Press release

Aelis Farma receives a positive recommendation from the DSMB to continue, with no modification to the protocol, the phase 2b clinical study with AEF0117 in cannabis addiction

The compound's favorable safety and tolerability profile allows to confidently continue the phase 2b of AEF0117, with the first results expected in mid-2024

Bordeaux, July 5, 2023 – 7:00 a.m. CEST – **Aelis Farma** (ISIN: FR0014007ZB4 – Ticker: AELIS), a clinical-stage biopharmaceutical company focused on developing treatments for brain diseases, today announced that it has received a unanimous positive recommendation from the Data Safety Monitoring Board (DSMB) to continue, without modifying the protocol, the phase 2b clinical study with AEF0117 for the treatment of cannabis addiction.

A DSMB is a committee of independent experts, specialized in clinical research, that reviews studies' data with a particular emphasis on tolerability and safety.

The DSMB that analyzed the data from the phase 2b study with AEF0117 met to assess the safety and tolerability data on the first 115 patients treated for at least 4 weeks with AEF0117. Following the meeting, the committee observed no serious adverse events or significant events associated with the treatment and recommended that the study be continued without any modifications to the protocol.

The phase 2b study with AEF0117, currently being undertaken in 11 clinical centers in the United States, aims to demonstrate the efficacy of AEF0117 in treating cannabis use disorder, the modern medical definition of cannabis addiction. This double-blind placebo-controlled study should include a total of around 330 patients who will be administered either a placebo or one of the three test doses of AEF0117 (0.1 mg, 0.3 mg and 1 mg) once daily for 3 months. The primary objective of this study is to evaluate whether AEF0117 reduces cannabis use, measured by the increase in the proportion of subjects who use cannabis ≤1 day a week compared to the placebo. The proportion of patients achieving other levels of reduction of their use and a potential improvement in their quality of life will also be investigated.

Enrollment in the study is continuing at a sustained pace, enabling the first results to be anticipated in mid-2024, as expected.

Pier Vincenzo Piazza, CEO of Aelis Farma, said: "*Firstly, we would like to thank all the participants to the phase 2b with AEF0117 and the teams of investigators who are helping advance our understanding of the usefulness of AEF0117 as a treatment of cannabis addiction. The positive recommendation of the DSMB shows once again the favorable safety and tolerability profile of AEF0117, confirming the observations of the previous clinical and non-clinical evaluations, recently published in Nature Medicine. The fact that AEF0117 is also well tolerated in the real-life condition of the phase 2b is key and very positive for the further development of this compound, which currently is the most advanced drugs offering genuine hope for many people suffering from cannabis use disorder*".

AEF0117, discovered and developed by Aelis Farma, is the first drug candidate of the new CB_1-SSi pharmacological class, which is based on a natural mechanism used by the brain to combat CB_1 receptor hyperactivity. It is the first compound that appears to selectively inhibit the CB_1 receptor signaling pathway responsible for the addictive effects of cannabis without interfering with the receptor's fundamental physiological and behavioral functions. This innovative approach differs from the previous generation of CB_1 receptor antagonists that, by blocking all CB_1 receptor cellular activities, cause significant adverse effects preventing their clinical use.

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About AELIS FARMA

Founded in Bordeaux in 2013, Aelis Farma is a biopharmaceutical company that is developing a new class of drugs, the Signaling-Specific inhibitors of the CB_1 receptor of the endocannabinoid system (CB_1-SSi). CB_1-SSi have been developed by Aelis Farma based on the discovery of a natural brain defense mechanism by the team led by Dr. Pier Vincenzo Piazza, the Company's CEO, when he was director of Neurocentre Magendie of the INSERM in Bordeaux. By mimicking this natural mechanism, CB_1-SSi appear to selectively inhibit the disease-related activity of the CB_1 receptor without disrupting its normal physiological activity. CB_1-SSi have consequently the potential to provide new treatments for several brain diseases.

Aelis Farma is currently developing two first-in-class clinical-stage drug candidates: AEF0117 for the treatment of CUD, currently being tested in a phase 2b study in the United States; and AEF0217 for cognitive disorders, including those of Down Syndrome (Trisomy 21), currently in a phase 1/2 study in Spain in people with Down syndrome. The Company also has a portfolio of new innovative CB_1-SSi for the treatment of other disorders associated with a dysregulation of the activity of the CB_1 receptor.

Aelis Farma draws on the talents of more than 20 highly qualified employees.

For more information, visit **www.aelisfarma.com** and follow us on **LinkedIn** and **Twitter**.

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described in detail in Chapter 3 "Risk Factors" of Aelis Farma's Universal Registration Document approved by the Autorité des Marchés Financiers on April 26, 2023, under number R.23-018.

These forward-looking statements are made only as of the date of this press release and Aelis Farma expressly disclaims any obligation or undertaking to release any updates or corrections to the forward-looking statements included in this press release to reflect any change in expectations or events, conditions, or circumstances on which any such forward-looking statement is based. Forward-looking information and statements are not guarantees of future performance and are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond Aelis Farma's control. Actual results could differ materially from those described in, or implied or projected by, forward-looking information and statements.