Press release

Aelis Farma announces the Last Patient, Last Visit in its clinical phase 2b trial with AEF0117 for the treatment of cannabis use disorder

- **The last patient in the clinical phase 2b trial with AEF0117 for the treatment of cannabis use disorder has completed its last medical visit, paving the way for the release of study results in the third quarter of 2024**
- **This achievement is a key milestone in the clinical development of AEF0117, which could represent the first treatment of cannabis use disorder**
- **Aelis Farma's partner Indivior retains a $100 million license option, exercisable within 90 days of promising phase 2b results and FDA feedback at future End-of-Phase 2 (EOP2) meeting**

Bordeaux, April 18, 2024 – 6:00 p.m. CEST – Aelis Farma (ISIN: FR0014007ZB4 – Ticker: AELIS), a clinical-stage biopharmaceutical company specializing in the development of treatments for brain diseases, is pleased to announce today a significant milestone in the clinical development of AEF0117: the last patient visit in the clinical phase 2b study, which included 333 individuals seeking treatment for cannabis use disorder (CUD), has been completed.

AEF0117 represents a novel class of drugs developed by Aelis Farma, the Signaling-Specific inhibitor of the CB_1 receptor ("CB_1-SSi"). This phase 2b multicenter study aims to demonstrate the efficacy and safety of this "first-in-class" compound in treating cannabis addiction, currently defined as CUD in the DSM-5, the reference diagnostic manual of mental disorders.

This significant advancement marks the conclusion of clinical data collection and the start of in-depth analysis. The company confirms its intention to announce the study results in the third quarter of this year.

Pr. Frances Levin, the study's principal investigator and Professor of Psychiatry at Columbia University, comments: *"Completion of the last patient, last visit is a crucial step towards unveiling the potential efficacy of AEF0117 as a treatment of cannabis addiction. This milestone marks the end of data collection and the beginning of in-depth analysis. We eagerly await results that could offer a crucial and innovative therapeutic alternative for the treatment of cannabis use disorder. We also wish to thank all the medical teams involved in the study for their efforts and dedication and send a special thanks to the CUD participants for their trust and participation to the study."*

AEF0117 has a favorable therapeutic index >13,000 times the active dose confirmed in long-term chronic oral toxicity studies (6 months in rats and 9 months in dogs) which support the potential chronic use of AEF0117 in humans without time restriction. In addition, the lack of adverse effect in juvenile toxicity studies would support administration of AEF0117 in adolescents, an important target population in CUD. Finally, the reproductive toxicology studies show that AEF0117 does not modify embryonic and embryofetal development.

The successful early completion of the toxicity studies described above and of additional non-clinical development studies, positions AEF0117 to enter phase 3 clinical trials for the treatment of CUD upon positive results of the present phase 2b clinical trial and regulatory agreement of the phase 3 protocol. To reach this goal, the company plans to request an end-of-phase 2 (EOP2) meeting with the FDA in the fourth quarter of this year.

Pier Vincenzo Piazza, CEO of Aelis Farma, concludes: *"Completion of the last patient, last visit in the phase 2b study with AEF0117, the largest study ever performed for a treatment of cannabis addiction, marks a significant milestone in our clinical journey and demonstrates our ability to respect timelines announced to the market. I would like to send heartfelt thanks to all the persons who have contributed to this significant advancement in AEF0117's development, the investigators, the patients and the extremely dedicated Aelis team. We remain committed to our roadmap for AEF0117 to offer an effective treatment of cannabis addiction, an increasingly prevalent and worrying condition worldwide."*

Phase 2b clinical study with AEF0117 for the treatment of cannabis addiction

Under the coordination of Professor Frances Levin at Columbia University (New York) and of Aelis Farma clinical team, recruitment and randomization of the 333 patients for the phase 2b trial of AEF0117 at 11 clinical centers in the United States were completed in December 2023. The last visit for the last patient was completed mid-April 2024.

Patients received 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 can reduce cannabis use by increasing the proportion of subjects consuming cannabis ≤1 day per week compared to the placebo. Secondary endpoints include the proportion of patients achieving other levels of reduced cannabis use including abstinence, and potential improvement in their quality of life. These secondary endpoints, if positive, could potentially serve as alternative primary objectives for the future phase 3 trials.

The Phase 2b study is part of the clinical program for AEF0117, which received $7.8 million of total funding from the National Institutes of Health (NIH), with $4.5 million allocated in late 2021 for the current developmental phase, aiming to ready the compound to enter phase 3. The remaining $3.3 million were previously dedicated to help financing phase 1 and a Phase 2a study with AEF0117. The phase 2a study, conducted by Pr. Margaret Haney (Columbia University, NY) in volunteers with cannabis addiction, provided initial evidence of the efficacy of AEF0117 and confirmed a favorable safety profile.

License Option with Indivior

Based on promising phase 2a results, Aelis Farma entered an exclusive option and license agreement in 2021 with Indivior UK Limited, a subsidiary of Indivior PLC, which is a leading pharmaceutical group in addiction treatment, for the development and commercialization of AEF0117 as a treatment for disorders due to excessive cannabis use. Per agreement, Aelis Farma has already received $30 million (license option fee). Within three months following the end of phase 2 meeting with the FDA, Indivior will be able to exercise its license option, triggering the payment of a $100 million license fee, up to an additional $340 million in milestone payments contingent upon the achievement of development, regulatory, and commercial milestones, as well as royalties on net sales of AEF0117 ranging from 12% to 20%. Following the exercise of the option, all development, registration, and commercialization activities for AEF0117 in CUD shall be conducted by Indivior and those costs 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 CB_1 hyperactivity made by the team led by Dr. Pier Vincenzo Piazza, the Company's CEO, when he was the director of the Neurocentre Magendie of 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), that has just completed a phase 2b study in the United States with result expected in Q3 2024; 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 25 highly qualified employees.

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

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B Compartment of Euronext Paris

Contacts

AELIS FARMA
Arsène Guekam
Chief Corporate Development Officer
contact@aelisfarma.com

NewCap
Dusan Oresansky / Aurélie Manavarere
Investor Relations
aelis@newcap.eu
+33 1 44 71 94 92

NewCap
Arthur Rouillé
Media Relations
aelis@newcap.eu
+33 1 44 71 00 15

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