Press Release

Göteborg January 17, 2023

IRLAB announces top-line results from Phase IIb trial of mesdopetam (IRL790) in Parkinson's disease

Gothenburg, Sweden, January 17, 2023 – IRLAB Therapeutics AB (Nasdaq Stockholm: IRLAB A), a company discovering and developing novel treatments for Parkinson's disease, today announced the top-line results from the Phase IIb study of mesdopetam in people with Parkinson's disease levodopa-induced dyskinesias (PD-LIDs). The primary endpoint, change in daily hours of ON-time without troublesome dyskinesia, as assessed with patient diaries, did not reach statistical significance by mesdopetam compared to placebo. Mesdopetam demonstrated significant anti-dyskinetic effects as measured by a secondary endpoint UDysRS (nominal p-value = 0.026 at 7.5 mg bid at twelve weeks), a comprehensive measure taking both objective physician ratings and patient ratings into account. Mesdopetam displayed an adverse event and tolerability profile similar to placebo. The top-line results will be presented at a webcast on January 18, 2023, at 10:00 CET, access details below.

The Phase IIb trial objective was to investigate efficacy and safety of three doses of mesdopetam (2.5, 5.0, and 7.5 mg bid), as compared to placebo, in people with Parkinson's disease experiencing troublesome dyskinesia caused by their levodopa treatment and to support dose selection for further clinical development. The primary endpoint, change in daily ON-time without troublesome dyskinesia ("good ON"-time), did not reach statistical significance by mesdopetam compared to placebo. A secondary efficacy endpoint, UDysRS (part 1, 3 and 4, full analysis set), a comprehensive scale measuring ON-phase dyskinesia, showed significant anti-dyskinetic effects by mesdopetam already at four weeks (nominal p-value = 0.045), at eight weeks (nominal p-value = 0.004), continuing for the full twelve-week study period (nominal p-value = 0.026) at the 7.5 mg bid dose. This effect was corroborated by the numerical improvement in scales measuring disability associated with dyskinesia. Further, the daily time spent in OFF showed a dose-dependent pattern and a numerical decrease compared to placebo also favoring the 7.5 mg bid dose. The secondary endpoint MDS-UPDRS part II (motor aspects of experiences of daily living) was unchanged by mesdopetam treatment, which was the desired outcome as it shows that mesdopetam does not impair normal motor function in this study population.

"Although the study did not meet its primary efficacy endpoint, a well-established scale used to assess dyskinesia, the UDysRS, demonstrated anti-dyskinetic effects by mesdopetam. Notably, these anti-dyskinetic properties were obtained without impairing normal motor function and are further strengthened by an apparent reduction in OFF-time. The effect is observed at doses with a side effect profile on par with placebo. This was also a dose-finding study and we now have a

clear understanding that 7.5 mg bid is the preferred dose for further clinical studies. We will now together with our partner Ipsen continue analyses of the study data and prepare to present further results at scientific conferences during 2023," said Nicholas Waters, EVP and Head of R&D, IRLAB.

The findings from the Phase IIb trial showed that mesdopetam was well tolerated and displayed an acceptable safety profile. The adverse event profile of mesdopetam in the Phase IIb study was similar to placebo. Early withdrawal from the study due to any adverse events occurred in similar proportions in the mesdopetam treatment arms and the placebo arm, indicating good tolerability. Any reported adverse events were 56.9% in mesdopetam-treated subjects compared to 46.2% in placebo. The most common adverse events reported by system organ class (SOC) were nervous system disorders reported by 19.8% of mesdopetam-treated subjects and 23% of placebo-treated subjects. Parkinsonism was reported by 4.3% of mesdopetam-treated subjects and 10.3% of placebo-treated subjects. A small number of subjects treated with mesdopetam (6.9%), compared to 0% placebo, reported decreased mobility during the first month of treatment which was not seen during the second and third months of treatment. There were seven randomized patients reporting Serious Adverse Events (SAEs) of which four were in the mesdopetam treatment arms and three in placebo. One SAE was considered probably related to mesdopetam treatment. There were two deaths not considered related to mesdopetam. In the study, 195 patients were screened, 156 patients were randomized, and 125 patients completed the twelve-week treatment period.

"Unfortunately, the primary endpoint to increase "good ON"-time compared to placebo was not met. I am, however, encouraged that the UDysRS results suggest that mesdopetam has potential to become an effective treatment of Parkinson's disease. Clearly, further detailed analysis is required to fully understand the potential of this first-in-class compound. I am grateful to the clinical development team, PIs and CRO for their diligent and hard work with the Phase IIb trial, and I would like to thank the patients and their caregivers for their trust and participation in this study," said Richard Godfrey, Chief Executive Officer, IRLAB.

Further analysis of the full data will be carried out and full disclosure of the detailed results from the Phase IIb trial will be made in abstracts at future scientific congresses and publications in scientific journals.

The global specialty pharma company Ipsen holds the exclusive right for further clinical development and commercialization of the mesdopetam program in PD-LIDs and potentially other indications.

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For more information:

Richard Godfrey, CEO
Phone: +46 730 70 69 00
E-mail: richard.godfrey@irlab.se

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

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 2023-01-17 21:15 CET.

Webcast for investors, analysts, and media

The company will hold a live webcast in conjunction with the top-line results announcement on January 18, 10:00 CET.

Access webcast via link: https://channel.royalcast.com/landingpage/hegnarmedia/20230118_2/

About the Full Analysis Set (FAS)

The Full Analysis Set (FAS) consisted of all randomized and treated patients who received one or more doses and who provided post-baseline data.

About patient-completed 24-hour diaries

Clinical diaries are a standardized method for patients to assess their health status. Patients log their motor status every 30 minutes for 24 hours. Patients record whether their motor status is:

- "OFF" denotes stiffness, marked decrease of mobility or immobility
- "ON" denotes good or practically normal mobility
- "ON with troublesome dyskinesias" is when the patient is troubled by involuntary twisting and turning movements.
- Additionally, sleep time is recorded

About Unified Parkinson's Disease Rating Scale (MDS-UPDRS)

The Unified Parkinson's Disease Rating Scale (MDS-UPDRS) is a standardized and validated estimation scale developed for assessment of symptoms in Parkinson's disease. The instrument has been tested for good reliability and validity and consists of the following four parts:

- Part I – Non-Motor Aspects of Experiences of Daily Living
- Part II – Motor Aspects of Experiences of Daily Living
- Part III – Motor Examination
- Part IV – Motor complications of therapy

Each section has questions that rate the symptoms from 0 to 4 where higher values indicate more severe symptoms.

About Unified Dyskinesia Rating Scale (UDysRS)

The Unified Dyskinesia Ratings Scale (UDysRS) evaluates the involuntary movements that can be associated with long-term treatment with dopaminergic medication. The UDysRS has four parts:

- Part 1 – Historical Disability (patient perceptions) of ON-Dyskinesia impact
- Part 2 – Historical Disability (patient perceptions) of OFF-Dystonia impact
- Part 3 – Objective Impairment (dyskinesia severity, anatomical distribution over seven body regions, and type (choreic or dystonic) based on four activities observed or video-recorded
- Part 4 – Objective disability based on Part III activities

The modified UDysRS was used in the Phase IIb trial, which constitutes Part 1, Part 3 and Part 4.

About Phase IIb study with mesdopetam

The Phase IIb study with mesdopetam was a randomized, double-blind, placebo-controlled study with objective to investigate efficacy and safety of three doses of mesdopetam (2.5, 5.0, and 7.5 mg bid), as compared to placebo, in people with Parkinson's disease experiencing troublesome dyskinesia caused by their levodopa treatment and to support dose selection for further clinical development. The primary endpoint was change in daily hours of ON-time without troublesome dyskinesia ("good ON"-time) as assessed with 24-hour patient home diaries. The study randomized 156 subjects distributed across four treatment arms, three dose levels of mesdopetam and a placebo arm with approximately 40 subjects in each arm with a treatment period of twelve weeks. The study was conducted at 46 study sites in Europe, Israel and in the US. More information can be found on clinicaltrials.gov: NCT04435431, and EudraCT number: 2020-002010-41.

About mesdopetam

Mesdopetam (IRL790) is an oral dopamine D3-receptor antagonist being developed for the treatment of levodopa-induced dyskinesias (LIDs), a severe form of troublesome involuntary movements commonly occurring in Parkinson's disease. In Phase I and IIa studies, mesdopetam reduces time spent with troublesome dyskinesia and thereby increases daily "good ON"-time in patients with Parkinson's disease. Preclinical studies show that mesdopetam is a potent and efficacious anti-dyskinetic, and that mesdopetam also has the potential to prevent the development of dyskinesia as well as treating Parkinson's disease Psychosis (PD-P). In 2021, Ipsen, a specialty pharma company, acquired exclusive global rights to the development and commercialization of mesdopetam.

About IRLAB

IRLAB discovers and develops novel treatments of Parkinson's disease and other CNS disorders. The company's most advanced drug candidates, mesdopetam (IRL790) and pirepemat (IRL752), are in Phase IIb and are designed to treat some of the most difficult symptoms related to Parkinson's. In 2021, Ipsen, a specialty pharma company, acquired exclusive global rights to the development and commercialization of mesdopetam.

IRLAB has discovered and generated all its drug candidates and continues to discover innovative drug candidates for the treatment of CNS disorders through its proprietary systems biology-based Integrative Screening Process (ISP) research platform. In addition to IRLAB's strong clinical pipeline, the company is also progressing three preclinical programs, IRL942, IRL757, and IRL1117, towards Phase I studies. IRLAB is listed on Nasdaq Stockholm. More information on www.irlab.se.

Attachments

IRLAB announces top-line results from Phase IIb trial of mesdopetam (IRL790) in Parkinson's disease