

## **NFL BIOSCIENCES: Inclusion of the first volunteer in the PRECESTO study, which aims to demonstrate the complementarity of NFL-101 with other smoking cessation treatments**

**NFL BIOSCIENCES (Euronext Growth Paris – FR0014003XT0 – ALNFL), a biopharmaceutical company developing botanical medicines for the treatment of addiction, announces the inclusion of the first volunteer in its PRECESTO clinical trial, designed to evaluate the complementarity of its NFL-101 treatment as a smoking cessation therapy with other smoking cessation treatments, notably nicotine replacement therapies.**

This Phase IIa clinical study, entitled PRECESTO, was approved by the French National Agency for the Safety of Medicines and Health Products (ANSM), and received a positive opinion from the French Committee for the Protection of Individuals (CPP) in November 2022. Its main objective is to validate the complementarity of NFL-101 with other smoking cessation treatments, in particular nicotine substitutes (transdermal patches, tablets, gum, inhalers and nicotine sprays), with a view to developing an innovative treatment method combining NFL-101 with other smoking cessation methods. PRECESTO is being implemented at Eurofins Optimed's clinical research center in Gières, in the Grenoble area.

In this new treatment method, for which a patent was filed in October 2022, the administration of NFL-101 prior to the quit attempt aims to break the link between cigarettes and the satisfaction they provide, and to reduce the desire to smoke. Smokers can then focus on their quit attempt and manage their nicotine withdrawal symptoms (irritability, nervousness, anxiety, etc.) with the help of other smoking cessation treatments, including nicotine replacement therapies.

The PRECESTO study compares the ability of NFL-101 to reduce cigarette satisfaction and craving with placebo. It is a randomized, double-blind study that will include a total of 34 smokers who do not wish to quit and have high smoking satisfaction in a cross-over design. Each subject is his or her own control and receives either NFL-101 or placebo randomly and alternately at the beginning of each of two periods during which he or she assesses satisfaction with cigarettes and craving for cigarettes using international questionnaires. The periods are each one month long. The Modified Cigarette Evaluation Questionnaire (mCEQ) is used as the main instrument. It measures satisfaction with smoking, psychological reward, aversion, pleasant sensations in the airways, and reduction in craving. Results of the PRECESTO study are expected in the third quarter of 2023. This study is expected to increase the attractiveness of NFL-101 to pharmaceutical companies marketing smoking cessation drugs and who may be interested in licensing it.

Bruno Lafont, Chief Operating Officer and co-founder of NFL Biosciences, said: *"PRECESTO complements the ongoing CESTO II study (318 smokers, 9 clinical investigation centers in France) designed to validate the efficacy of NFL-101 as a smoking cessation therapy. PRECESTO is a proof-of-concept study that aims to increase the addressable market for NFL-101 by expanding it, by administering it in combination with other smoking cessation treatments, in particular nicotine substitutes. The global market for smoking cessation drugs is estimated to be close to USD 6 billion, with a growth rate of around 6% in the years to come."*

### *About NFL Biosciences*

NFL Biosciences is a biopharmaceutical company based in the Montpellier area which develops botanical drug candidates for the treatment of addictions. NFL Biosciences' ambition is to bring new, natural, safer and more effective therapeutic solutions to the entire world population, including low- and middle-income countries. Its most advanced product, called NFL-101, is a standardized, nicotine

free tobacco leaf extract protected by two patent families. NFL Biosciences intends to offer smokers who want to quit a natural, safe, easy-to-administer and personalized alternative.

NFL Biosciences is also developing NFL-301, a natural drug candidate for the reduction of alcohol consumption and has a drug development project for the treatment of cannabis use disorders.

The shares of NFL Biosciences are listed on Euronext Growth Paris (FR0014003XT0 – ALNFL). Find out more at [www.nflbiosciences.com](http://www.nflbiosciences.com)

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