



Press release

NFL Biosciences presents the immunological analysis results of its phase 2 CESTO II study confirming the efficacy of NFL-101, its first-in-class treatment for tobacco addiction

- **NFL-101 induces a dose-dependent increase in anti-tobacco immunoglobulin (IgG) levels, a specific biomarker of treatment-induced biological response**
- **There is an association between NFL-101-induced increase in anti-tobacco IgG and continuous abstinence**
- **This association strengthens the evidence that the superior efficacy observed in terms of continuous abstinence is indeed attributable to NFL-101**

Montpellier, France, March 24th, 2025, 05:45pm CET – NFL BIOSCIENCES (Euronext Growth Paris - FR0014003XT0 - ALFNL), a biopharmaceutical company developing botanical drugs for the treatment of addictions, today presents the results of the immunological analysis of its phase 2 CESTO II study, confirming the efficacy of NFL-101, its first-in-class treatment for tobacco addiction.

In the Phase 2 study, CESTO II, a secondary objective was to explore a possible association between anti-tobacco IgG induction and continuous smoking abstinence, providing additional biological evidence to support behavioral observations based on abstinence measurements. While continuous abstinence was already confirmed using the urinary cotinine biomarker, the increase in IgG serves as a distinct immunological marker, reflecting the specific biological response triggered by the treatment.

Immunogenicity assays, now available, conducted at multiple time points, have enabled this analysis and confirmed a dose-dependent increase in anti-tobacco IgG levels—an effect not observed in the placebo group—indicating that NFL-101 has an intrinsic immunogenic effect. When comparing anti-tobacco IgG levels over time between continuously abstinent and non-abstinent subjects, statistically significant differences ($p < 0.05$) were observed, with higher IgG levels in continuously abstinent individuals, regardless of the dose of NFL-101 received. These findings suggest an association between the increase in anti-tobacco IgG following NFL-101 administration and the likelihood of maintaining continuous abstinence. This association strengthens the evidence that the superior efficacy observed in terms of continuous abstinence is indeed attributable to NFL-101 administration. These results mark the completion of the data analysis for the CESTO2 study and have been included in the publication project.

“The results of the immunological analysis of the CESTO II study confirm the positive impact of our first-in-class NFL-101 treatment in the treatment of tobacco addiction. We are delighted to see that the increase in anti-tobacco IgG in response to treatment is directly associated with continued abstinence, providing strong biological evidence to support its superior efficacy.” **comments Bruno Lafont, Chief Executive Officer of NFL Biosciences.**

[The results published in September 2024 from the Phase 2 clinical trial, CESTO II](#), evaluating NFL-101 in the treatment of tobacco addiction, demonstrated for the first time the efficacy of a single-dose drug in the treatment of tobacco addiction. NFL-101 could thus become an effective, natural and safe alternative to current treatments, while presenting a lighter and simpler administration method for smokers. Given its unique mechanism of action, NFL-101 could also be administered to any smoker using another smoking cessation medication.

NFL Biosciences is currently pursuing discussions with the regulatory authorities to establish the best possible development plan to enable NFL-101 to reach the market, and is continuing its industrial development to produce GMP batches for use in Phase 3, [based on the manufacturing process validated by the recent production of an engineering batch](#).

About NFL Biosciences: www.nflbiosciences.com

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).

Contacts:

NewCap

Investors relations / Media relations
Mathilde Bohin / Arthur Rouillé
Tel.: +33 (0)1 44 71 94 94
E-mail: nfl@newcap.eu

NFL Biosciences

Bruno Lafont
Tél.: +33 (0)4 11 93 76 67
E-mail: info@nflbiosciences.com