Press Release

ELIGIBLE PEA PME

Aelis Farma announces the approval of its Registration Document by the *Autorité des marchés financiers* in the context of its planned initial public offering on the regulated market of Euronext Paris

- **Aelis Farma has developed a new class of drugs, the CB_1-SSi, which targets the CB_1 receptor of the endocannabinoid system. CB_1-SSi have an innovative mechanism of action, never previously tested in humans, which seems to enable the treatment of brain diseases without inducing side effects on normal behavior.**

- **AEF0117, the first CB_1-SSi drug candidate, has successfully completed a phase 2a clinical trial, which has confirmed its potential for the treatment of disorders linked to excessive cannabis use (addiction and psychosis). These behavioral disorders are progressing significantly in the context of the wave of cannabis legalization, increasing the demand on healthcare systems in western countries.**

- **AEF0217, the second CB_1-SSi drug candidate, is currently being evaluated in phase 1 and should enable the treatment of several cognitive deficits, including those associated with Down syndrome (Trisomy 21), which constitute major unmet medical needs that put a serious strain on the persons, their families and healthcare systems.**

- **Under an option license agreement for AEF0117 with Indivior PLC, a world leader in the treatment of addiction, Aelis Farma has already received a payment of $30 million. If Indivior exercises the option at the end of the phase 2b clinical trial, Aelis Farma will receive a license fee of $100 million. This agreement also includes up to $340 million in supplementary milestone payments and royalties between 12% and 20% on net sales.**

- **Indivior PLC has made an irrevocable commitment to subscribe for the equivalent of $11 million in the initial public offering of Aelis Farma's shares on Euronext Paris.**

- **Aelis Farma's current investors have made irrevocable commitments to subscribe for the equivalent of €4.5 million in the initial public offering of Aelis Farma's shares on Euronext Paris.**

Bordeaux, France, January 17, 2022 - Aelis Farma (the "Company"), a clinical-stage biopharmaceutical company specializing in the development of treatments for brain diseases, announces the approval of its Registration Document by the *Autorité des marchés financiers* (AMF) under number I.22-003 as of January 14, 2022.

The approval of this Registration Document constitutes the first step in the proposed initial public offering of Aelis Farma on the regulated market of Euronext Paris, subject to favorable market conditions and the approval by the AMF of the prospectus (the "Prospectus"), relating to the admission

and the offering of the Company's shares, consisting of the Registration Document, the offering memorandum relating to the securities offered, and the summary of the prospectus (included in the offering memorandum).

Dr. Pier Vincenzo Piazza, co-founder and CEO of Aelis Farma, stated: *"I am delighted and proud to present Aelis Farma to the financial community, a company founded on the discovery of a new natural defense mechanism of the brain. This mechanism protects the brain from the effects of a pathological hyperactivity of the CB_1 receptor of the endocannabinoid system. The CB_1 receptor, one of the main receptors in the brain, is involved in several diseases that are without treatment today. This major discovery, made with my team at Inserm (the French national institute of health), has enabled us to develop a new class of drugs, the CB_1-SSi, which seems able to treat behavioral pathologies without causing side effects on normal behavior. This is a real first for treatments of brain diseases. Thanks to the experience of our team, we have succeeded in bringing two CB_1-SSi to the clinical stage in a mere 8 years, thereby benefitting from long periods of exclusivity.*

The first CB_1-SSi, AEF0117, is designed to treat cannabis addiction and other disorders related to excessive cannabis use. The results generated to date have enabled us to conclude a major partnership with an international leader in the field of addiction, the Indivior group, which will accelerate the development and market access of AEF0117.

Our second drug candidate, AEF0217, should enable, for the first time, the treatment of several cognitive deficits including those associated with Down syndrome (Trisomy 21).

These two development programs, which target areas of high unmet therapeutic needs, have generated strong interest from the international medical and academic communities. We believe that we can successfully address these unmet medical needs, and thanks to the new compounds generated by our innovative platform, many others, thereby delivering a true paradigm shift in the treatment of brain diseases."

Mark Crossley, CEO of Indivior, commented: "*Aelis Farma has developed some of the most advanced and innovative new chemical entities to address the growing unmet public health needs associated with cannabis use disorder and other behavioral pathologies. These new drug candidates open up new therapeutic areas and correspond perfectly to Indivior's desire to provide innovative solutions to treat addiction and other serious behavioral disorders that are without safe and effective treatment today. We are delighted to support Aelis Farma in this new phase of its development, which will enable the Company to deploy the full potential of its compounds and to address the growing worldwide threat of addiction and cognitive deficits."*

AELIS FARMA'S VISION

"To treat brain diseases thanks to a new class of drugs: Signaling Specific inhibitors of the CB_1 receptor"

The CB_1 receptor is one of the most expressed neurotransmitter receptors in the brain[1]. It plays a very important role in the regulation of physiology and behavior[2] and its pathological hyperactivity is involved in several diseases of the brain (cognitive deficits, addiction, psychosis, autism, Attention Deficit Hyperactivity Disorder - ADHD)[3] and peripheral organs (obesity, diabetes and atherosclerosis, fibrosis, muscular dystrophy).

To date, only one pharmacological class, antagonists, has been tentatively used to treat CB_1 hyperactivity. However, antagonists tend to completely block the activity of the CB_1 and consequently induce significant side effects, which make their clinical use difficult, if not impossible, thereby leaving many patients without treatment[4].

The drug candidates developed by Aelis Farma are not antagonists but belong to a new proprietary pharmacological class: the Signaling Specific inhibitors of the CB_1 receptor (CB_1-SSi). These molecules, which are the result of decades of academic research conducted by the Company's co-founder and CEO, Dr. Pier Vincenzo Piazza, previously Director of the Inserm Magendie Neurocentre in Bordeaux, mimic a natural mechanism that the brain uses to fight hyperactivity of the CB_1 receptor. This major discovery was published in Science[5], one of the most prestigious scientific journals. The clinical trials performed to date by Aelis Farma have been able to show that CB_1-SSi, thanks to their innovative mechanism of action never tested in humans before, are not only effective, but also well tolerated, and could provide therapeutic solutions to many diseases that are currently without treatment. The enthusiasm of the scientific community for the innovation provided by CB_1-SSi has enabled the Company to involve in its clinical programs leading research institutions such as Columbia University, Yale University and NIH-NIDA in the United States as well as the IMIM in Spain. The Company has also secured an international industrial partnership with the Indivior group, to finance and accelerate the development of Aelis Farma's first molecule, AEF0117, for the treatment of disorders related to excessive cannabis use.

Two first-in-class drug candidates at clinical stage for indications with high unmet medical needs

- **AEF0117 to treat the harmful effects of excessive cannabis use**

The innovative mechanism of action of CB_1-SSi was first demonstrated in mice by studying the hyperactivity of the CB_1 induced by THC, the active ingredient of cannabis. The subsequent work undertaken by Aelis Farma's platform has allowed the improvement of the characteristics of CB_1-SSi enhancing their bioavailability, safety and efficacy profiles, allowing the Company to select its first drug candidate, AEF0117.

AEF0117 is being developed to treat disorders due to excessive cannabis use, which are a growing health and societal problem in Western countries, in which there are an estimated 17.9 million daily

[1] Busquets-Garcia et al. 2018a
[2] Piazza et al. 2017
[3] National Academies of Sciences, Engineering, and Medicine, 2017
[4] Christensen et al. Efficacy and safety of the weight-loss drug rimonabant: a meta-analysis of randomised trials, Lancet. 2007.
[5] "Pregnenolone can protect the brain from cannabis intoxication." (Science, January 3, 2014).

or near-daily cannabis users[6]. This excessive cannabis use is accompanied by increasingly documented adverse effects:

- 7.2 million people have been diagnosed with cannabis addiction (Cannabis Use Disorders, CUD);
- the number of emergency room hospitalizations due to the toxic effects of cannabis, of which psychosis is the most serious manifestation, was 1.1 million in the United States in 2014, and has been increasing since then, surpassing today those due to opioids;
- Negative long-term effects are also observed both on cognitive functions (a loss of up to 8 IQ points[7]) and on mental health and social integration, with the risk of developing psychiatric diseases, dropping out of studies or being unemployed increasing by up to 5 times[8].

AEF0117 successfully completed a phase 2a study in the first quarter of 2021 in collaboration with Columbia University (New York, United States). A phase 2b clinical trial, for which the protocol has been discussed with the FDA, will start in the second quarter of 2022 in the United States. This study will evaluate the efficacy of AEF0117 in the treatment of cannabis addiction and include approximately 330 patients. The coordinator and principal investigator of the study will be Prof. Frances Levin of Columbia University.

AEF0117's development program for CUD has been scientifically validated and has received financial support from the National Institute on Drug Abuse (NIDA), the entity dedicated to combating drug addiction within America's National Institute of Health (NIH). NIDA and the NIH, for whom the development of a therapy for cannabis addiction is a priority, have awarded AEF0117's program grants totaling $7.8 million ($3.3 million for phases 1 and 2a and $4.5 million in the context of the future phase 2 program to prepare AEF0117 to enter phase 3).

Based on the results of the phase 2a, Aelis Farma has entered an option license agreement with Indivior PLC for the development and commercialization of AEF0117 as a treatment of the harmful effects of excessive cannabis use (see the section 'A strong value-creating partnership with Indivior…' below).

- **AEF0217 to treat cognitive deficits in Down syndrome (Trisomy 21)**

AEF0217 could become the first treatment for cognitive deficits caused by a hyperactivity of the CB_1 receptor, such as those associated with Down syndrome (Trisomy 21), the first indication of this compound. Down syndrome is a genetic condition caused by the presence of an extra copy of chromosome 21. There are an estimated 0.8 million people living with Down syndrome in the major Western countries[9] and Japan, with a prevalence that is rising due to the significant increase in recent decades of late pregnancies and of the life expectancy of people living with this syndrome. To date, there is no medical treatment for the cognitive deficits associated with Down syndrome, which constitutes a significant unmet medical need and a significant burden on the persons, their families, and healthcare systems.

During preclinical studies, AEF0217 was able to restore the deficit in working memory, the key cognitive deficit in Down syndrome, without inducing identifiable behavioral or physiological side effects in mice models of Trisomy 21. Thanks to this unique combination of efficacy and safety, which is particularly important for the fragile Down syndrome population, AEF0217 could provide major improvements in the quality of life and the social integration of people living with Down syndrome.

AEF0217 is currently being evaluated in phase 1 clinical studies in healthy volunteers, with no major adverse effects reported to date in the first three patient cohorts. The drug candidate is expected to

[6] Data includes the European Union, the United States, Canada, and Australia.
[7] Grant et al. 2012; Meier et al. 2012
[8] Fergusson and Boden, 2008
[9] The European Union, the United States, Canada and Australia. The details of the summary prepared by the Company on the basis of several sources of public information can be found in Table 3 of Section 5.3.2 of the Registration Document.

enter clinical studies in Down syndrome subjects, which could provide the first proof of efficacy, in the fourth quarter of 2022. This clinical program is being conducted in the framework of the *Improving Cognition in Down syndrome* ("ICOD") consortium in collaboration with the Institut Hospital del Mar d'Investigacions Mèdiques ("IMIM") in Barcelona, and other European clinical centers. The EU's Horizon 2020 program awarded the ICOD project a grant of €6m (H2020 Program N° 899986).

Aelis Farma also plans to extend the phase 2 clinical program of AEF0217 to at least one other type of cognitive impairment, such as those accompanying Fragile X syndrome or aging, for which AEF0217 has demonstrated efficacy in preclinical models.

Aelis Farma intends to develop AEF0217 independently at least until the end of the phase 2 program and, after this stage, to bring the compound to market approval, while remaining open to potential partnerships.

A strong value-creating partnership with Indivior for AEF0117 to treat cannabis related disorders worldwide

Based on the excellent results of AEF0117's phase 2a clinical study, Aelis Farma signed an exclusive option license agreement in June 2021 with Indivior PLC ("Indivior"), a leading biopharmaceutical company in the treatment of addiction, for the development and commercialization of AEF0117 as a treatment for disorders due to excessive cannabis use. If the phase 2b study proves positive, Aelis Farma and Indivior intend to initiate phase 3 studies in late 2024 or early 2025, in order to obtain rapid approval in the United States and in Europe. The development of AEF0117 is managed by a joint steering committee. Under the terms of the agreement, Aelis Farma is in charge of operations until the end of the phase 2b program and following exercise of the license option, Indivior will manage the execution of the phase 3 program.

As part of this collaboration, Aelis Farma has received $30 million (option payment) and is eligible to receive, if the option is exercised after phase 2b, a $100 million license fee (potentially in 2024) and supplementary payments, up to $340 million, in development, regulatory and commercial milestones, as well as royalties ranging from 12% to 20% on net sales of AEF0117. Following the exercise of the option, all of the costs of development, registration, and commercialization of AEF0117 will be borne by Indivior.

In addition, in January 2022, Aelis Farma received an irrevocable subscription commitment of $11 million from Indivior in the context of the offer of new shares in the Company to occur during the Company's planned IPO on the regulated market of Euronext Paris.

An efficient R&D platform to expand further the product portfolio

One of Aelis Farma's key success factors is its method of selecting drug candidates on its proprietary R&D platform, which consists of 3 main components:

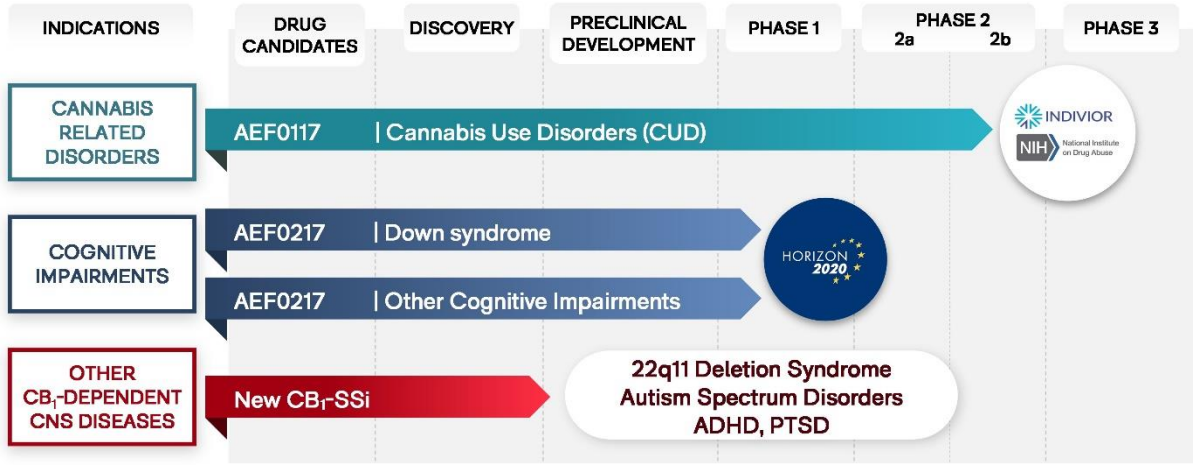
- a high content screening laboratory;
- a multifactorial screening process;
- innovative behavioral models.

The early screening of toxicity and pharmaceutical characteristics of its molecules combined with the development of innovative behavioral models with high predictivity of clinical efficacy is likely to significantly increase the success rate of Aelis Farma's drug candidates.

Given the involvement of the CB_1 receptor in numerous pathologies and the strength of its diverse and exclusive library of CB_1-SSi, Aelis Farma is also developing a portfolio of new CB_1-SSi with differentiated pharmacological properties.

The immediate priority of these programs is orphan indications, such as 22q11 deletion syndrome or certain autism spectrum disorders (ASD), but also non-orphan indications such as attention deficit hyperactivity disorder (ADHD). Aelis Farma intends to initiate the development of a new drug candidate in one of these indications by the end of 2023.

- **Aelis Farma's diversified portfolio of drug candidates**



Aelis Farma holds an exclusive worldwide license for AEF0117 and AEF0217. These molecules and their use are covered by patents and patent applications that offer protection that can go up to 2039 with additional possible extensions in Europe and the United States. The Company has full ownership of the new CB_1-SSi molecules generated by its platform.

Financial strategy and resource allocation

The company has the necessary financial resources today to perform the phases 2b for AEF0117 in cannabis addiction (Cannabis Use Disorders, CUD) and for AEF0217 in the cognitive deficits of Down syndrome. The planned capital raise aims to finance the acceleration of the development of these drug candidates performing the complementary studies enabling them to enter phase 3 clinical trials after the phase 2b and to start the development of a third candidate drug, selected from the new CB_1-SSi of the company. This development plan will generate a dense news flow between 2022 and 2024.

Subscription commitments of current investors

In the context of its planned initial public offering on the Euronext Paris stock exchange, the Company has received subscription commitments from some of its current shareholders for a minimum of €4.5 million. The breakdown of which is as follows:

- Inserm Transfert Initiative 0.5 million euros;
- Aelis Innovation, a fund represented by the management company Irdi Capital Investissement, 1 million euros;
- Nouvelle Aquitaine Co-Investissement (NACO) 1.392 million euros;
- Aqui-Invest 0.454 million euros;
- Aquitaine Création Investissement (ACI) 1.154 million euros.

Aelis Farma's current investors cited above are not represented by a director on the Company's board of directors.

Provision of the registration document

Aelis Farma's registration document, approved by the AMF on January 14, 2022 under I.22-003 is available on Aelis Farma's website dedicated to the transaction (https://www.aelis-finance.com) and on the AMF's website (https://www.amf-france.org). It is also available free of charge upon request at Aelis Farma's registered office, 146 rue Léo Saignat, 33076 Bordeaux, France.

Risk factors

Aelis Farma draws the public's attention to section 3 "Risk Factors" in the Registration Document approved by the AMF.

About AELIS FARMA

Founded in 2013, Aelis Farma is a biopharmaceutical company that has developed a new class of drugs, the Signaling Specific inhibitors of the endocannabinoid system's CB_1 receptor (CB_1-SSi), which has great potential in the treatment of many brain diseases. CB_1-SSi were developed by Aelis Farma on the basis of the discovery of a new natural defense mechanism of the brain made by the team of Dr. Pier Vincenzo Piazza, CEO of the Company, when he was Director of the Inserm Magendie Neurocentre in Bordeaux. For these discoveries, Dr. Piazza was awarded Inserm's Grand Prix, and the French Academy of Sciences' Grand Prix of Neurology, which are among the most prestigious French awards for medicine and neurology, respectively.

Aelis Farma is developing two first-in-class CB_1-SSi, AEF0117 and AEF0217, which are at clinical stage, and has a portfolio of innovative early stage CB_1-SSi for the treatment of other diseases involving the activity of the CB_1 receptor.

AEF0117, which targets disorders due to an excessive use of cannabis, such as addiction and psychosis, has completed a phase 2a study that showed positive signs of efficacy and will enter a phase 2b in the United States in 2022. For the development and commercialization of AEF0117, Aelis Farma benefits from an exclusive option license agreement with Indivior PLC, a leading pharmaceutical group in the treatment of addiction. Under the agreement, Aelis Farma has already received $30 million (option fee). If Indivior exercises the option Aelis Farma will receive a €100 million license fee and payments up to €340 million in development, regulatory and commercial milestones, as well as royalties between 12% and 20% on net sales of AEF0117.

AEF0217, which targets cognitive disorders such as those due to Down syndrome, is currently being evaluated in a phase 1 clinical program. This compound has been the subject of extensive preclinical proof of concept studies using highly innovative and highly predictive models of cognitive functions. In this context, AEF0217 demonstrated the ability to reverse cognitive deficits in several models of cognitive disorders such as Down's syndrome and Fragile X syndrome, as well as in models of aging-related cognitive impairments.

Based in Bordeaux, France, within the Inserm Magendie Neurocentre, Aelis Farma has a team of 23 highly qualified employees and has benefited from investments from the Nouvelle-Aquitaine Region, Inserm Transfert Initiative, Bpifrance, regional funds ACI, NACO, and Aqui-invest, and IRDI Capital Investissement.

For more information: www.aelisfarma.com

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