Press Release

Göteborg February 6, 2024

IRLAB's pioneering Phase IIb study with pirepemat – React-PD – provides new insights in specific Parkinson's patient population and enables a data driven prediction of study timelines

Gothenburg, Sweden, February 6, 2024 – IRLAB Therapeutics AB (Nasdaq Stockholm: IRLAB A) is a company discovering and developing novel treatments for Parkinson's disease. Pirepemat has the potential to become the first treatment for the largest unmet need in Parkinson's, prevention and reduction of falls and fall injuries, and is in the forefront of the treatment of falls in Parkinson's. The ongoing pioneering Phase IIb study, React-PD has already generated invaluable new knowledge about the specific group of recurrent fallers. Baseline fall rates show that subjects enrolled in the study fall 2-3 times more than previously anticipated, providing a higher probability to observe treatment dependent effects. Enrollment of study subjects has been ongoing at all study sites since May 2023, and the enrollment rate has stabilized. Based on the new information, IRLAB is able to more accurately predict the enrollment timelines for the remainder of the React-PD study, now anticipating that study enrollment will be completed in the third quarter 2024.

The ongoing pioneering Phase IIb study, React-PD, in people at more advanced stages of Parkinson´s disease evaluates effects of pirepemat with the main objective to identify the optimal dose for Phase III. The React-PD study has been running with all 38 clinics activated since May 2023, and the enrollment of patients is now progressing at a steady pace. Factors influencing the initial enrollment rate are, among others, the logistical support needed for study subjects to make visits to the clinics and the relatively large number of visits during the study.

Baseline data in the React-PD study also show that subjects fall 2-3 times more often than anticipated. Further, the individual fall rates are stable during the one-month study run-in before starting study medication. Combined, this provides a higher likelihood to detect treatment-dependent effects on fall rates. These observations, in combination with lower drop-out rates than anticipated, have prompted IRLAB to initiate discussions to submit a study amendment with a reassessment of the sample size for the study. Thus, it is possible that the planned study sample size can be reduced with retained power of the study, i.e., its potential to detect a treatment-dependent effect on fall rate.

Based on the experience from the React-PD study, IRLAB now have compiled information regarding this specific patient population, enabling more accurate data driven predictions of enrollment rate and study timelines. Based on the new data obtained from this specific patient population, the Company now anticipates that study enrollment will be completed in the third quarter 2024.

"Instability and falls are an important challenge in the treatment of Parkinson's disease, since they represent a problem that significantly affects patients' quality of life. Being able to participate in this study, with such an important goal, could help to improve this circumstance for many patients. Although it is a double-blinded phase II study, participating patients describe a relevant improvement in their general condition," said dr Eric Freyre, Investigator in the React-PD study

"Participants enrolled in the study are reported to be highly satisfied during the study treatment period, which is further corroborated by repeated requests from patients and physicians for continued treatment beyond the clinical trial. I interpret this positive feedback from participants, caretakers, and treating physicians as a clear signal of the benefit of participating in this study," said Joakim Tedroff, Chief Medical Officer IRLAB. "We continue to work closely with our CRO, the investigators, and participating clinics with the aim of optimizing outcomes and simplify for patients to enroll. This includes reducing the number of hospital visits by allowing home visits where applicable. We are, thus, confident with the updated timeline estimation given the steady enrollment pace and the lower drop-out rates in this study," said Joakim Tedroff, Chief Medical Officer IRLAB.

"Based on what we have learned about pirepemat, we see a great possibility to have a first-in-class drug for the treatment of falls in Parkinson's that can change the treatment algorithm to benefit patients and their families. I see a major commercial potential for pirepemat as it targets untreated symptoms and a high unmet need with a potential to decrease overall healthcare cost. The potential is further strengthened by the recently reported granted patent for pirepemat. We are looking forward to the completion of the study and to intensify our BD activities to identify partnership ahead of the Phase III program and the commercialization of the product," said Gunnar Olsson, CEO IRLAB.

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For more information

Gunnar Olsson, CEO
Phone: +46 70 576 14 02
E-mail: gunnar.olsson@irlab.se

Nicholas Waters, EVP and Head of R&D
Phone: +46 730 75 77 01
E-mail: nicholas.waters@irlab.se

About pirepemat (IRL752)

Drug candidate pirepemat (IRL752) has the potential to be the first treatment in a new class of drugs designed to improve balance and reduce falls and fall injuries in people living with Parkinson's disease. Pirepemat is designed to strengthen nerve cell signaling in the prefrontal cortex via antagonism at 5HT7 and alpha-2 receptors leading to increased dopamine and noradrenaline levels. 45 percent of all people living with Parkinson's fall recurrently, which approximates 2.6 million people suffering from a significantly reduced quality of life also due to fear of falling. There are no available treatments at present, despite the great medical need. Pirepemat is currently in a Phase IIb study to evaluate the efficacy, safety, and tolerability of different doses of pirepemat in people living with Parkinson's disease to identify the optimal dose for Phase III. The study is active at 38 study sites across France, Germany, Poland, the Netherlands, Spain, and Sweden.

About the Phase IIb React-PD study with pirepemat

The Phase IIb study of pirepemat (IRL752C003 – React PD) is a double blinded and placebo-controlled Phase IIb study with the aim to evaluate the effect of pirepemat on falls frequency in people with Parkinson's, at two dose levels and placebo over a three-month treatment period. The secondary study objectives include cognitive and neuropsychiatric assessments and further safety and tolerability studies. The study comprises two groups with different dose levels of pirepemat and one placebo group. The ongoing study is recruiting patients at the planned sites in France, Germany, the Netherlands, Poland, Spain and Sweden. The company's assessment is that patient recruitment to the study will be completed during the third quarter of 2024. This is followed by a one month baseline period, a three month treatment period with follow-up visits, data mangement and database lock before top-line results can be reported. More information can be found on EudraCT number: 2019-002627-16 and www.clinicaltrials.gov: NCT05258071.

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About IRLAB

IRLAB is discovering and developing a portfolio of transformative therapies targeting all stages of Parkinson's disease. The company has its origin in Nobel Laureate Prof. Arvid Carlsson's research group and the discovery of a connection between the brain's neurotransmitters and CNS disorders. Mesdopetam (IRL790), in development for the treatment of levodopa-induced dyskinesias, has completed Phase IIb and is in preparation toward Phase III. Pirepemat (IRL752), is currently in Phase IIb, being evaluated for its effect on balance and fall frequency in Parkinson's disease. In addition, the company is also progressing the three preclinical programs IRL757 (financially supported by the Michael J. Fox Foundation), IRL942, and IRL1117 towards Phase I studies. IRLAB's pipeline has been generated by the company's proprietary systems biology-based Integrative Screening Process (ISP) research platform. Headquartered in Sweden, IRLAB is listed on Nasdaq Stockholm (IRLAB A). For more information, please visit www.irlab.se.

Attachments

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