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IRLAB reports positive topline results from Phase I study with IRL757 in healthy older adults

Gothenburg, Sweden, January 31, 2025 - IRLAB Therapeutics AB (Nasdaq Stockholm: IRLAB A), a company discovering and developing novel treatments for Parkinson's disease, today announces positive topline results from its Phase I clinical study with the drug candidate IRL757 in healthy adults aged 65 years and older. The results show that IRL757 is well absorbed and provides good exposure in the body. All participants completed the study, and no serious adverse events were recorded. Collectively, the safety, tolerability and pharmacokinetic profile supports further development of IRL757.

The Phase I study evaluated the pharmacokinetics, safety, and tolerability of ascending oral doses of IRL757 in healthy individuals aged 65 years and older. The findings confirm earlier results reported from the first part of the Phase I study, conducted in younger healthy participants. These results demonstrate that IRL757 is well absorbed and provides good systemic exposure without the occurrence of serious adverse events. This milestone marks the completion of the second clinical study with IRL757. It is also the first study conducted under the collaboration with the McQuade Center for Strategic Research and Development, LLC (MSRD), a member of the global Otsuka family of pharmaceutical companies.

"We are pleased to present these excellent topline results for IRL757 in healthy older adults. IRL757 is the first in a completely new class of drug candidates and is being developed to treat apathy – a very common but often overlooked symptom in neurodegenerative disorders. This condition impacts the quality of life of millions of elderly patients suffering from diseases, particularly those affected by Alzheimer's and Parkinson's," said 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 leads to significant disability and caregiver distress, affecting a substantial 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 proposed to underly 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 younger healthy participants. This study, funded by The Michael J. Fox Foundation for Parkinson's Research (MJFF), is expected to be concluded during the first half of 2025.

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 signalling, 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.

Attachments

[IRLAB reports positive topline results from Phase I study with IRL757 in healthy older adults](#)