

# IRLAB has administered the first dose in a Phase I clinical trial with the drug candidate IRL757

Gothenburg, Sweden, May 22, 2024 – IRLAB Therapeutics AB (Nasdaq Stockholm: IRLAB A), a company discovering and developing novel treatments for Parkinson's disease, today announced that dosing has been initiated in a Phase I study of the drug candidate IRL757. IRL757 has been shown in preclinical disease models to counteract apathy – a condition that impairs the quality of life for millions of people with Parkinson's disease and other CNS diseases. Through a development collaboration with MSR/D/Otsuka and a grant from The Michael J. Fox Foundation, IRLAB has secured full project funding all the way to clinical Proof-of-Concept.

"We are very pleased to be able to start the clinical program with our drug candidate IRL757 so soon after the Medical Products Agency's approval. Our recently established development collaboration with MSR/D/Otsuka and the extensive research support we receive from The Michael J. Fox Foundation are clear evidence that world-leading external assessors share our confidence in the potential of IRL757 to treat apathy, a condition affecting millions of people living with neurodegenerative diseases," says Dr. Joakim Tedroff, MD, Chief Medical Officer, IRLAB.

The Michael J. Fox Foundation (MJFF) has awarded a grant of more than 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.

IRLAB has also recently announced a collaboration with McQuade Center for Strategic Research and Development, LLC (MSRD), part of the global pharmaceutical company Otsuka, to develop IRL757 further. By this, IRLAB has secured full financing of the project through clinical proof-of-concept studies. IRLAB retains full ownership and all patent rights to IRL757 during the collaboration period, and is also entitled to an upfront payment of USD 3 million as well as potential milestone payments totaling USD 5.5 million during the term of the agreement. According to the agreement, MSR/D has the option to extend the collaboration upon the occurrence of certain triggering events, but only after negotiating a new agreement. If the parties choose not to extend the collaboration, MSR/D may also, under certain circumstances, receive low single-digit percentage royalty payments.

Apathy is characterized by indifference, resignation and a lack of response to what is happening in the world around them. 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. Currently, there are 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. This effect is believed to be associated with the drug candidate's unique ability to counteract disturbances in nerve signaling that are believed to cause 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, ascending doses of the drug candidate are administered (Single Ascending Dose, SAD), and in the second part, repeated and ascending doses are given (Multiple Ascending Dose, MAD). In addition, the possible influence of concomitant food intake will be documented. The study is expected to be fully completed in 2024.

#### For more information:

Gunnar Olsson, CEO

Phone: +46 70 576 14 02

E-mail: [gunnar.olsson@irlab.se](mailto:gunnar.olsson@irlab.se)

#### 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 also 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](http://www.irlab.se).

## Attachments

[IRLAB has administered the first dose in a Phase I clinical trial with the drug candidate IRL757](#)