Press Release

Göteborg October 8, 2024

IRLAB receives milestone payment of USD 2.5 million in conjunction with first dosing in a Phase I study with IRL757 in healthy older adults

Gothenburg, Sweden, October 8, 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 clinical study of the drug candidate IRL757 in healthy adults aged 65 and older. This is the second clinical study with IRL757 and the first study under the collaboration framework with the McQuade Center (MSRD) a member of the global Otsuka family of pharmaceutical companies and will grant IRLAB a milestone payment of USD 2.5 million.

The single-center, open-label, phase I study evaluates the pharmacokinetics, safety and tolerability of single ascending oral doses of IRL757 in healthy individuals aged 65 and older. The study is expected to be completed in the end of Q4 2024.

"We are very pleased to continue the clinical development with IRL757 with a study in healthy older adults. IRL757 is a new first-in-class drug candidate for apathy, a condition affecting millions of people living with neurodegenerative diseases, most of which are elderly," says Dr. Joakim Tedroff, MD, Chief Medical Officer, IRLAB.

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 caregiver distress affecting 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 central nervous system nerve signaling believed to be an underlying cause of apathy in several neurological conditions.

In parallel with the study in healthy adults aged 65 and older, IRLAB is conducting a Phase I study consisting of two parts to document the safety, tolerability, and pharmacokinetic properties of IRL757 in healthy younger subjects. This study is expected to be fully completed in 2024 and is funded by The Michael J. Fox Foundation for Parkinson's Research (MJFF).

Under the current collaboration with McQuade Center for Strategic Research and Development, LLC (MSRD), IRLAB has received 3 million USD in up-front payment and can receive an additional 5.5 million USD following the achievement of certain development milestones. MSRD will also fund the drug development activities during the term of the agreement, with the exception of the currently ongoing Phase I program in healthy younger subjects, funded by The Michael J. Fox Foundation.

Further, under the terms of the current collaboration agreement, MSRD has the opportunity to elect to expand the collaboration upon the occurrence of certain triggering events, subject to negotiations of a new agreement. MSRD might also, if the parties do not expand the collaboration, under certain circumstances receive low single-digit percentage royalty payments.

For more information

Kristina Torfgård, CEO
Phone: +46 730 60 70 99
E-mail: kristina.torfgard@irlab.se

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 2024-10-08 11:00 CEST.

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 signalling, a key factor believed to contribute to apathy in neurological disorders.

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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.

Attachments

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