
Press release

# Aelis Farma Announces Completion of Patient Randomization for Phase 2b Study with AEF0117 for the Treatment of Cannabis Addiction

- **As planned, 333 patients have been randomized at end of December 2023 across 11 clinical centers in the United States**
- **This major milestone confirms the announced availability of the first results of the study for the end of the second quarter of 2024**

**Bordeaux, January 9, 2024 – 6:00 pm CET** – Aelis Farma (ISIN: FR0014007ZB4 – Ticker: AELIS), a clinical-stage biopharmaceutical company specializing in the development of treatments for brain disorders, today announces to have reached a key milestone by successfully completing the recruitment of 333 patients suffering from cannabis addiction in its Phase 2b clinical study with AEF0117.

AEF0117 is the first of a new class of proprietary drugs developed by Aelis Farma, the Signaling Specific inhibitors of the $CB_1$ receptor of the endocannabinoid system ($CB_1$-SSi). The ongoing multicenter Phase 2b study aims to demonstrate the effectiveness of this "first-in-class" compound in treating cannabis addiction, currently defined as CUD (Cannabis Use Disorder) in the DSM-5, the reference diagnostic manual of mental disorders.

The recruitment and randomization of the 333 study patients were accomplished across 11 clinical centers in the United States, under the coordination of Pr. Frances Levin from Columbia University (New York). The double-blind, placebo-controlled trial involves the administration of either placebo or one of the three tested doses of AEF0117 (0.1 mg, 0.3 mg, and 1 mg) once daily for 3 months. The primary objective of the study is to assess whether AEF0117 reduces cannabis consumption by demonstrating an increase in the proportion of subjects consuming cannabis ≤1 day per week compared to the placebo. The proportion of patients achieving other levels of reduced consumption, along with the potential improvement in their quality of life, will also be examined as secondary endpoint. Initial results are expected in line with the timeline previously announced for the second quarter of 2024.

**Pr. Frances Levin, the study's principal investigator and Professor of Psychiatry at Columbia University,** commented: *"The successful recruitment of 333 patients, according to the predetermined schedule, demonstrates the real demand for treatment experienced by individuals suffering from CUD. We would like to thank the participants as well as the medical teams of the eleven centres of this study, for their trust, effort, and dedication to this important clinical trial. We eagerly await results that could be a critically important and novel therapeutic intervention for the treatment of moderate to severe cannabis use disorder."*

To ensure a smooth transition of AEF0117 to the Phase 3 study after a positive Phase 2b, Aelis Farma initiated, in parallel with the Phase 2b, a series of toxicology studies required by the regulatory authorities. Announced last November, the favourable safety profile observed in this context validates

the positive observations of the independent Data Safety Monitoring Board (DSMB) for the initial 115 patients in the Phase 2b study, confirming the good tolerance of AEF0117 in individuals with cannabis addiction. Thanks to the completion of these non-clinical developments ahead of schedule, AEF0117 will be ready to enter the Phase 3 clinical study for cannabis addiction at the end of a positive Phase 2b, subject to regulatory approval of the Phase 3 design.

**Pier Vincenzo Piazza, CEO of Aelis Farma,** concluded: *"We are delighted to announce the completion of the recruitment phase of this study, which is the largest ever conducted for the treatment of cannabis addiction. This important milestone, once again, demonstrates Aelis Farma's ability to deliver and meet deadlines. We are determined to continue our roadmap with the goal of offering an effective treatment against cannabis addiction, a condition affecting an increasing number of people worldwide. In this regard, I would like to thank Professor Levin, the investigators, the Aelis team, and naturally, the participants to the study for their trust and dedication to the development of this promising new treatment."*

The Phase 2b study is an integral part of the clinical program for AEF0117, which received USD 7.8 million of total funding from the National Institutes of Health (NIH), with USD 4.5 million allocated in late 2021 for the current development phase. Previously, a Phase 2a study, conducted by Pr. Margaret Haney (Columbia University, NY) in volunteers with cannabis addiction, provided initial evidence of the efficacy of AEF0117 with a favourable safety profile.

Based on encouraging Phase 2a results, Aelis Farma entered into an exclusive option and license agreement in 2021 with Indivior PLC, a leading pharmaceutical group in addiction treatment, for the development and commercialization of AEF0117 as a treatment for disorders due to excessive cannabis use. As part of this agreement, Aelis Farma has received already USD 30 million (option payment). If Indivior exercises the license option at the end of the Phase 2b (H2 2024), Aelis Farma will receive a USD 100 million license fee and up to USD 340 million in additional payments contingent on the achievement of development, regulatory and commercial milestones as well as, royalties on net sales of AEF0117 ranging between 12% and 20%. Following the exercise of the option, all development, registration, and commercialization costs of AEF0117 will be borne by Indivior.

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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 regulatory mechanism of CB1 activity made by the team led by Dr. Pier Vincenzo Piazza, the Company's CEO, when he was the director of the 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 safe treatments for several brain diseases.
Aelis Farma is currently developing two first-in-class clinical-stage drug candidates: AEF0117 for the treatment of cannabis use disorder (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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**Forward-looking statements**

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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.