

## **NFL Biosciences: Phase II/III clinical trial for NFL-101 for smoking cessation approved in France**

The CESTO II Phase II/III clinical trial 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)

The CESTO II trial, which had already been approved in Australia at the end of May 2021, will now be an international trial covering 318 patients

**NFL BIOSCIENCES (Euronext Growth Paris – FR0014003XT0 – ALNFL), a biopharmaceutical company developing botanical drugs for the treatment of addictions, is announcing that its Phase II/III clinical trial to assess the efficacy and safety of its NFL-101 smoking cessation treatment 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).**

The Phase II/III trial for NFL-101 covers 318 patients. It had already been approved at the end of May 2021 in Australia, with NFL Biosciences targeting this country for the quality of its clinical trials and its competitive research tax credit system. Thanks to this approval, NFL Biosciences will be able to recruit patients in France, initially at the Clinical Investigation Centers (CIC) in Poitiers, Bordeaux and Rennes.

The trial will be multicentric, randomized, double blind and placebo controlled. It will include three arms (two dose arms and one placebo arm) and monitor patients over 12 months. CESTO II's primary objectives are to select the best dose and assess the efficacy of NFL-101 versus the placebo, for both immediate and gradual smoking cessation. The main criteria for assessment are the person's continued abstinence for four weeks (US Food & Drug Administration (FDA) criterion) and six months (European Medicines Agency (EMA) criterion). 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.

The treatment is administered with an initial subcutaneous injection, at the same time as an attempt to stop smoking, followed by a second injection one week later. The aim is to facilitate success over the days that follow an attempt to stop smoking, a period that is essential to considerably increase the chances of success in the long term. An optional injection may be offered after three months and then six months for patients who are not abstaining by these dates and who commit to making a new attempt to stop smoking with each injection. The aggregate efficacy at the end of treatment, after two, three or four injections, will also be measured, assessing the potential for the treatment to be personalized.

*"We are very satisfied with this latest approval for a clinical trial in France. This trial's international approach represents the starting point for our future development, which aims to make NFL-101 available to the 780 million smokers that the World Health Organization estimates want to stop smoking. Tobacco consumption is a global issue and more than three quarters of the smokers who receive help still fail in their attempts to stop smoking. NFL-101 aims to offer real support for smokers with the treatment of their dependence, and is positioned to deliver a major step forward in the field to fight this particularly persistent addiction",* confirms Bruno Lafont, Chief Operating Officer and co-founder of NFL Biosciences.

## *About NFL Biosciences*

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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 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](http://www.nflbiosciences.com)

## *Contact*

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