Press Release

Göteborg October 29, 2024

IRLAB reports continued progress ahead of the mesdopetam Phase III program

Gothenburg, 29 October 2024 - IRLAB Therapeutics AB (Nasdaq Stockholm: IRLAB A), a company discovering and developing novel treatments for Parkinson's disease, today reports several advances in the preparations for Phase III with its drug candidate mesdopetam. The regulatory authorities in Germany and Portugal are positive about IRLAB's proposed study design for the Phase III program. New market research validates the high commercial potential of mesdopetam, and a meta-analysis recently presented at the MDS scientific conference confirms the pronounced effect against levodopa-induced dyskinesias in people with Parkinson's disease.

"The recent progress in the preparation for Phase III with mesdopetam strengthens our position in the ongoing discussions with potential partners. We continue to experience strong interest from various stakeholders and are now evaluating options in the further development and potential commercialization of our unique drug candidate, mesdopetam," says IRLAB's CEO, Kristina Torfgård.

Positive feedback from regulatory authorities

IRLAB has recently held scientific advisory meetings with the German regulatory authority BfArM and its Portuguese counterpart INFARMED. In the meetings, both authorities provided clear guidance on, among other things, the critical components of the Phase III program, which are essentially in line with the plans agreed upon between IRLAB and the US Food and Drug Administration (FDA). As in the dialogues with the FDA, a consensus was reached on, among other things, the patient population, the primary and secondary endpoints, that the protocol follows regulatory guidelines of at least a 3-month treatment period, essential inclusion and exclusion criteria, the dose selection (7.5 mg twice daily), the number of participants in the program, as well as details on safety evaluation and documentation requirements.

The interactions with BfArM and INFARMED are part of the strategic regulatory activities, including the previously successful End-of-Phase 2 meeting with the FDA and the upcoming interaction with the European Medicines Agency (EMA). The aim is to ensure that the Phase III program and further development of mesdopetam are designed to meet the regulatory requirements in both the US and Europe.

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New market research confirms the commercial potential

IRLAB has recently conducted in-depth market research to guide the company and its future commercial partners in positioning for a future launch of mesdopetam in the US and Europe. Structured interviews have been carried out with healthcare organization officials in both regions to better understand current treatment practices and the medical need for new treatments that can reduce levodopa-induced dyskinesias in Parkinson's disease. The results of the market research indicate a high willingness to pay for an anti-dyskinetic drug with a novel and effective mechanism of action. Thus, providing significant commercial potential for mesdopetam in both the US and Europe. It also shows that the planned design of the Phase III program aligns with the desires of the healthcare funders.

New meta-analysis highlights the medical benefits of mesdopetam

A meta-analysis recently presented at the International Congress of Movement Disorders (MDS) in Philadelphia, USA, shows that treatment with mesdopetam provides clinically meaningful anti-dyskinetic efficacy without causing impairment of motor function. Further, the drug candidate reduces "OFF time", the total time of the day when classic Parkinson's symptoms recur. The meta-analysis is based on two previously conducted Phase II studies with four and twelve weeks of treatment, respectively. The acknowledgment of the meta-analysis for presentation at such a prestigious international conference underscores its quality and the medical relevance of the results.

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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