

## **NFL BIOSCIENCES: CLINICAL TRIAL APPROVED TO DEMONSTRATE THE COMPLEMENTARITY OF NFL-101 WITH OTHER SMOKING CESSATION TREATMENTS**

**NFL BIOSCIENCES (Euronext Growth Paris – FR0014003XT0 – ALNFL), a biopharmaceutical company developing botanical drugs for the treatment of addictions, is announcing that its clinical trial to assess the complementarity of NFL-101 as a smoking cessation treatment with other smoking cessation treatments and particularly nicotine substitutes, has been approved by the French National Agency for the Safety of Medicines and Health Products (ANSM) and has received a favorable opinion from the French Ethical Review Board (CPP).**

NFL Biosciences will carry out a Phase IIa clinical trial, entitled PRECESTO, with the primary objective of validating the complementarity of NFL-101 with other smoking cessation treatments and particularly nicotine substitutes (transdermal patches, tablets, chewing gums, inhalers and nicotine sprays) with a view to develop an innovative treatment method by associating NFL-101 with other smoking cessation methods. With this new treatment method, which is covered by a patent application filed on October 24, 2022, the administration of NFL-101 before attempting to stop aims to break the link that exists between cigarettes and the satisfaction they provide, and to reduce the urge to smoke. Smokers can then focus on their attempt to stop and manage their nicotine withdrawal symptoms (irritability, nervousness, anxiety, etc.) with the help of the other smoking cessation treatments and particularly nicotine substitutes.

The PRECESTO trial will compare against placebo the ability of NFL-101 to reduce smoking satisfaction and cravings. This is a randomized, double-blind, cross-over design trial that will include 34 smokers who are not looking to stop smoking and get high satisfaction from smoking. Each participant will be his or her own control and will receive, on a random and alternating basis, either NFL-101 or placebo at the start of each of the two periods during which they will assess smoking satisfaction and desire to smoke using standardized international questionnaires. Each period will run for one month. The modified Cigarette Evaluation Questionnaire (mCEQ) will primarily be used. It makes it possible to measure the following aspects: smoking satisfaction, psychological reward, aversion, enjoyment of respiratory tract sensations and craving reduction. The PRECESTO trial results are expected in the third quarter of 2023. This trial would further strengthen the appeal of NFL-101 for pharmaceutical companies that sell smoking cessation drugs and could be interested in taking out licenses.

Bruno Lafont, Chief Operating Officer and co-founder of NFL Biosciences: *“PRECESTO is being carried out alongside the CESTO II trial that is underway (318 smokers, nine clinical investigation centers in France) to validate the efficacy of NFL-101 as a smoking cessation treatment. PRECESTO is a proof-of-concept trial that aims to expand the potential market for NFL-101 by including its administration in association with other smoking cessation treatments and particularly nicotine substitutes. The global market for smoking cessation drugs is estimated at nearly USD 6 billion<sup>1</sup>, with growth of around 6% in the coming years”.*

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(1) Source: Coherent Market Insights.

## *About NFL Biosciences*

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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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