

NFL BIOSCIENCES: Approval for its patent to be granted on NFL-101 in Europe and approval of the clinical development plan for NFL-101 by the EMA

NFL BIOSCIENCES (Euronext Growth Paris – FR0014003XT0 – ALNFL), a biopharmaceutical company developing botanical drugs for the treatment of addictions, is announcing that it has received approval from the European Patent Office for issuing its patent (17 716 853.1) for NFL-101, a nicotine-free botanical drug candidate comprising natural proteins extracted from tobacco leaves, focused primarily on smoking cessation. This patent will protect the innovation that NFL-101 is based on through to 2036 in 17 European countries. Alongside this, the European Medicines Agency (EMA), following the request for scientific advice submitted by NFL Biosciences, approved the clinical development plan for NFL-101.

Approval for its patent to be granted on NFL-101 in Europe

NFL Biosciences has adopted a knowledge management and protection strategy that led it to submit three patent families granting it exclusive rights to its drug candidate NFL-101. From the second patent family, this product patent, initially registered and approved in France, China, South Korea and the United States, concerns an “aqueous extract of tobacco leaves and its use for the treatment of dependence”. The innovation that NFL-101 is based on is therefore protected through to 2036 in 17 European countries (Austria, Belgium, Bulgaria, Denmark, Estonia, Finland, France, Germany, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Portugal, Slovenia and Sweden). National registration applications based on this second patent family are also in the review phase in the following regions and countries: Japan, Canada, Australia, Brazil, India, Indonesia, Israel, Mexico, Philippines, Eurasia, Saudi Arabia, United Arab Emirates and Nigeria.

EMA approval of the clinical development plan for NFL-101

In February 2023, NFL Biosciences submitted a request for scientific advice to the EMA with a view to approving the clinical development plan for NFL-101 through to its marketing authorization. This scientific advice was issued on June 20, 2023, approving NFL Biosciences’ proposed clinical development plan for NFL-101. This plan includes provisions for the CESTO II study that is underway, depending on its results, to be recognized as a first phase 3 trial for a registration application. If this is approved, there would be just one phase 3 study still to be carried out before obtaining a marketing authorization.

NFL Biosciences is currently conducting two clinical trials. PRECESTO is studying the effect of NFL-101 on the desire to stop or reduce cigarette consumption and the sensations triggered by cigarettes with 34 smokers who do not want to stop smoking. The objective is to validate the complementarity of NFL-101 with nicotine substitute treatments with a view to potentially being used in combination. CESTO II is studying the efficacy of NFL-101 as a cessation aid with 318 smokers who want to stop smoking. The objective is to provide a demonstration of efficacy to be part of a marketing authorization application. In accordance with the business plan, the PRECESTO trial results are expected to be available in the third quarter of 2023, followed by the first results of the CESTO II trial in the fourth quarter of 2023.

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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