Press release

NFL Biosciences announces enrollment of the first participant in its Phase 2 TONIC study evaluating NFL-102 for smoking and nicotine cessation

- **Effective start of the clinical trial with the enrolment of the first participant in Part A, involving 40 smokers**
- **First clinical evaluation of NFL-102 in smokers wishing to quit**
- **Initial results from Part A are expected in April 2027**

Smoking cessation remains a major public health challenge. Quitting smoking involves managing withdrawal symptoms and resisting cravings, which can persist for several months after quitting and contribute to relapse.

Montpellier, France, November 19, 2026, at 8:00 a.m. CET – NFL Biosciences (Euronext Growth Paris – FR0014003XT0 – ALNFL), a biopharmaceutical company developing immunotherapies for smoking and nicotine cessation, today announces that the first participant has been enrolled in its Phase 2 TONIC clinical study evaluating its drug candidate NFL-102 for smoking and nicotine cessation.

The first participant was enrolled at the Eurofins Optimed clinical center in Gières (Isère, France), marking the start of the TONIC study. On October 22, NFL Biosciences announced that it had obtained the necessary regulatory approvals from the French National Agency for Medicines and Health Products Safety (ANSM) and the Committee for the Protection of Human Subjects (CPP).

Bruno Lafont, Chief Executive Officer of NFL Biosciences, said *"Enrolling the first participant in TONIC marks an important step forward in the clinical development of NFL-102. This study is central to evaluating the potential of our approach. Our aim is to give smokers a new option to help them quit tobacco and nicotine and reduce the risk of relapse. We expect the first results in April 2027. We thank the participants and the teams at our contract research organization, RCTs, and at the Eurofins Optimed clinical center for their commitment to the study."*

A Phase 2 study with an adaptive design

TONIC is a multicenter, randomized, double-blind, placebo-controlled study that plans to enroll 310 smokers in France. It aims to assess the efficacy of NFL-102, a drug candidate designed to enhance neuroplasticity, which plays a role in addiction.

The study's adaptive design allows for the most effective dose to be selected in stages from the three doses initially evaluated. The primary endpoint is four weeks of continuous abstinence, verified by measuring urinary cotinine.

Part A is now underway and will enroll 40 participants at the Eurofins Optimed clinical center in Gières. At the end of Part A, an Independent Data Monitoring Committee (IDMC) and the Company will review the safety and efficacy data after unblinding. This analysis will determine which of the three initial doses will be dropped.

The results from Part A are expected to be analyzed and reported in April 2027.

The study will continue with Part B, which plans to enroll 270 additional participants at approximately ten clinical centers in France. A further dose selection will take place once the first 150 participants in Part B have been enrolled. The next 120 participants will be assigned to either the selected dose or placebo for the final assessment.

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