



InBrain Pharma receives EMA Positive Scientific Advice supporting Phase 3 clinical development of A-dopamine for the treatment of advanced Parkinson's disease

Lille, France - July 3rd, 2025 - InBrain Pharma, a biopharmaceutical company specializing in neurodegenerative diseases, today announced that the European Medicines Agency (EMA) has issued a positive Scientific Advice, for conducting a single pivotal Phase 3 trial (DEEP-DIVE) with A-dopamine. This product is a 100mg/ml dopamine hydrochloride solution, free of oxygen, administered via the intracerebroventricular route for the management of patients with advanced-stage Parkinson's disease.

The Committee for Medicinal Products for Human Use (CHMP) validated the overall clinical and regulatory strategy, including the conduct of a single pivotal trial for submission of a centralized marketing authorization application at the European level. The proposed Phase 3 pivotal trial fully meets current EMA requirements for the submission of an MA application for a new anti-Parkinsonian drug under the centralized European procedure.

This randomized, double-blind, placebo-controlled, parallel-group trial will enroll 170 patients and features an adaptive design, allowing for sample size adjustments if necessary. Patients in the placebo arm will receive a brain infusion of saline solution on top of an optimized oral anti-Parkinsonian treatment based on L-dopa or a L-dopa derivative, for a maximum of 24 weeks — ensuring ethical acceptability. At the end of the double-blind evaluation phase, all patients, including those in the placebo group, will enter a 52-week open-label extension phase during which they will receive A-dopamine.

"This positive feedback from EMA marks a major regulatory and strategic milestone for InBrain Pharma," said **Dr. Véronique Foutel, CEO of InBrain Pharma**. *"It validates the preclinical and clinical programs carried out to date and officially brings the program into the late stage of clinical development."*

"Our therapy is not only designed to relieve symptoms, but to fundamentally personalize dopamine supplementation for every patient," commented **Professor Caroline Moreau, co-founder and medical advisor at InBrain Pharma**.

"This approach paves the way for precision medicine in neurology – delivering treatment directly to the right brain location, at the right dose. With the EMA's green light, we are one step closer to our goal: delivering this therapeutic breakthrough to patients with advanced Parkinson's disease, for whom current options are no longer satisfactory", added **Professor David Devos, co-founder and scientific advisor at InBrain Pharma**.

The phase III pivotal trial is planned to take place in both Europe and the United-States. A-dopamine is expected to become the first neurotransmitter administered intracerebrally with the aim of correcting disorders caused by a neurological disease. It could significantly and durably transform treatment strategies for advanced Parkinson's patients who no longer respond to L-dopa-based therapies or its derivatives.

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About InBrain Pharma

InBrain Pharma positions itself as a pioneer in personalized medicine for neurology by performing dopamine titration directly at the brain level, through circadian intracerebroventricular infusion, to treat patients with advanced-stage Parkinson's disease. Founded in 2018, InBrain Pharma is a biopharmaceutical company that holds an exclusive global license from SATT Nord to develop a disruptive therapeutic approach for Parkinson's disease. This approach is based on the research conducted by Professors David Devos and Caroline Moreau within their academic team at the University of Lille, Lille Neuroscience & Cognition UMR-S 1172 INSERM, and the Lille University Hospital (CHU de Lille). In May 2025, InBrain Pharma secured €1.8 million in funding under the "Première Usine" (First Factory) initiative of the France 2030 plan, to industrialize the production of anaerobically formulated A-dopamine for the treatment of Parkinson's disease.