Press Release

Göteborg December 21, 2021

IRLAB obtains regulatory approval to conduct Phase IIb study with pirepemat – one step closer to improving balance and reducing fall injuries for people living with Parkinson's disease

IRLAB (Nasdaq Stockholm: IRLAB A) IRLAB receives regulatory approval from the Swedish MPA for conducting a Phase IIb study with the investigational drug candidate pirepemat. Following approvals from regulatory authorities in additional participating countries and from ethics committees, patient recruitment will start in Q1, 2022. Recruitment is expected to continue for 18 months.

The application to conduct the Phase IIb study was filed using the Voluntary Harmonization Procedure (VHP). The VHP makes it possible to obtain a coordinated assessment of an application for a clinical trial that is to take place in several European countries. In addition to the Swedish MPA, which acts as the reference country, Polish and Spanish regulatory authorities are participating. IRLAB is also applying to regulatory authorities and ethics committees in other selected European countries.

"Pirepemat has potential to be the first treatment in a new class of drugs designed to improve balance and reduce fall injuries in people living with Parkinson's disease," said Nicholas Waters, CEO at IRLAB. "After receiving advice from regulatory authorities and in collaboration with external experts, we have designed a study to support the continued development of pirepemat, for which we have now received regulatory approval."

"Treating impaired balance and reducing risk for falls is a top priority in the battle to fight the complications of Parkinson's disease, as today these are the most troubling consequences of living with Parkinson's, leading to reduced quality of life." added Joakim Tedroff, CMO at IRLAB.

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For more information

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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 2021-12-21 23:05 CET.

About the Phase IIb study with pirepemat

The approved Phase IIb study with Pirepemat is designed as a randomized, double-blind and placebo-controlled study with the aim to evaluate the effect of pirepemat on fall frequency, as compared to a placebo, over a three-month treatment period. The planned primary outcome measure is reduction in number of falls as assessed through electronic fall diaries. The study is designed to randomize 165 patients distributed across three groups, two groups with different dose levels of pirepemat and one placebo group with 55 patients in each group. For this study, which will involve clinics across several countries in Europe, IRLAB is collaborating with a Clinical Research Organization (CRO) that has longstanding expertise and experience in running studies in Parkinson's disease.

About pirepemat (IRL752)

Pirepemat is in development for the treatment of impaired balance (postural dysfunction) and falls in Parkinson's disease (PD). Impaired balance and falls are linked to cognitive decline and the progression of Parkinson's disease. In clinical research, it has been shown that these symptoms are associated with a reduction of the neurotransmitters noradrenaline and dopamine in the frontal cortex of the brain. Pirepemat can increase the levels of these neurotransmitters in the frontal cortex and activate specific genes involved in nerve cell communication. The reduced cortical neurotransmission in PD could therefore be counteracted by treatment with Pirepemat, leading to improvement of balance and cognitive and psychiatric symptoms for people living with PD. The results from a clinical Phase IIa study indicate that Pirepemat has the potential to improve balance and reduce the risk of falls.

About IRLAB

IRLAB is a Swedish research and development company that focuses on discovery and development of novel treatments in Parkinson's disease. The company's most advanced drug candidates, Mesdopetam (IRL790), licensed to Ipsen, and Pirepemat (IRL752), have completed Phase IIa studies and are designed to treat some of the most difficult symptoms related to Parkinson's disease: involuntary movements (PD-LIDs), psychosis (PD-P) and symptoms linked to cognitive decline such as impaired balance and increased risk of falls (PD-Falls). Through its proprietary research platform, the Integrative Screening Process (ISP), IRLAB has discovered and developed all its projects within Parkinson's disease and will have an ability to also discover drug candidates for other disorders related to the central nervous system (CNS), where large and growing medical needs exist. In addition to the Phase IIb clinical candidates, the ISP platform has also generated several CNS programs that are now in preclinical phases. IRLAB is listed on Nasdaq Stockholm Main Market. More information is found on www.irlab.se.

Attachments

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