



Press release

NFL Biosciences receives Regulatory Approval to Begin Its Phase 2 TONIC Trial for Smoking and Nicotine Cessation

- **The TONIC Phase 2 trial evaluating NFL-102 consists of Part A (the first 40 participants) and Part B (the next 270 participants)**
- **Enrollment of the first participants (Part A) is scheduled to begin in November 2026**
- **Analysis and communication of the results from Part A expected in April 2027**

Montpellier, France, October 22, 2026, at 08:30 am CEST – NFL BIOSCIENCES (Euronext Growth Paris – FR0014003XT0 – ALNFL), a biopharmaceutical company developing immunotherapies for smoking and nicotine cessation, announced today that it has obtained the necessary approvals from the French National Agency for Medicines and Health Products Safety (ANSM) and the Committee for the Protection of Human Subjects (CPP) to begin its Phase 2 TONIC study evaluating NFL-102 for smoking and nicotine cessation.

NFL-101 AND NFL-102: TWO DISTINCT IMMUNOTHERAPIES

NFL-101 is designed to reduce neuroinflammation and has demonstrated statistically significant efficacy in a Phase 2 trial in a population defined by an immune biomarker predictive of response, identified in post-hoc analyses. A manuscript presenting these results is currently being submitted to an international peer-reviewed scientific journal. NFL-102, on the other hand, targets a root cause of addiction: alterations in brain plasticity. The TONIC study will now evaluate its efficacy in smoking and nicotine cessation.

TONIC STUDY

The TONIC study plans to enroll 310 smokers in France in a multicenter, randomized, double-blind, placebo-controlled trial. Its adaptive design will allow for the gradual selection of one dose from among three initial doses. The primary endpoint will be continuous abstinence for four weeks, confirmed by urinary cotinine.

Part A

An initial analysis will focus on **the first 40 participants**, included in the Eurofins Optimized Clinical Center (Gières, 38), and one dose will be eliminated based on safety and efficacy data analyzed—after unblinding—by an Independent Data Monitoring Committee (IDMC) and the company.

The first enrollments are scheduled for November 2026, and the analysis of the results from Part A is scheduled for April 2027. These two milestones will be the subject of dedicated announcements.

Part B

After enrolling an **additional 150 participants** (50 per arm, randomized between the two selected dose arms and the placebo) at about ten clinical centers in France, an interim analysis conducted by the IDMC will identify the most effective dose, without unblinding the other parties involved in the study. The study will then continue exclusively with this selected dose compared to placebo, with the enrollment of an additional 120 participants (60 per arm, randomized between the selected dose and placebo).

The Company's current cash position enables it to fund Part A of this TONIC study. The Company is actively pursuing efforts to identify strategic and financial partners to ensure the clinical development of Part B.

About NFL Biosciences: www.nflbiosciences.com

NFL Biosciences is a biopharmaceutical company based in the Montpellier region (France) that is developing a portfolio of innovative immunotherapies for smoking cessation and nicotine dependence. The Company is developing two drug candidates derived from tobacco leaves, NFL-101 and NFL-102, which target complementary biological mechanisms involved in addiction. NFL-101, whose efficacy and safety have been evaluated in a Phase 2 trial, is being developed using a precision medicine approach based on a biomarker that identifies patients most likely to respond to treatment. It is currently preparing for a Phase 3 trial and is intended to be the subject of a licensing agreement. NFL-102 represents a second immunotherapeutic approach and enters Phase 2 to evaluate its efficacy, select the optimal dose, and characterize responders. Both treatments are designed to be administered as just two subcutaneous injections one week apart.

NFL Biosciences shares are listed on Euronext Growth Paris (FR0014003XT0 - ALNFL).

Contacts

NewCap

Investor Relations / Media Relations
Mathilde Bohin / Jérémy Digel
Tel.: 01 44 71 94 94
E-mail : nfl@newcap.eu

NFL Biosciences

Bruno Lafont
Tél.: 04 11 93 76 67
E-mail : info@nflbiosciences.com