Press Release

Göteborg October 10, 2023

IRLAB signs Phase III regulatory US consultants to support preparation for mesdopetam's end-of-Phase 2 meeting with the US FDA

Gothenburg, Sweden, October 10, 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 secured top expertise in supporting the preparations for Phase III with mesdopetam. The collaboration starts immediately with Clintrex leading IRLAB's US regulatory strategy, and ProPharma Group acting as IRLAB's regulatory US agent. The first milestone is the preparation of a briefing package to be able to request an end-of-Phase 2 meeting with the US Food & Drug Administration (FDA), in which the Phase III program of mesdopetam will be defined.

"I am pleased to have world-leading expertise supporting us to rapidly take our mesdopetam project to an end-of-Phase 2 meeting. We are very proud that these renowned US advisory groups, Clintrex and ProPharma, share our understanding of mesdopetam's great potential in reducing the burden and transforming the lives of people living with Parkinson's disease. I am looking forward to working with these experts on the next step in the development journey of mesdopetam," said Gunnar Olsson, CEO, IRLAB.

Clintrex is a clinical research company that works with pharmaceutical organizations to operationalize development pathways for new treatments for central nervous system (CNS) diseases. Its team members are internationally renowned leaders in the global scientific and neurological communities and have extensive experience in all aspects of the development process for new drugs, devices, and biologics. Clintrex members have held important leadership and consulting positions in academic, pharmaceutical, and regulatory communities.

"I see great potential of mesdopetam changing lives of people living with Parkinson's and we at Clintrex are honored to continue to support the program in interactions with the FDA. Our collective experience working with and at the FDA, including evaluating end-of-phase 2 meeting requests, is advantageous in successfully supporting IRLAB and mesdopetam through the same process," said Karl Kieburtz, MD, MPH, Professor in Neurology; President and co-founder of Clintrex; Former chairman of the Peripheral and Central Nervous System US FDA Advisory Committee; chairman of the Scientific Evaluation Committee for the Cooperative Studies Program, Veterans Administration, and advisor to the National Institute of Neurologic Disorders and Stroke.

ProPharma is the premier Research Consulting Organization (RCO), delivering fully customizable consulting solutions to empower biotech, med device, and pharmaceutical organizations of all sizes to advance scientific breakthroughs confidently and introduce new therapies. From clinical to commercialization, and any point in between, ProPharma Group partners with pharmaceutical, biotechnology, and medical device clients to ensure regulatory expectations are met, business goals are achieved, and patient safety is protected.

"We are very happy to be working with IRLAB on this critical Parkinson's project. As the world's leading RCO and given our significant, successful regulatory experience with Parkinson's therapies, we are excited at the prospect and improvements represented by mesdopetam. ProPharma has recently driven the successful submission of multiple Parkinson's NDAs and we look forward to assisting IRLAB as it moves forward." said Matthew Weinberg, President, Regulatory Sciences, ProPharma Group.

The work with Clintrex and ProPharma is already ongoing with the aim to prepare needed documentation to request the end-of-Phase 2 meeting with the US FDA. The purpose of the end-of-Phase 2 meeting with the US FDA, 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 assess effectiveness of the drug candidate. The US FDA may, in addition, note if any additional information is necessary to support a future marketing application.

For more information:

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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.

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Attachments

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