THERAPEUTIC SOLUTIONS
FOR NEURODEGENERATION
Alzprotect

Press Release

Alzprotect gets green light from French Regulator to start phase 2a clinical trial in Progressive Supranuclear Palsy (PSP)

Lille (France), September 18, 2019 – ALZPROTECT, a biopharmaceutical company engaged in the development of drugs for the treatment of Alzheimer's disease, today announced that the French regulator has given the company permission to launch a phase 2a clinical trial with its drug candidate AZP2006 in Progressive Supranuclear Palsy (PSP), an orphan disease for which the company had already been granted the "orphan drug" status by the Food and Drug Administration (FDA) and European Medicines Agency (EMA).

Phase 2a study with AZP2006 in PSP

Just approved by the French Agency for the Safety of Health Products (Agence nationale de sécurité du médicament et des produits de santé – ANSM), this study will be conducted at the Pitié-Salpêtrière University Hospital in Paris, under the leadership of Professor Jean-Christophe Corvol, and at the University Hospital of Lille, France, in the unit of Professor Luc Defebvre. This clinical trial will aim to evaluate the tolerability of the product in PSP patients; to strengthen the pharmacokinetic data of the product in patients after 3 months of treatment; and to evaluate the impact of the treatment on the disease's 20-plus biomarkers. This phase 2a study should be completed by the end of 2020, and its first results will be published in 2021. As part of the study, 36 PSP patients will receive alternatively a placebo or one of two AZP2006 doses (60 and 80, then 50 milligrams). AZP2006 will be administered orally for 3 months, followed by an additional 3-month weaning observation period.

Philippe Verwaerde, Chairman and CEO of Alzprotect said: *"The launch of phase 2a trials with AZP2006 is a significant step forward for Alzprotect. We are pleased to advance the development of our drug candidate in PSP according to schedule. As PSP keeps evolving, this is a promising treatment to address the growing, unmet medical needs of patients suffering from this orphan disease, for which no treatment currently exists."*

"AZP2006 is the result of intense research centered on a unique and highly promising mechanism of action. Patients are eager to have access to a neuroprotective treatment. As for us, we are impatient and extremely committed to start this study," said Dr. David Devos, Professor in Neuropharmacology at the University Hospital of Lille, INSERM U1171.

"This phase 2a milestone rounds off years of research efforts by Alzprotect. The first administration of AZP2006 in PSP patients will reward the remarkable work done by our team so far. We are looking forward to the results of this trial and are already planning the next steps for the development of AZP2006 in other neurodegenerative diseases," said Noelle Callizot, Director of Pharmaceutical Development at Alzprotect.

"The beginning of this phase 2a study is an opportunity for patients with PSP, a rare disease whose progression cannot currently be curbed by any available treatment," said Dr. Jean-Christophe Corvol, Professor of Neuropharmacology and Head of the Center for Clinical Research in Neuroscience at the Pitié-Salpêtrière University Hospital.

About d'Alzprotect

Alzprotect imagines and develops therapeutic solutions to slow down or stop neurodegenerative diseases and restore patients' brain capacity. Founded in 2007, Alzprotect is a French Lille-based company created by Dr. André Delacourte, one of the pioneers of research on Alzheimer's disease, and Dr. Patricia Melnyk, expert in medicinal chemistry, in collaboration with Lille 2 University. and INSERM. The company employs 8 people and is supported by BPI France, the National Research Agency and Eurasanté. Alzprotect is committed to the development of innovative therapeutic solutions in the field of neurodegenerative diseases.

Alzprotect has 4 international patent families covering the medicines it develops and their indications worldwide.

For more information : http://www.Alzprotect.com/en – LinkedIn page – video presentation

About AZP2006:

Alzprotect is developing a drug candidate, AZP2006, whose mode of action and effects are clearly different from products developed in the last 15 years by the pharmaceutical industry. The flagship product of Alzprotect, AZP2006, which is kicking off phase 2a trials, has an innovative mechanism of action: it is a bioavailable neurotrophic inducer. Unlike most products developed by the competition, AZP2006 targets all causes of neurodegeneration and is not only targeted at markers such as Abeta protein or Tau protein. AZP2006 has obtained the status of "orphan drug" in Europe (European Medicines Agency) and in the United States (Food and Drug Administration) in the indication of PSP. It has been tested in humans, 88 healthy subjects, in two phase I clinical trials and has demonstrated excellent tolerability, with no adverse effects.

About neurodegenerative diseases:

With its compound AZP2006, Alzprotect mainly targets two neurodegenerative diseases: progressive supranuclear palsy (PSP) and Alzheimer's disease.

PSP is a tauopathy with predominant accumulation of Tau isoforms with four repeat motifs (4R). It is characterized by neurofibrillary degeneration and neuronal loss in the brainstem, basal ganglia, frontal motor and associative cortex. The disease causes brainstem damage that progressively affects balance, vision, mobility, swallowing and speech. The number of PSP cases in Europe and the United States is estimated at 30,000 and 25,000, respectively. The life expectancy in the patient with PSP is estimated between 5 and 7 years. There is no treatment, to date, to stop or slow down the disease.

Alzheimer's disease is the most common form of dementia with an estimated 47 million patients worldwide in 2017, a figure that should increase to 75 million by 2030 or even 132 million by 2050, according to the 2017 World Alzheimer Report. The pharmacological targets are Abeta protein, Tau protein and neuroinflammation. There is currently no reliable early diagnosis or treatment that can change the course of this disease: it is a major public health issue.

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