InBrain Pharma to Present Positive Results from Its DIVE-I Phase I/II Clinical Trial for Parkinson's Disease at the Congress of Parkinson's Disease and Movement Disorders from September 27 to October 1 in Philadelphia

Lille, September 25, 2024 - InBrain Pharma, a biopharmaceutical company specialized in neurodegenerative diseases, will present the positive results of its Phase I/II DIVE-I clinical trial for Parkinson's disease at the upcoming International Congress of Parkinson's Disease and Movement Disorders, held in Philadelphia from September 27 to October 1, 2024.

This clinical trial, conducted in collaboration with Lille University Hospital (CHU de Lille), aimed to evaluate the safety and efficacy of a new device-assisted therapy (DAT) for advanced-stage Parkinson's disease. The therapy involves the direct administration of missing dopamine into the brain of patients to control severe motor symptoms resulting from disease progression, as well as those induced by conventional oral treatments. Dopamine plays a crucial role as a neurotransmitter in controlling motor, intellectual, and emotional behavior, as it is present in high concentrations in the basal ganglia. Its deficiency over time in this neurodegenerative disease leads to both motor and non-motor symptoms.

"*I am very pleased to present the positive safety and efficacy results of our DIVE-I Phase I/II clinical trial for Parkinson's disease to the scientific community at this prestigious congress. This study, which included 12 patients, evaluated A-dopamine administered intracerebroventricularly (i.c.v.) on top of an optimized oral antiparkinsonian background regimen, compared to optimized oral antiparkinsonian background regimen alone. The clinical results are exceptional, showing a very good safety profile, and a remarkable clinical effect on controlling severe motor symptoms (walking and communication difficulties, involuntary movements, agitation), allowing for a reduction in the dosage of underlying oral treatments based on L-dopa, which often cause abnormal movements. Moreover, all our treated patients decided to continue the therapy,"* explains **Professor David Devos, neurologist and pharmacologist at CHU de Lille, Lille University and INSERM and co-founder of InBrain Pharma.**

"The availability of these highly promising clinical results in such a disabling stage of this disease left without any satisfactory therapeutic options is a true opportunity for InBrain Pharma not only to reinforce relationship with the global field experts but also to meet and discuss with the Regulatory Agencies the next clinical development step" explains **Dr. Véronique Foutel, CEO of InBrain Pharma**.

The results will also be submitted for publication in a peer-reviewed scientific journal.

Date and Time: Saturday, September 28, from 1:30 PM to 2:30 PM, Pennsylvania Convention Center, Philadelphia.

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About the DIVE-I Clinical Trial

Initiated in 2020, the single-center Phase I/IIB DIVE-I clinical trial included 12 patients with Parkinson's disease who experienced motor complications (freezing and dyskinesia). It was a randomized, controlled, open-label crossover trial with three phases: an initial feasibility and safety phase (Phase I), a second phase evaluating efficacy and safety, which has just been completed (Phase II), and a long-term follow-up phase that is still ongoing.

Before treatment, patients had a small precision dosing pump implanted under the skin in the abdominal area, along with a thin, flexible catheter that runs subcutaneously and reaches the patient's third brain ventricle. The pump reservoir was refilled every 7 to 15 days. In the ongoing long-term follow-up phase, the pump is now refilled at the patient's home by a home care provider, with the clinical investigator neurologist giving instructions to adjust the administration rate and total volume of dopamine introduced at each refill based on the patient's needs. This trial, initially randomized, open-label, and single-arm in Phase I, became a two-arm crossover trial in Phase II by splitting the initial group of patients into two subgroups. During the first 30 days of Phase II, six patients received a placebo (saline solution via i.c.v.) in addition to optimized oral treatment, while the other six received A-dopamine alongside optimized oral treatment. In the following 30 days, patients in the placebo group received the active treatment, and patients previously on active treatment received the saline solution, with all patients continuing their optimized oral treatments. At the end of Phase II, all patients entered the long-term follow-up phase and were placed back on A-dopamine.

The primary endpoint of Phase II was an objective measure, assessed in a single-blind fashion, evaluating the percentage of time over 24-hour periods with insufficient control of motor symptoms, recorded at home using a wrist-worn actimetry device. Secondary evaluation criteria included the evolution of ON and OFF fluctuations and dyskinesia assessed using the Dyskinesia Rating Score (DRS) and MDS-UPDRS scales, safety, and neuropsychological and psychiatric assessments of behavior.

About InBrain Pharma

InBrain Pharma, a biopharmaceutical company, created in 2018, exploits through a worldwide exclusive patent license signed with SATT Nord, a novel therapeutic approach to Parkinson's disease based on the research work of Prof. David DEVOS and Prof. Caroline MOREAU in their academic research team at the University of Lille, Lille Neuroscience & cognition UMR-S 1172 INSERM and Lille University Hospital. In July 2024, Professors Devos and Moreau were finalists in the Research category of the European Inventor Award 2024 organized by the European Patent Office. InBrain Pharma was also a winner of the University of Lille Foundation Prize, the i-Lab competition, and received Deeptech support.

About Parkinson's disease

Parkinson's disease is the world's fastest-growing neurological disorder, prevalence having doubled over the last 25 years. 2.6 million people[1] are affected in the top 5 European markets[2], the United States and Japan, half of them being in advanced stage. The disease is caused by a progressive dopaminergic neuron loss, triggering a dopamine deficit, and leading to major painful motor disability, coupled to cognitive-behavioral and psychiatric disorders. Today therapeutic options in advanced stage rely on few device-aided therapies, useful for less than 50% of patients, given either their limited efficacy or their invasiveness or both. The brain infusion of dopamine is a disruptive treatment modality contributing to address this unmet need.

[1] GlobalData's figures
[2] France, Spain, United-Kingdom, Germany and Italy