

IRLAB's drug candidate pirepemat's Phase I data published in scientific journal CPDD

IRLAB (Nasdaq Stockholm: IRLAB A) today announced that a scientific publication reporting the results from the clinical first-in-human (Phase I) study with pirepemat has been published in the journal *Clinical Pharmacology in Drug Development (CPDD)*. Pirepemat is in development to improve balance and reduce falls in Parkinson's disease, and has completed Phase IIa studies. A Phase IIb study to evaluate effects of pirepemat on frequency of falls in patients with Parkinson's disease is planned to be initiated during 2021.

The scientific paper describes the randomized, double-blind, placebo-controlled Phase I, first-in-human (FIH), study with pirepemat. The study evaluated the safety, tolerability, and pharmacokinetics of escalating single and multiple doses of pirepemat. It was concluded that pirepemat was safe and well-tolerated in healthy male volunteers. Pharmacokinetic analysis indicated rapid absorption and dose-linear pharmacokinetics of pirepemat upon single and repeated dosing. The pharmacokinetics of pirepemat supports three-times-daily use in patients with Parkinson's disease.

"Publication of results from preclinical and clinical studies are an important part of drug development and is at the center of our strategy to establish our science and pipeline broadly in the industry. This is the second publication of Phase I results from our drug candidates in a short time that supports validation of our pipeline's great potential in Parkinson's disease," said Susanna Waters, M.D., Ph.D, Director of Biology & Biostatistics at IRLAB.

Clinical Pharmacology in Drug Development (CPDD) is an international, peer-reviewed, online publication focused on publishing high-quality clinical pharmacology studies in drug development which are primarily, but not exclusively, performed in early development phases and in healthy subjects.

Publication: Rein#Hedin E, Sjöberg F, Waters S, Sonesson C, Waters N, Huss F, Tedroff J. First#in# Human Study to Assess the Safety, Tolerability, and Pharmacokinetics of Pirepemat, a Cortical Enhancer, in Healthy Volunteers. *Clinical Pharmacology in Drug Development*. 2021,0 (0);1-10. <https://doi.org/10.1002/cpdd.959>.

For more information

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About pirepemat (IRL752)

Pirepemat is in development for the treatment of impaired balance (postural dysfunction) and falls in Parkinson's disease. The results from a clinical Phase IIa study indicate that pirepemat has the potential to improve balance and reduce the risk of falls. Pirepemat has the ability to increase the levels of the neurotransmitters norepinephrine and dopamine in the frontal cortex and activate specific genes involved in nerve cell connections. In clinical research, it has been shown that the neurotransmitters noradrenaline and dopamine are decreased in the frontal cortex in Parkinson's disease. This could be counteracted by treatment with pirepemat, leading to improvement of balance, cognitive and psychiatric symptoms for these patients. A Phase IIb study to evaluate the effect of pirepemat on fallrate is planned to begin in 2021.

About IRLAB

IRLAB is a Swedish research and development company that focuses on developing novel treatments in Parkinson's disease. The company's most advanced candidates, mesdopetam (IRL790) and pirepemat (IRL752), both of which completed Phase IIa studies, intends 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 the proprietary research platform, ISP (the Integrative Screening Process), IRLAB discovers and develops unique drug candidates for central nervous system (CNS) related disorders where large and growing medical need exist. In addition to the clinical candidates, the ISP platform has also generated several CNS programs that are now in preclinical phase. IRLAB is listed on Nasdaq Stockholm Main Market. More information on www.irlab.se.

Attachments

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