

NFL BIOSCIENCES: PATENT APPLICATION FILED IN THE UNITED STATES FOR REDUCING ALCOHOL CONSUMPTION WITH NFL-301 & PREPARATION OF A PRE-IND APPLICATION SUBMISSION WITH THE FDA

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 patent application in the United States for its drug candidate NFL-301, focused on reducing alcohol consumption. This patent application submission is a precondition for a pre-IND application with the FDA in the United States¹ and a commitment to extending this new patent application internationally.

Patent application filed in the United States for the formulation of NFL-301 and commitment to extend it internationally

NFL Biosciences is continuing to move forward with its intellectual property strategy with the filing of a first patent for NFL-301. It aims to protect prolonged-release formulations of extracts of kudzu, a plant used in traditional Chinese medicine, as well as their uses for the treatment of alcohol consumption reduction.

Under the co-development agreement set up at the start of 2022, NFL Biosciences and its industrial partner ATHENA Pharmaceutiques have developed a prolonged-release form of kudzu extracts in microgranule form, NFL-301.

NFL Biosciences aims to develop the first oral delivery drug based on kudzu extracts to tackle excessive alcohol consumption. NFL-301 will stand out from kudzu-based nutritional supplements through:

- its positioning as a drug that is compliant with marketing authorization (MA) regulations;
- its dosage that is higher and in line with the expected efficacy range in the countries that limit daily concentrations as a nutritional supplement (e.g. France, Belgium and other European countries);
- its quality, controlled in accordance with good manufacturing practices (GMP);
- its prolonged effect enabling a single daily dose;
- its flexibility for taking and adapting dosage levels thanks to the microgranule form, compared with capsules or tablets.

Preparation of a pre-IND application in the United States for NFL-301

NFL is preparing a pre-IND application in the United States, which is expected to be submitted in September, with a view to obtaining FDA approval for the manufacturing process, product quality and development strategy through to MA.

This project is being carried out working with Prof. Scott Lukas, Director of the Behavioral Psychopharmacology Research Laboratory and the McLean Hospital Imaging Center at Harvard Medical School in Boston, who is a world-renowned addiction research specialist and has led recent clinical trials covering the effect of the administration of kudzu extracts in terms of reducing alcohol consumption: *“I am delighted with NFL Biosciences’ development of a prolonged-release form of pharmaceutical grade kudzu extract. We had reached the clinical development limits with the traditional forms. This formulation should enable us to continue developing this potentially disruptive treatment, because, to date, it has been very well tolerated, free from side-effects and effective”*.

Bruno Lafont, Chief Operating Officer leading the scientific development of the Company’s projects: *“We would like to sincerely thank Athena Pharmaceutiques for the development of this formulation, which is the result of 18 months of work, as well as Ipsilon and Francis Ahner, a member of our Board of Directors and global intellectual property expert, for the preparation of this patent application. The clear commitment that we set out when we listed on the stock market to develop a second drug candidate in addition to NFL-101 is gradually being confirmed and it is expected that further progress will be established by the end of the year”*.

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.

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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