COMMUNIQUÉ DE PRESSE

TREATMENT OF ALZHEIMER'S DISEASE WITH NANOLITHIUM
FIRST INCLUSION OF PATIENTS IN THE PHASE II CLINICAL STUDY

Montpellier, June 13, 2022 at 8:00 am CET – MEDESIS PHARMA, a pharmaceutical biotechnology company developing drug candidates based on its proprietary technology Aonys® for the administration of active ingredients in nano micelles by the buccal route, announces the first inclusions of patients in the Phase II clinical trial of its NanoLithium program for the treatment of Alzheimer's disease.

In parallel, Medesis Pharma is carrying out developments for the treatment of severe forms of COVID-19, in clinical Phase II in Brazil, preclinical developments for the administration of small interfering RNAs for the genetic treatment of Huntington's disease and certain cancers resistant to treatments, and the development of 3 products for treatment for populations contaminated or irradiated after a civilian or military nuclear accident.

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, allowing therapeutic activity to be obtained with very low doses of lithium. Lithium has been marketed since 1971 to treat Bipolar Disorder.
Numerous research works have highlighted the neuroprotective potential (protection of brain cells) of Lithium, giving rise to more than a hundred scientific publications. Studies carried out in Alzheimer's disease have highlighted the effect of lithium on the pathological mechanisms involved in the disease (amyloid beta protein, Tau protein, neurofibrils, neuroinflammation, Bace 1, GSK3b, autophagy, etc... and stimulates neurogenesis). However, clinical studies in Alzheimer's disease have been short and inconclusive, the therapeutic doses being very close to the toxic doses complicating its repeated use in weakened and elderly patients.
Thanks to the association of Aonys with Lithium, the bioavailability of lithium is optimized; thus, with Nanolithium, a very small quantity of lithium (more than 30 times less than the effective dose used in current practice) is capable of producing the therapeutic effect.
The effectiveness of NanoLithium has been demonstrated in several preclinical studies on an animal model of Alzheimer's disease, carried out in the Neuropharmacology Laboratory at McGill University in Montreal, which have been the subject of several scientific publications.

Phase II clinical study: a treatment dedicated to psychosis associated with Alzheimer's disease

Medesis Pharma is conducting a Phase II clinical study whose main objective is the treatment of behavioral and psychological symptoms that impact the daily life of patients: aggressiveness, agitation, anxiety, irritability, memory loss, difficulty planning or solving problems, difficulty to perform 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. There is currently no treatment that can effectively treat these symptoms that make the severity of the early stages of the disease.

The effect on cognitive symptoms, biomarkers and brain imaging will also be assessed in the second phase of the study.

The study includes a 3-month phase of double-blind treatment (patients treated with placebo or Nanolithium), giving rise to first results, followed by an additional 9-month open-label phase (all patients will be treated with Nanolithium).

The clinical study will be conducted in 6 University Hospitals in France: Toulouse, Montpellier, Marseille, Lille, Lyon and Paris and plans to include 68 patients. The results of the first phase of the study could be obtained at the beginning of 2023. The entirety of this clinical study is budgeted in the company's cash flow.

Medesis Pharma is driven by the possibility of offering non-invasive and patient-friendly therapeutic innovations; the NanoLithium is administered in the mouth once a day. Resulting from a widely available active ingredient with accessible administration techniques, the sale price of the potential drug is anticipated to be low and would represent a treatment suitable for use in all countries of the world, regardless of the social protection systems.

According to the WHO, 50 million people are affected by dementia in the world and 152 million by 2050, among whom 60 to 70% are affected by Alzheimer's disease.

The study was prepared with Professor Maria Soto, Geriatrician at the Toulouse University Hospital, President of the National Federation of Memory Centers, National Coordinator of the study and with the contribution of 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'*).

- *(1) NP03, a microdose Lithium Formulation, Blunts Early Amyloid Post-Plaque Neuropathology in McGill-R-Thy1-APP Alzheimer-Like Transgenic Rats J. of Alzheimer's Disease, 73 (2020) 723-739.*
- *BACE1 inhibition by microdose lithium formulation NP03 rescues memory loss and early stage amyloid neuropathology - Translational Psychiatry (2017) 7, e1190*
- *Microdose Lithium NP03 Diminishes Pre-Plaque Oxidative Damage and Neuroinflammation in a Rat model of Alzheimer's-like Amyloidosis – Current Alzheimer Research, 2018, 15, 1220-1230.*

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 contaminated or 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 11 patents family and 71 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

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