Press Release

Göteborg October 3, 2024

Positive data from the first part of IRLAB's Phase I study with the drug candidate IRL757

Gothenburg, Sweden, October 3 2024 - IRLAB Therapeutics AB (Nasdaq Stockholm: IRLAB A) – a company discovering and developing novel treatments for Parkinson's disease – today announces that the company has successfully completed the first part of its Phase I clinical trial with single ascending doses (SAD) of the drug candidate IRL757, which is being developed for the treatment of apathy. The results show that IRL757 is well absorbed, provides good exposure in the body and has a good tolerability and safety profile. IRLAB has recently secured full funding for the project through clinical proof-of-concept studies.

"We are very pleased to see that our drug candidate IRL757 is well absorbed, provides good exposure in the body and has a favorable safety profile. This bodes well for the further clinical development of a potential treatment that can counteract the apathetic conditions that affect millions of patients with neurodegenerative diseases," says Dr. Joakim Tedroff, Chief Medical Officer, IRLAB.

IRLAB will now proceed with the second part of the study, in which the study participants will receive multiple ascending doses (MAD). The study program is expected to be fully completed in 2024.

The Phase I study is funded by The Michael J. Fox Foundation for Parkinson's Research (MJFF) through a grant of approximately SEK 20 million. MJFF is the world's largest non-profit funder of Parkinson's disease research, and the organization's support of IRL757 provides a strong external validation of the project's potential.

In the spring of 2024, IRLAB entered a collaboration with MSRD, a part of the global pharmaceutical company Otsuka, to further develop IRL757. In this collaboration, the parties jointly design studies and activities, which IRLAB conducts while MSRD/Otsuka funds the project through "proof of concept" in selected larger patient populations.

About the Phase I study

The Phase I study consists of two parts and aims to document the safety, tolerability and pharmacokinetic properties of IRL757 in healthy subjects. In the first part of the study, single ascending doses of the drug candidate are administered (SAD) and in the second part, multiple ascending doses are given (MAD). In addition, the possible influence of concomitant food intake will be documented. The study is expected to be fully completed by the end of 2024 and top-line results are expected to be presented in the first quarter of 2025.

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For more information

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About IRL757

The drug candidate IRL757 is being developed as a treatment for apathy in Parkinson's disease and other neurological conditions. Apathy, a widespread and debilitating issue, affects over 20 million people in the U.S. and Europe alone without a currently available treatment. The prevalence is high, occurring in 1.1-4 million people (20–70 percent) being treated with Parkinson's in the eight major markets (China, EU5, Japan, and the US), and in 4.9-6.7 million people (43–59 percent) being treated for Alzheimer's disease in the ten major markets (Canada, China, EU5, Japan, South Korea, and the US).

IRL757 has the potential to become the first treatment for apathy. IRL757 has shown promising results in various preclinical models, which assess different aspects of cognitive function and motivation. The observed efficacy of IRL757 is thought to be linked to its unique ability to reverse disruption in cortical to sub-cortical nerve signaling, a key factor believed to contribute to apathy in neurological disorders.

About IRLAB

IRLAB discovers and develops a portfolio of transformative treatments for all stages of Parkinson's disease. The company originates from Nobel Laureate Prof Arvid Carlsson's research group and the discovery of a link between brain neurotransmitter disorders and brain diseases. Mesdopetam (IRL790), under development for treating levodopa-induced dyskinesias, has completed Phase IIb and is in preparation for Phase III. Pirepemat (IRL752), currently in Phase IIb, is being evaluated for its effect on balance and fall frequency in Parkinson's disease. IRL757, a compound being developed for the treatment of apathy in neurodegenerative disorders, is in Phase I. In addition, the company is developing two preclinical programs, IRL942 and IRL1117, towards Phase I studies. IRLAB's pipeline has been generated by the company's proprietary systems biology-based research platform Integrative Screening Process (ISP). 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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