

NFL Biosciences: Phase II/III clinical trial launched for smoking cessation

International trial conducted on 318 smokers over a period of 24 months.

Four centers opened simultaneously in France and Australia

Inclusion of patients from January 2022

NFL Biosciences SA, a biopharmaceutical company that is developing botanical drugs for the treatment of addictions, is officially launching its CESTO II Phase II/III clinical trial to assess the efficacy and safety of its NFL-101 smoking cessation treatment. Approved by the Human Research Ethics Committee (HREC) in Australia (see press release from June 2, 2021) and by the French National Agency for the Safety of Medicines and Health Products (ANSM) (see press release from September 15, 2021), CESTO II will include its first patients beginning January 2022 at the four clinical centers opened.

Bruno Lafont, Chief Operating Officer and co-founder of NFL Biosciences: *“We are delighted to pass this latest significant milestone with our CESTO II trial. The choice to include the first patients beginning in January should make it possible to capitalize on the good resolutions adopted by smokers at the start of the new year. The primary objective of this trial, which will take place at four centers - three in France and one in Australia - is to demonstrate that NFL-101, the most innovative natural drug candidate in an advanced clinical development phase, could be a first-line solution providing real support for people looking to stop smoking and for the treatment of their addiction”.*

EXTENSIVE INTERNATIONAL TRIAL WITH CORE CRITERIA THAT CAN BE APPROVED.

The CESTO II Phase 2/3 clinical trial will be multicentric, randomized, double blind and placebo controlled. The trial is being conducted as follows:

- three arms (two dose arms and one placebo arm);
- 318 smokers aged 18 and over;
- Monitoring of patients over 12 months (CESTO2, NCT04571216);
- The subjects will receive two initial subcutaneous injections one week apart. Additional follow-up injections could be provided after three and six months for patients who have not stopped smoking by these dates;
- The opened centers are the University of Tasmania’s clinical center in Australia, and the Clinical Investigation Centers (CIC) in Poitiers, Bordeaux and Rennes in France.

REMINDER OF CESTO II’S PRIMARY OBJECTIVES

This study’s primary objectives are to select the best dose and assess the efficacy of NFL-101 versus placebo, for both immediate and gradual smoking cessation. The criteria for assessment are the subject’s continued

abstinence for four weeks (FDA) and six months (EMA). The biomarkers used to confirm abstinence are exhaled carbon monoxide and urinary cotinine. A range of secondary criteria will also be assessed, including the number of cigarettes smoked, withdrawal symptoms and level of craving.

ABOUT NFL-101: A BOTANICAL DRUG CANDIDATE WITH STRONG POTENTIAL

NFL-101 is a clinically developed, nicotine-free botanical drug candidate, comprising natural proteins extracted from tobacco leaves. NFL-101 is covered by two patent families and has been subject to preclinical and Phase I trials, highlighting a significant reduction in the desire to smoke, without any toxicity.

NFL-101 is derived from a subcutaneous desensitization treatment that had been developed by Institut Pasteur for tobacco allergies among people working in tobacco factories. Used on an over-the-counter basis by a French doctor with over 10,000 smokers, the repositioned Pasteur extract showed promising results, substantiated by a retrospective study. NFL-101 is a standardized version of this for pharmaceutical use. A Phase II/III trial with 318 patients is now an international trial following approval from the ANSM and the favorable opinion issued by the French Ethical Review Board (CPP) in September 2021.

About NFL Biosciences

NFL Biosciences is a biopharmaceutical company based nearby Montpellier, France, whose most advanced botanical drug candidate is an aid to stop smoking. Known as NFL-101, this natural nicotine-free product, extracted from standard tobacco leaves, is protected by two patent families. NFL Biosciences aims to offer smokers who would like to stop smoking a safe, natural solution that is effective over the long-term, with short-term personalized administration.

Alongside NFL-101, NFL Biosciences has various development projects focused on botanical drugs for the treatment of cannabis use disorder and alcoholism.

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

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