

## NFL Biosciences: CESTO II trial progressing on schedule

Nine clinical sites active: more than 72% of the clinical trial participants recruited

Main results expected by the end of 2023

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

CESTO II is a placebo-controlled Phase II/III clinical trial that aims to include 318 smokers and choose the most effective dose. Nine clinical investigation sites are currently involved in the trial: the CHU teaching hospital centers in Bordeaux, Clermont-Ferrand, Dijon, Lorient, Marseille, Montpellier, Poitiers and Rennes, as well as the Eurofins-Optimed research institute in Grenoble. With 232 subjects recruited to date, NFL Biosciences expects to finalize recruitments during the second quarter, which would enable results to be obtained for the main criteria at the end of 2023.

CESTO II's objectives are to select the best dose and assess the efficacy of NFL-101 versus placebo. The primary end-point for assessment is the subjects' continued abstinence for four weeks (US Food & Drug Administration (FDA) accepted end-point). Many other secondary end-points will also be assessed, including the subjects' continued abstinence for six months (European Medicines Agency (EMA) accepted end-point), the number of cigarettes smoked, withdrawal symptoms and level of craving.

### NFL-101: a botanical drug candidate from Institut Pasteur

NFL-101 is a clinically developed, nicotine-free botanical drug candidate, comprising natural proteins extracted from tobacco leaves. NFL-101 is covered by three 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 Institut Pasteur extract showed promising results, substantiated by a retrospective study. NFL-101 is a standardized version for pharmaceutical use.

#### 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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