Press Release

Göteborg January 23, 2025

IRLAB has received a waiver from the EMA regarding pediatric studies with mesdopetam in Parkinson's Disease

Gothenburg, Sweden, January 23, 2025 – IRLAB Therapeutics AB (Nasdaq Stockholm: IRLAB A), a company discovering and developing novel treatments for Parkinson's disease, today announced that a waiver regarding pediatric studies of mestopetam has been granted by the European Medicines Agency (EMA), which means that IRLAB does not have to perform studies of mesdopetam in children. The waiver enables IRLAB to concentrate its efforts on developing mesdopetam for patient groups where Parkinson's disease is more prevalent, thereby avoiding resource-demanding and lengthy studies in the pediatric population.

EMA's Paediatric Committee ("PDCO") recommended, and EMA has granted, a waiver for mesdopetam for all pediatric subsets of the pediatric population to treat Parkinson's disease. This waiver frees IRLAB from the obligation to conduct clinical studies of mesdopetam in children, which would otherwise have been mandatory to support a European marketing authorization application for the treatment of Parkinson's disease.

"We are pleased that EMA has confirmed that pediatric studies evaluating mesdopetam are not needed to support a market authorization application for Parkinson's disease.
Since we have previously received a corresponding decision from the US Food and Drug Administration (FDA), the decision from EMA means that we can now focus our development efforts entirely on activities in more relevant patient groups," says Kristina Torfgård, CEO of IRLAB.

In 2007, the European Union introduced the Paediatric Regulation, transforming the development of medicines for children. A fundamental principle is that pharmaceutical development companies need to submit pediatric investigation plans for all new drugs. A key component of this initiative was the establishment of the PDCO, which coordinates EMA's pediatric medicine efforts and specifies required studies for companies. In certain cases, the PDCO may recommend a waiver for a Pediatric Investigation Plan when developing a medicine for children is not feasible or appropriate.

For more information

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About mesdopetam

The investigational drug mesdopetam (IRL790), a dopamine D3 receptor antagonist, is being developed as a treatment for Parkinson's disease levodopa-induced dyskinesias (PD-LIDs). The objective is to improve the quality of life for people living with Parkinson's and having a severe form of involuntary movements commonly occurring after chronic levodopa treatment. Around 25-40 percent of all people being treated for Parkinson's develop LIDs, which equates to approximately 1.4-2.3 million people in the eight major markets globally (China, EU5, Japan and the US). Mesdopetam has also potential as a treatment for Parkinson's disease Psychosis (PD-P), and other neurological conditions such as tardive dyskinesia, representing an even larger market. The Phase Ib and Phase IIa studies showed a good safety and tolerability profile as well as proof-of-concept with potential for a better anti-dyskinetic effect compared with current treatment options. A Phase IIb study, completed in 2023, showed that mesdopetam has a dose-dependent anti-dyskinetic and anti-parkinsonian effect in combination with a tolerability and safety profile on par with placebo. The mesdopetam program is now undergoing preparations for Phase III.

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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