PRESS RELEASE

MEDESIS PHARMA : NANOMANGANESE DEVELOPMENT PROGRAM REPOSITIONNED OUTSIDE OF EU POST ANSM AUTHORISATION DENIED

Montpellier, August 26, 2021 at 5:45 p.m. - Medesis Pharma (ISIN: FR0010844464, MNEMO: ALMDP), a pharmaceutical biotechnology company developing drug candidates with its proprietary technology for the administration of active ingredients in micelles through oral route, announces that French National Agency for Medicines and Health Products Safety (ANSM) denied the request to run a clinical trial on the product NanoManganese for the treatment of severe forms of COVID-19. Health authorities in Hungary, where a request for the study had also been filed at the end of May, also did not give the authorization.

Even if the favorable tolerance profile of the product has been demonstrated through pre-clinical studies, the refusals are mainly motivated by the absence of data on pharmacokinetics, i.e. the effects of the product in terms of absorption, distribution, metabolism and elimination. The time needed to carry out these additional studies does not match the urgency of the pandemic situation. As European countries and health authorities are highly targeted by COVID clinical trial authorization requests, Medesis Pharma has decided to reposition its NanoManganese COVID clinical development program in countries outside the European Union, where the emergency of the situation and expected benefits of the NanoManganese could be better appreciated.

The stability of the clinical batches produced for studies in Europe supports their use in the countries targeted. The emergency procedures in countries considered, if accepted, could partially make it up for the delay in the development program in Europe and offer a new possibility to patients and medical community still in demand of effective therapeutic options.

The NanoManganese development program beyond the COVID pandemic; for treatment of acute respiratory distress syndrome in emerging viral diseases (including seasonal flu), and for radioprotection and radiosensitization in the treatment of cancer; is meanwhile still ongoing.

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 nine 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).

Learn more at
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