PRESS RELEASE

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NFL BIOSCIENCES: PRE-IND APPLICATION FILED WITH THE FDA IN THE UNITED STATES FOR NFL-301, INDICATED FOR REDUCING ALCOHOL CONSUMPTION

NFL BIOSCIENCES (Euronext Growth Paris – FR0014003XT0 – ALNFL), a biopharmaceutical company developing botanical drugs for the treatment of addictions, is announcing that it has today submitted a pre-IND application to the FDA in the United States[1] for its drug candidate NFL-301, a product for the reduction of excessive alcohol consumption. The objective of this approach is to formalize the development program for NFL-301 and represents an essential preliminary step in order to formalize the optimum clinical development plan for the product.

In line with the initial strategy presented at the time of its IPO, NFL Biosciences is moving forward with the development of two drug candidates. On the one hand, NFL-101, a tobacco extract administered subcutaneously, targets smoking cessation and is in a phase 2b clinical trial with 318 participants, with the main results expected for July 2024. On the other hand, NFL-301, a purified kudzu plant extract administered orally to reduce excessive alcohol consumption, has taken a new significant step forward with the submission of a pre-IND application to the FDA following the patent application filed in July 2023.

This pre-IND application is an essential step in the development of the product. It allows for the NFL-301 development plan to be presented to the FDA. This plan includes the manufacturing and quality control methods, as well as preclinical data and future clinical trials. The aim is to ensure the NFL-301 development plan is compliant with the FDA's expectations in order to reduce potential obstacles related to the regulatory process.

The FDA response to the pre-IND application is expected by the end of the first quarter of 2024. It will lead to the formalization of the development plan, as well as to its budgeting, over a period that could run through to the third quarter of 2024. These preparatory stages do not require any significant cash outlays, while drawing up a development plan aligned with the FDA's expectations will ultimately reduce regulatory risks and ensure more effective budget control.

The two therapeutic approaches, based on NFL-101 and NFL-301, illustrate NFL Biosciences' commitment to offering innovative treatments for addictions, capitalizing on the company´s expertise in the development of botanical drugs and addictions. The effective approach for conducting the Phase 2b clinical trial with NFL-101 for smoking cessation, involving 318 participants across nine clinical centers, and the swift management of the timeframes and budget, highlight NFL Biosciences' ability to move forward with ambitious projects, while maintaining minimum fixed costs.

This balanced development strategy, supported by a pipeline of two drug candidates in the high-potential field of addiction treatment, is ramping up NFL Biosciences' appeal, further strengthening its position on the pharmaceutical market.

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 disorder.

The shares of NFL Biosciences are listed on Euronext Growth Paris (FR0014003XT0 – ALNFL). Find out more at www.nflbiosciences.com

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1 The pre-IND application (Pre-Investigational New Drug (IND) Application) with the Food and Drug Administration (FDA) aims to prepare, through early communications between companies and the FDA's new drug review divisions, the data necessary to warrant IND submission.