Press release

NFL Biosciences clarifies the objectives and evaluation criteria for a predictive biomarker associated with NFL-101

Montpellier, France, May 11, 2026, 5:45 p.m. CEST – NFL BIOSCIENCES (Euronext Growth Paris – FR0014003XT0 – ALNFL), a biopharmaceutical company developing innovative botanical drugs for the treatment of addictions, today clarifies the objectives and criteria selected for the analysis of a predictive biomarker associated with NFL-101, its drug candidate for smoking cessation.

The objectives associated with the validation of a predictive efficacy biomarker are to strengthen the probability of success of NFL-101's Phase 3, notably by improving the expected effect size and, where applicable, optimizing the operational and financial conditions of its development. They also aim to support the development of a treatment with greater efficacy than current standards of care.

The validation of a predictive biomarker is based on four main criteria:

- NFL-101 efficacy must be higher in biomarker-positive patients, demonstrating that the biomarker identifies a population that is genuinely more responsive to the treatment.

- Placebo efficacy must be comparable between biomarker-positive and biomarker-negative patients, in order to exclude the possibility that the biomarker is associated with a difference in response independent of the treatment.

- In biomarker-negative patients, NFL-101 efficacy must be close to that of placebo, confirming that the treatment benefit is concentrated in the biomarker-positive population.

- Lastly, the biomarker must have a biologically coherent link with NFL-101's mechanism of action.

If these criteria are met, a mechanical relationship applies: the larger the biomarker-positive population, the lower the efficacy observed in this population, as the efficacy calculation includes a greater number of subjects while the number of subjects achieving smoking cessation remains fixed. Conversely, the smaller the biomarker-positive population, the higher the efficacy reported in this population.

The results of the ongoing analyses are expected in June 2026. Based on these results, and subject to confirmation of the validation criteria outlined above, the Company will decide whether to continue the development of NFL-101 in a biomarker-positive subpopulation identified as more responsive.

This decision will notably be based on the magnitude of the observed gain in effect size, which could translate into a significant reduction in the number of subjects required to demonstrate efficacy in Phase 3, on the absolute level of efficacy achieved compared with reference treatments, and on the size of the target population.

Beyond this enrichment strategy, the Company is also continuing the development of its second drug candidate, NFL-102. Depending on the efficacy results obtained, notably in the TONIC study, the Company will select the most promising candidate between NFL-101 and NFL-102 for prioritized advancement into Phase 3. The candidate not selected at this stage may nevertheless be developed subsequently, given the complementary positioning of the two products.

About NFL Biosciences: www.nflbiosciences.com

NFL Biosciences is a biopharmaceutical company based in the Montpellier region (France) developing botanical drug candidates for the treatment of addictions. NFL Biosciences' ambition is to provide new natural therapeutic solutions that are safer and more effective for people worldwide, including in low- and middle-income countries. NFL-101 and NFL-102 are standardized tobacco leaf extracts protected by four patent families. NFL Biosciences aims to offer smokers who wish to quit a natural, safe, easy-to-administer and personalized alternative. NFL Biosciences is also developing NFL-301, a natural drug candidate intended to reduce alcohol consumption and has a drug development program targeting cannabis use disorders.

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

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