

ANNOUNCEMENT FOR EUROPEAN MEDICAL & PHARMACEUTICAL TRADE MEDIA AND
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IRLAB Receives Approval for a Phase Ib Study with IRL757 in Parkinson's Disease

Gothenburg, Sweden, December 23, 2025 – IRLAB Therapeutics AB (Nasdaq Stockholm: IRLAB A), a company focused on discovering and developing new treatments for Parkinson's disease, has received regulatory and ethical approvals for a Phase Ib study of IRL757 to assess safety, tolerability, and signal finding in patients with Parkinson's disease who experience apathy. The study will be conducted at 16 sites across four European countries and is fully funded by IRLAB's development collaborator, the McQuade Center for Strategic Research and Development, LLC (MSRD) –an indirect subsidiary of Otsuka Pharmaceutical Co., Ltd.

"We are excited about the Phase Ib Signal Finding Study of our drug candidate, IRL757, in Parkinson's patients experiencing apathy. This condition causes significant disability for many individuals living with Parkinson's disease. Currently, there is a substantial medical need for an effective treatment of apathy which lacks treatment options. With strong scientific and financial backing from our collaborator MSRD, we have developed this first-in-class drug candidate very efficiently," says Kristina Torfgård, CEO of IRLAB.

The study, which will include 75 patients with Parkinson's disease who experience apathy, will be conducted at study sites in Germany, Bulgaria, Poland, and Spain.

Two previous Phase I studies, one in healthy young adults and one in healthy older adults aged 65 and above, both showed that IRL757 was well absorbed and provided good systemic exposure after 10 days of dosing. All participants completed both studies, and no serious adverse events were recorded.

Apathy is characterized by indifference, resignation, and a lack of response to what is happening in the outside world. The condition often leads to significant disability affecting a substantial proportion of people living with Parkinson's disease, and with other neurodegenerative diseases. Currently, there are no drugs on the market to treat apathy.

IRLAB and MSRD, a member of the global Otsuka group of companies, formed a collaboration in May 2024 to advance IRL757 through proof-of-concept trials as a potential treatment for 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 ability to counteract disturbances in central nervous system nerve signalling proposed to underly apathy in several neurological conditions.

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. The 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 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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