Press Release

Göteborg May 6, 2024

IRLAB has received approval from the Swedish Medical Products Agency to conduct a Phase I study of the drug candidate IRL757

Gothenburg, Sweden, May 6, 2024 – IRLAB Therapeutics AB (Nasdaq Stockholm: IRLAB A), a company discovering and developing novel treatments for Parkinson's disease, today announced that the Swedish Medical Products Agency has approved the initiation of a Phase I clinical study of the drug candidate IRL757. IRL757 is being developed as a treatment to counteract apathy – a condition that impairs the quality of life for millions of people with Parkinson's disease, Alzheimer's disease and other CNS diseases. The Phase I study is fully financed by the world's largest non-profit funder of Parkinson's research, The Michael J. Fox Foundation for Parkinson's Research.

"Following the positive announcement from the Swedish Medical Products Agency, we now look forward to initiating the first clinical study of our drug candidate IRL757 shortly. The extensive research support granted by The Michael J. Fox Foundation for Parkinson's Research shows that world-leading external assessors share our confidence in the potential of IRL757 to counteract apathy, which today has no treatment and affects millions of individuals with neurodegenerative diseases and their relatives", comments Joakim Tedroff, MD, PhD, Chief Medical Officer, IRLAB.

Individuals suffering from apathy are characterized by indifference and resignation, rarely reacting to what is happening in the environment. The condition often causes significant disability and affects a large proportion of people living with Parkinson's disease, Alzheimer's disease and other diseases related to the central nervous system. There are currently no drugs on the market to treat apathy.

IRLAB's drug candidate IRL757 has shown positive effects in several preclinical models of cognitive function, including improved motivation. The effect is believed to be associated with the drug candidate's unique ability to counteract disruptions in the nerve signaling that occurs between the cerebral cortex and deeper brain parts and which is considered to be the cause of the onset of apathy in several neurological diseases.

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) whereas the second part covers multiple ascending doses (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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The Michael J. Fox Foundation for Parkinson's Research (MJFF) has awarded a grant of approximately SEK 20 million to conduct this first Phase I clinical trial of IRL757. 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.

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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).

RL757 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. IRL757 is considered Phase I ready as all preclinical studies and development work necessary to start Phase I is completed.

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.

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Attachments

IRLAB has received approval from the Swedish Medical Products Agency to conduct a Phase I study of the drug candidate IRL757