Press release

Preclinical data demonstrating the efficacy of AEF0217 in a genetic mouse model of autism spectrum disorder has been presented at the 2nd European Conference on Phelan-McDermid Syndrome

The 2nd European Conference on Phelan-McDermid Syndrome was held in Madrid from June 9 to 11, 2023

Bordeaux, June 12, 2023 – 7:00 a.m. CEST – **Aelis Farma** (ISIN: FR0014007ZB4 – Ticker: AELIS), a clinical-stage biopharmaceutical company specialized in the development of treatments for brain diseases, today announced the presentation of new preclinical data on its drug candidate AEF0217 at the 2nd European Conference on Phelan-McDermid Syndrome, which was held from June 9 to 11, 2023 at CEU San Pablo University in Madrid[1].

Phelan-McDermid Syndrome (PMS), which is caused by the deletion of chromosome 22q13 including the *SHANK3* gene or by a sequence variation in this gene, is one of the most frequently observed genetic mutations in autism. It is an orphan disease for which there is currently no treatment. In affected people, these mutations can lead to development delays in multiple areas, in particular delayed speech, intellectual disability and often autism spectrum disorder.

Dr. Pier Vincenzo Piazza, CEO of Aelis Farma, alongside Flavio Tomasi, PhD student in Dr. Catalina Betancur's INSERM/CNRS laboratory at the Sorbonne university, gave an oral communication entitled: "Inhibition of the cannabinoid CB_1 receptor rescues deficits in a mouse model of Phelan-McDermid syndrome" at the 2nd European Conference on Phelan-McDermid Syndrome, organized by the Spanish Phelan-McDermid Syndrome Association.

The presented data was obtained within the context of a collaboration between several laboratories coordinated by Dr. Betancur. The results showed the ability of AEF0217 to statistically significantly reverse behavioral, cognitive and motor deficits observed in a genetic mouse model of Phelan-McDermid Syndrome. In these mice, ARF0217 also reversed a neurological alteration (cortical hyperactivity), considered as a neurobiological marker of autism. Based on these promising results Aelis will now analyze the feasibility to develop of AEF0217 in this indication and more generally in autism spectrum disorder.

Pier Vincenzo Piazza, CEO of Aelis Farma, said: "*The preclinical data obtained by Dr. Betancur's group have generated considerable excitement in the scientific community present at the meeting and encourage us to evaluate, in addition to the ongoing program in trisomy 21, the feasibility of developing AEF0217 in this new indication. More generally, the data suggest that AEF0217 could also help patients with autism spectrum disorder, which would significantly expand the fields of application of our second drug candidate".*

Dr. Catalina Betancur of the Neuroscience Paris Seine laboratory (INSERM, CNRS, Sorbonne University, Paris), who coordinated the studies presented, commented: "*We are delighted to have had the opportunity to present the results of the effects of AEF0217 on a mouse model of Phelan-McDermid Syndrome at this conference, which brings together the most prominent international experts in this rare disease for which there is no effective treatment. Our preclinical data have been very favorably received by scientists and families attending the conference and encourage us to push forward the evaluation of*

[1] Aelis Farma is one of the partners of this conference.

AEF0217 in autism spectrum disorder. We are delighted to be participating in the development of a potential new treatment for a population of patients in dire need".

AEF0217 is the second drug candidate developed by Aelis Farma. It belongs to a new generation of drugs discovered by the Company, the Signaling-Specific inhibitors of the CB_1 receptor of the endocannabinoid system (CB_1-SSi). The CB_1 is one of the most expressed neurotransmitter receptors in the brain implicated in many diseases. AEF0217 is currently being developed for the treatment of cognitive disorders in people with Down syndrome (trisomy 21) and evaluated in a phase 1/2 study in this population.

About Phelan-McDermid Syndrome[2]

Phelan-McDermid Syndrome (PMS) is one of the most frequent genetic causes of autism spectrum disorder. It is an orphan disease resulting from the loss of genetic material at the terminal end of chromosome 22 (22q13 deletion) or from a mutation in the *SHANK3* gene. The genetic characteristic that affected people have in common is the absence or the mutation of the *SHANK3* gene. The absence or the mutation of a copy of this gene results in a general developmental delay, and in particular in a delayed or absent speech, intellectual disability, autism spectrum disorder and motor skill deficits. Some affected people may also suffer from epilepsy. This mutation generally occurs spontaneously and it is not hereditary.

About the European Conference on Phelan-McDermid Syndrome

This conference, organized by the Spanish Phelan-McDermid Syndrome Association, aims to inform professionals and families about the latest advances in the scientific research and care of Phelan-McDermid Syndrome (PMS). It brings together international experts in various disciplines and provides the families of people with this syndrome an opportunity to discuss the difficulties and challenges they face.

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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 people with Down syndrome in Spain. The Company also has a portfolio of 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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[2] Sources: Phelan-McDermid Syndrome Associations in Spain and France

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Forward-looking statements

Some information contained in this press release are 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, or 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 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.