam, good safety, and it is assessed as offering significantly better tolerability compared to existing treatments.

Preclinical studies show that mesdopetam is a potent and efficacious anti-dyskinetic drug, and that mesdopetam also has the potential to prevent the development of dyskinesia as well as treating Parkinson's disease Psychosis (PD-P).

Press Release

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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 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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