

# NFL BIOSCIENCES: POSITIVE FDA RESPONSE FOLLOWING THE PRE-IND APPLICATION FOR NFL-301 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 received formal guidance from the FDA in the United States for the pre-IND application<sup>1</sup> relating to its drug candidate NFL-301, focused on reducing excessive alcohol consumption. This process, launched in December 2023, will enable the NFL-301 development program to be formalized under optimal conditions.**

NFL Biosciences aims to develop the first oral delivery botanical drug based on kudzu extracts to tackle excessive alcohol consumption. In connection with the pre-IND application, the FDA recognized the interest of the new indication proposed by NFL Biosciences for disorders relating to alcohol use, covering the treatment of excessive alcohol consumption or binge drinking. This represents a key success factor for the development strategy and positioning of this innovative new drug candidate.

To benefit from the botanical drug candidate status, the kudzu extract used to develop NFL-301 will need to comply with the botanical drug candidate development guidance<sup>2</sup>. The formulation retained will need to be presented to the FDA prior to the clinical trial authorization application. This status makes it possible to considerably streamline the preclinical program, particularly before phase 1.

With this new indication, targeting the major public health issue of excessive alcohol consumption, NFL Biosciences is once again setting out its commitment to delivering new, natural, safer and more effective therapeutic solutions for the treatment of addictions.

In the United States, excessive alcohol consumption or binge drinking is defined as the consumption of four or more glasses during a binge occasion for women or five or more glasses during a binge occasion for men. The CDC (Centers for Disease Control & Prevention) estimates that one in six American adults binge drinks, with 25% doing so at least weekly, on average, and 25% consuming at least eight drinks during a binge occasion. Binge drinking is responsible for more than 40% of the deaths and three-quarters of the costs due to excessive alcohol use. It represents 56,000 deaths per year and an annual societal cost of 187 billion dollars<sup>3</sup>.

The pre-IND application for the NFL-301 development plan covers the manufacturing and quality control methods, as well as the preclinical data and clinical trials. Following the meeting of 17 FDA experts and the FDA report, NFL Biosciences will gradually roll out the NFL-301 development plan, in line with the FDA's expectations. NFL-301 is covered by an initial patent application, filed in the United States in July 2023.

Bruno Lafont, Chief Operating Officer and co-founder of NFL Biosciences: *"We are very happy with this positive feedback from the FDA, which validates the choices made with our partner Athena Pharmaceutiques and our scientific expert, Professor Scott Lukas, who could lead the first clinical trials at McLean Hospital, which is affiliated with Harvard Medical School. 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

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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](http://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.

(2) <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/botanical-drug-development-guidance-industry>

(3) Source:

<https://www.cdc.gov/chronicdisease/resources/publications/factsheets/alcohol.htm#:~:text=Binge%20drinking%2C%20defined%20as%20consuming,or%20anyone%20younger%20than%2021.>