



Phase 2 clinical trial for the treatment of Alzheimer's disease
Completion of the 1st phase of double-blind treatment, with good patient retention and acceptance of the treatment

Scientific publication: "Nanolithium, a new treatment for Alzheimer's disease".

Participation to BIOMED Forum in Paris on January 30, 2024

New cash contribution

Montpellier, January 29, 2024 at 6:00pm CET – **MEDESIS PHARMA**, a pharmaceutical biotechnology company developing drug candidates with Aonys®, its proprietary buccal nanodroplet active ingredient administration technology, has successfully completed a key milestone in its Phase 2 clinical trial for the treatment of Alzheimer's disease, and announces a scientific publication on NanoLithium treatment, its participation in the BIOMED Forum on January 30, 2024, and the completion of a capital increase of around 400 k€.

Completion of 1st double-blind treatment phase of Phase 2 clinical trial for Alzheimer's disease: good patient retention and acceptance of treatment

Medesis Pharma has completed the 1st stage of double-blind treatment of the 72 patients enrolled in its "NanoLithium NP03" clinical trial, currently underway in 8 French university hospitals (Toulouse, Montpellier, Marseille, Lille, Limoges, Lyon, Paris and Strasbourg). To date, all patients have received at least 12 weeks of treatment, and the interim analysis is underway. All patients reaching the end of this phase have agreed to continue the open-label study, and a third of patients have already completed the study (1 year, including 9 to 12 months on Nanolithium depending on the treatment arm in the double-blind phase). The study thus shows good patient retention, which means that the treatment is well tolerated and well accepted in terms of its effects and galenic formulation.

Initial results from the interim analysis are expected in March 2024. For the record, this proof-of-concept study is evaluating the safety, tolerability and efficacy of NanoLithium NP03 in patients with mild to severe Alzheimer's disease. Its primary objective is to assess the clinical efficacy of NanoLithium versus placebo, on the progression of neuropsychiatric disorders associated with the disease between inclusion and 12 weeks of treatment. Follow-up of the study by the Expert Committee attests to the excellent clinical tolerance of NanoLithium.

Scientific publication in the « The Journal of Prevention of Alzheimer's Disease »

« [*Nanolithium, a New Treatment Approach to Alzheimer's Disease: A Review of Existing Evidence and Clinical Perspectives*](#) » was published on 24 January 2024.

The authors are international experts in Alzheimer's disease, as well as Solène Guillot, member of the Management Board, Medical Director and R&D Director of Medesis Pharma. The publication describes all the therapeutic actions of NanoLithium that have been demonstrated in animal models of the disease (3 scientific publications at McGill University in Montreal and Columbia University in Vancouver). The authors conclude the article with a discussion of the prospects for similar clinical results, particularly in terms of disease progression after 12 months of treatment.

Medesis Pharma will attend the BIOMED Forum in Paris on 30 January 2024

BIOMED Forum brings together investors and investment funds with listed biotech companies. Jean-Claude Maurel, Founder, Chairman of the Supervisory Board and CEO of Medesis Pharma, together with Alexandre Lemoalle, Counsel to the Chairman with extensive experience in M&A deals, and Mario Alcaraz, Chief Financial Officer, will be participating in meetings with investors interested in Medesis Pharma.

New cash contribution

Medesis Pharma has secured a new cash contribution of approximately €400k, which will be finalised in early February. The contribution will be made on the same principles as in December 2023 ([see press release of 20 December 2023](#)). It will ensure the company's business continuity and facilitate the search for the financing required for ongoing developments, in particular its phase 2 clinical trial on NanoLithium in the treatment of Alzheimer's disease.

On 29 September 2023, Medesis Pharma applied to the Montpellier Commercial Court for and obtained the opening of a safeguard procedure. This procedure can last up to twelve months and protects companies that are not in a state of suspension of payments in order to enable them to resolve their difficulties and continue their activities. Its aim is to provide a framework for overcoming the difficulties encountered and ensuring the continuity of the company's activities. In the case of Medesis Pharma, this approach leads to the temporary suspension of its financial and tax obligations. Cash and cash equivalents at 30 June 2023 amounted to €139k. 440 k€ was contributed in the form of a capital increase in December 2023. The resources from this forthcoming capital increase will enable Medesis Pharma to extend its cash horizon to February 2024.

Contacts are still underway for capital injections at the beginning of the year, and to make progress towards setting up licensing partnerships, particularly with regard to the clinical study on NanoLithium in the treatment of Alzheimer's disease, the results of which are expected in mid-march 2024.

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 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, resulting from 17 years of research.

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

For more information:

www.medesispharma.com

MEDESIS PHARMA

Jean-Claude Maurel

Tél.: +33 4 67 03 03 96

contact@medesispharma.com

CALYPTUS

Marie Calleux

Tél. : +33 1 53 65 68 66

medesispharma@calyptus.net