

NFL Biosciences: Recruitment completed for the PRECESTO study

PRECESTO clinical trial to demonstrate the potential complementarity of NFL-101 with other smoking cessation treatments: 100% of volunteers recruited and initial results expected in the third quarter of 2023.

NFL BIOSCIENCES (Euronext Growth Paris – FR0014003XT0 – ALNFL), a biopharmaceutical company developing botanical drugs for the treatment of addictions, is announcing that the final recruitments have been completed for the 34 volunteers in its PRECESTO clinical trial to evaluate the potential complementarity of its NFL-101 treatment as a smoking cessation therapy with other smoking cessation treatments, notably nicotine replacement therapies.

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 (transdermal patches, tablets, gum, inhalers and nicotine sprays). The global market for smoking cessation drugs is estimated to be close to USD 6 billion¹, with a growth rate of around 6% in the years to come.

After obtaining the necessary regulatory authorizations to carry out the trial in September 2022, volunteer recruitment started up in February 2023 and was completed on May 5, 2023. The initial results are expected in the third quarter of 2023. This study could increase the attractiveness of NFL-101 to pharmaceutical companies, especially those marketing smoking cessation drugs. Conducted at the Eurofins-Optimed research institute (Grenoble), PRECESTO compares against placebo the ability of NFL-101 to reduce the attributes that reinforce smoking, such as the satisfaction or psychological rewards offered by cigarettes. The PRECESTO study includes 34 smokers who do not wish to quit and have high smoking satisfaction.

The joint funding for the PRECESTO study includes a €200,000 non-refundable grant obtained on January 17, 2023 under “Programme d’Investissement d’Avenir 4” from the France 2030 plan, awarded jointly by the French government and the Occitanie region. This study complements the CESTO II (phase II/III) clinical trial to assess the efficacy of NFL-101 as a smoking cessation treatment. CESTO II includes 318 smokers, whose recruitment was also completed at the end of April 2023².

Bruno Lafont, Chief Operating Officer, and in charge of product development: *“Our ability to effectively manage complex projects with a streamlined team is a major asset for NFL Biosciences. We can be proud of having completed, on time and on budget, the recruitments for two clinical trials for NFL-101. With a very low fixed cost structure, the vast majority of our resources are allocated to financing clinical trials and therefore serve to increase the potential value of NFL’s addiction treatment projects”.*

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 disorder.

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

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¹ Source: Coherent Market Insights.

² See press release from April 25, 2023 “NFL Biosciences: 2022 full-year business and earnings update” available [here](#)