PRESS RELEASE

TREATMENT OF ALZHEIMER'S DISEASE: ANSM AUTHORIZES MEDESIS PHARMA PHASE II CLINICAL TRIAL

Montpellier, September 21, 2021 at 6:00 p.m. - MEDESIS PHARMA, a pharmaceutical biotechnology company developing drug candidates using its proprietary drug delivery platform, Aonys, enabling the administration of soluble active ingredients in inverse micelles by the buccal route, announces that it has received this day, world day of Alzheimer's disease, authorization from the French Medicines Agency (ANSM) for the conduct of a Phase II clinical trial of its NanoLithium program.

NanoLithium program: the added value of Aonys proprietary technology

The drug candidate developed by Medesis Pharma is NanoLithium: a formulation of lithium in its innovative microemulsion technology, Aonys. It allows therapeutic activity to be obtained with very low doses of lithium. Lithium has been marketed since 1971 to treat bipolar disorders, but the therapeutic window is small limiting its use in fragile and elderly patients. The significant added value of the drug candidate NanoLithium consists in the administration of a dose of lithium much lower than the usual dose of conventional lithium (dose divided by 70), thanks to Aonys.

NanoLithium, which efficacy has been demonstrated in several preclinical studies on animal models of Alzheimer's disease, carried out in the Laboratory of Neuropharmacology at McGill University in Montreal and outcomes published in several scientific publications.

Phase II clinical study: a treatment of behavioral and psychological symptoms associated with Alzheimer's disease

Medesis Pharma will conduct a Phase II clinical study whose primary objective is the treatment of behavioral and psychological symptoms that impact patients' quality of life: memory loss, difficulty planning or solving problems, difficulty performing familiar tasks at home or at work, confusion over time and place, difficulty understanding conversations, misplaced objects, social withdrawal, and often changes in mood and personality. The clinical assessment of these disorders will be carried out after 3 months of double-blind treatment. Treatment will be continued for a further 9 months to demonstrate a change in the overall course of the disease.

The clinical study will be conducted in 6 CHUs in France: Montpellier, Toulouse, Marseille, Lille, Lyon and Paris and plans to include 68 patients. Medesis Pharma plans to initiate pre-inclusion of patients in the last quarter of 2021, for a first administration of the drug in early 2022. The first outcomes could thus be obtained during the summer of 2022.

Medesis Pharma is driven by the possibility of offering non-invasive therapeutic innovations adapted to patients; NanoLithium is administered in the mouth once a day. Derived from a widely available asset and accessible administration techniques, the selling price of the potential drug is expected to be low and could represent a sustainable and global treatment approach across the world, regardless of social protection systems.

The design of the study, submitted at the beginning of june to the ANSM, was prepared with Professor Jacques Touchon (former Dean of the Faculty of Medicine of Montpellier and President of the international conferences on clinical trials in Alzheimer's disease 'Clinical Trials on Alzheimer's Disease conference '), and Professor Audrey Gabelle from the University Hospital of Montpellier (Neurologist, Head of the Memory Resource Research Center, and of the Rare and Early Dementia Reference Center, of the Behavioral Neurology medical team).

About Medesis Pharma

To advance the treatment of serious diseases without effective treatments, Medesis Pharma creates drug candidates based on its proprietary Aonys® technology for the oral administration of active ingredients in nanodroplet form, enabling active ingredients to be effectively delivered to all cells, with passage through the blood–brain barrier (BBB). This innovative approach is being applied for future drugs to treat major diseases that do not have effective treatments: Alzheimer's Disease, Huntington's Disease, certain resistant cancers and severe respiratory inflammations such as those linked to COVID-19. Medesis Pharma is also developing dedicated treatments for people irradiated following a civil or military nuclear accident.

Medesis Pharma, a French biopharmaceutical company based near Montpellier, has a track record of 15 scientific publications, holds eleven patents, reflecting 17 years of research, and is focused specifically on four projects that are moving into Clinical Phase II for neurodegenerative diseases and the treatment of Covid-19. Building on its world-renowned positions, Medesis Pharma is also working on new applications for its technology in partnership with public research laboratories (CNRS, CEA, IRBA), major teaching hospital centers in France, Canada and the United States, as well as private structures such as Transgene.

Medesis Pharma's shares are listed on Euronext Growth Paris (FR0010844464 – ALMDP).

For more informations :
www.medesispharma.com

MEDESIS PHARMA
Tessa Olivato
Tel: +33 4 67 03 03 96
contact@medesispharma.com

CALYPTUS
Marie Calleux
Tel : +33 1 53 65 68 66
medesispharma@calyptus.net