PRESS RELEASE

MEDESIS PHARMA: FAVORABLE REPORT FROM IDSMB EXPERTS ON THE ONGOING PHASE 2 CLINICAL STUDY ON NANOLITHIUM IN THE TREATMENT OF ALZHEIMER'S DISEASE

Montpellier, May 23, 2023 at 8:00 a.m. – MEDESIS PHARMA, a pharmaceutical biotechnology company developing drug candidates based on its proprietary technology for the administration of active pharmaceutical ingredients in nanomicelles by the buccal route, Aonys®, announces the receipt on May 22, 2023 of the account report by experts from the IDSMB (Independent Data and Safety Monitoring Board, composed of medical experts in Alzheimer's disease and a biostatistician). This review of the safety data recommends continuing the study, in line with Medesis Pharma's expectations.

This is the first interim review of safety data (35 patients had been treated for at least one month at the time the database was established). After reviewing the data, the IDSMB experts concluded that no SAE ("serious side effects") were observed, that there were no safety signals and they recommend continuing the trial as planned.

The Phase 2 clinical study is underway on 68 Alzheimer's patients in 8 Hospital Centers in France (Toulouse, Montpellier, Marseille, Paris, Strasbourg, Lille, Limoges and Lyon).

- A first phase with 3 months of double-blind treatment versus placebo to analyze the effect of nanolithium on behavioral disorders associated with the disease (anxiety, agitation, depression, etc.).
- A second phase with 9 months of open-label treatment, without placebo, to explore the potential disease-modifying effect of nanolithium through measurements of the effect of treatment on cognitive manifestations (memory loss, difficulty in planning or problem solving, difficulty understanding images and spatial relationships) and pathophysiology (imaging and biomarkers) of the disease.

Currently, 43 patients have been included in the clinical study. The results of the first phase are expected at the end of 2023, and under these conditions the results of the complete study could come in the 3rd quarter of 2024.

Lithium is a drug that has been on the market for the treatment of bipolar disorder for more than 50 years. It is very active, but requires high doses to allow it good cell penetration and therefore to exert its benefit. These high doses reveal progressive toxicity in young patients, incompatible with long-term treatment in fragile subjects, such as patients with a neurodegenerative disease. In recent years, numerous scientific studies have reported the mechanism of action of lithium studied in animal models of Alzheimer's disease, in particular by the inhibition of GSK-3β, an anti-Tau and anti-Amyloid effect; but also a regulatory effect on neuroinflammation and oxidative stress. The neuroprotective properties of lithium have also been well reported. Aonys technology, developed and patented by Medesis Pharma, makes it possible to optimize the delivery of lithium, and therefore to use very low doses for optimal efficacy, with a buccal administration mode, particularly suitable for an elderly outpatient population.

Aonys-lithium citrate, Nanolithium, has already been studied in animal models[1] of Alzheimer's disease and has achieved therapeutic results with doses 400 times lower than those required with traditional lithium. For the ongoing clinical study on patients with Alzheimer's disease, the dose of lithium is 50 times lower than that of the historic drug. The IDSMB report confirms at this stage the tolerance profile of Nanolithium, no toxicity has been observed in humans and the treatment is well tolerated by the patients.

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).

For more information:
www.medesispharma.com

MEDESIS PHARMA
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1 Preclinical studies were carried out on an animal model of Alzheimer's disease with NanoLithium by the Neuropharmacology laboratory of McGill University in Montreal. They have demonstrated these multiple therapeutic activities and have been the subject of 3 scientific publications.

This innovative approach is being applied to future drugs to treat major diseases that do not have effective treatments: Alzheimer's disease, Huntington's disease, and resistant cancers.

Medesis Pharma is also developing treatments dedicated to populations contaminated or irradiated after a civil or military nuclear accident.

French biopharmaceutical company based near Montpellier, Medesis Pharma is the author of 15 scientific publications, holds 12 patent families and 72 patents, the result of 20 years of research.

Medesis Pharma shares are listed on Euronext Growth Paris: FR001844464 - ALMDP

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