Press release

Aelis Farma receives a positive opinion from EMA Pediatric Committee on the Pediatric Investigation Plan for AEF0217 in Down syndrome

- **The EMA's Pediatric Committee (PDCO) has delivered a favorable consensus opinion on the Pediatric Investigational Plan (PIP) of Aelis Farma's first-in-class drug candidate AEF0217 for the treatment of adaptive behavior and cognitive impairments associated with Down syndrome.**
- **The PDCO has agreed on a clinical program that will include children from birth to less than 18 years of age with a descending stepwise approach. It has also accepted the current formulation of AEF0217 for pediatric use and deemed appropriate and sufficient the preclinical toxicology already performed, as well as the population PK modelling approach to determine doses in children.**
- **This major regulatory milestone, for a treatment that is likely to be destined to children, reinforces the program's credibility, de-risks late-stage regulatory requirements, and strengthens visibility on the European path toward marketing authorization for AEF0217.**

Bordeaux, France, January 12, 2026 – 07:30 a.m. CET – Aelis Farma (ISIN: FR0014007ZB4 – Ticker: AELIS, PEA-PME eligible), a clinical-stage biopharmaceutical company specializing in the development of treatments for brain and peripheral diseases involving the CB1 receptor, announces today that the Paediatric Committee (PDCO) of the European Medicines Agency (EMA) has emitted a favorable opinion on the Paediatric Investigation Plan (PIP) for AEF0217 (EMA/PE/0000243385; IRIS: 0075800000532) in the treatment of Down syndrome.

A PIP is a rigorous development scheme aimed at ensuring that the necessary data are obtained through dedicated studies to eventually support the market authorization of medicine for children. The positive opinion delivered by the EMA's Pediatric Committee (PDCO) on the PIP elaborated by Aelis Farma for AEF0217 confirms the alignment of AEF0217 development program with European pediatric development requirements.

A key regulatory milestone for AEF0217

The agreed PIP covers children from birth to less than 18 years of age and targets the treatment of adaptive behavior and cognitive impairments in Down syndrome.

It includes, among others, a staged clinical programme across age groups, supported by long-term extension studies and population pharmacokinetic modelling to confirm or adjust paediatric dosing, and if needed the adaptation of the current formulation for children less than 2 years of age. The PDCO also considered the preclinical toxicology package already completed to be appropriate and sufficient.

For Aelis Farma and AEF0217, the PDCO agreement is particularly significant as it:

- Strengthens regulatory credibility by endorsing a paediatric development plan judged robust from scientific and methodological perspectives;

- De-risks the programme by providing clear, agreed expectations for paediatric requirements and timelines, reducing the risk of late-stage "blocking" requests;
- Improves roadmap visibility toward future marketing authorization submissions in Europe, where paediatric obligations are a key component of regulatory validation and compliance;
- Enables a pragmatic stepwise approach allowing the programme to progress sequentially based on data generated in earlier studies before expanding into progressively younger populations.

A stepwise clinical strategy aligned with the Company's ongoing programme

The PIP is fully in line with Aelis Farma's extensive clinical development plan assessing the efficacy and safety of AEF0217 in people with Down syndrome, structured in two parts:

- The first part includes a Phase 2B study in older adolescents and young adults with Down syndrome aged 16 to 32 years.
- The second part, covered by the PIP, foresees subsequent studies progressively including children aged 6 to <16 years, then 2 to <6 years, and potentially from birth to <2 years.

This stepwise approach is designed to ground trials in each age group on data obtained from previous studies. The aim is to offer a treatment that complements the educational and rehabilitative care already in place, to give people with Down syndrome and their families more scope for progress in everyday life. By systematically collecting and analyzing observations and experiences from participants and their families, the program aims also to provide reliable information on the daily challenges and progress observed in children with Down syndrome. This program should facilitate the implementation of early care for children, which could have a positive impact on their development, particularly on their learning and cognitive abilities, as well as on their overall quality of life. The project has received significant support from families and associations, demonstrating their commitment to initiatives that seek to meet the needs of children with Down syndrome.

Pier Vincenzo Piazza, CEO of Aelis Farma, stated: *"The PDCO's favorable opinion on our Paediatric Investigation Plan for AEF0217, is a major milestone for Aelis Farma and—most importantly—for the Down syndrome community. It validates the robustness of our clinical development strategy and provides a clear, agreed framework to evaluate AEF0217 across the full paediatric age range (from birth to 18 years of age) fulfilling a major demand from families and patients' associations. After obtaining positive results of our ongoing Phase 2B study, which will include older adolescents and adults, we will continue the paediatric development including children of younger ages. The ability to reach children early in their development should lead to greater gains in learning, adaptive behavior and cognition and a stronger impact on quality of life. After this important milestone, we are even more committed to fulfill a major unmet medical need by delivering a treatment that could meaningfully improve quality of life for people with Down syndrome and their families."*

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About AEF0217 and the clinical program for the treatment of adaptive behaviors and cognitive disorders in Down syndrome: the European ICOD project

AEF0217 is Aelis Farma's second clinical-stage drug candidate. It belongs to a new class of drugs discovered by the company, the Signaling Specific inhibitors of the CB_1 receptor of the endocannabinoid system (CB_1-SSi). Hyperactivity of the CB_1 receptor is involved in many brain and peripheral disorders and particularly in cognitive impairments associated with various neurodevelopmental conditions and aging. AEF0217, like the other CB_1-SSi, is able to inhibit only certain components of CB_1 activity. This molecular selectivity generates the first CB_1 inhibitors that

show beneficial pharmacodynamic and therapeutic effects but lack the side effects characterizing the CB_1 inhibitors of the previous generation, the CB_1 antagonists that block the entire activity of the CB_1 receptor.

AEF0217 is being developed as a new potential pharmacological treatment for cognitive impairments with as first therapeutic target, the impairments in adaptive behaviors and cognition associated with Down syndrome.

The clinical development of AEF0217 has so far successfully completed a Phase 1 programme in healthy volunteers including three independent studies and a Phase 1/2 study in young adults with Down syndrome people. The current Phase 2B study in people with Down syndrome will be performed in 10 clinical centres in three countries (Spain, France and Italy) and will include older adolescents (16 to 18 years of age) and young adults (18 to 32 years of age). These trials are part of the European H2020 ICOD project (Improving COgnition in Down syndrome, Grant Agreement ID 899986); which received €6 million in funding from the European Commission.

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 CB1 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 and peripheral organ diseases.

Aelis Farma currently has two first-in-class clinical-stage drug candidates. AEF0117 for the treatment of cannabis use disorders (CUD), that has shown to be able to decrease cannabis use across two studies. AEF0217 for cognitive disorders, which has shown in a Phase 1/2 to be safe and able to improve adaptive behavior in young adults with Down syndrome (Trisomy 21) and has started a Phase 2B in Europe aiming to confirm its efficacy and safety. The clinical results obtained with these 2 compounds have confirmed the safety and therapeutic activity of CB_1-SSi in humans. The Company also develops 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, including diseases involving peripheral organs, such as obesity and related metabolic conditions. The different drugs developed by the company belong to the same general pharmacological class, the CB_1-SSi, but have distinct functional effects allowing to target different types of dysregulations of the CB_1 receptor and guaranteeing that the different compounds are not substitutable one with the others.

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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Disclaimer

Forward-looking statements

Some information contained in this press release is forward-looking statements, not historical data. These forward-looking statements are based on current beliefs, expectations, and assumptions, including, but not limited to, assumptions about Aelis Farma's current and future strategy and the environment in which Aelis Farma operates. They involve known and unknown risks, uncertainties, and other factors, which may cause actual results, performance, achievements, or industry results or other events, to differ materially from those described or implied by such forward-looking statements. These risks and uncertainties include those set out and described in detail in Chapter 3 "Risk Factors" of Aelis Farma's Universal Registration Document approved by the *Autorité des Marchés Financiers* on April 28, 2025, under number R. 25-0314s.

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.