

NFL Biosciences further strengthens its operational team with the arrival of a Head of Development and Manufacturing

To anticipate the production of the Phase 3 clinical batches for NFL-101, its drug candidate for smoking cessation, and move forward with the development of NFL-301, its drug candidate for the treatment of excessive alcohol consumption

NFL BIOSCIENCES (Euronext Growth Paris – FR0014003XT0 – ALNFL), a biopharmaceutical company that is developing botanical drugs for the treatment of addictions, is today announcing that a Head of Development and Manufacturing has joined its operational team, in line with its commitment to planning ahead for the requirements of the Phase 3 clinical trial for NFL-101 and its objectives to drive progress with NFL-301.

Lara Babich has more than 10 years' experience in drug candidate development in clinical and pre-commercial phases. She has a masters in industrial biotechnology from the University of Padua in Italy and a PhD in bioorganic chemistry from the University of Amsterdam. She began her career in the Netherlands, with Janssen Infectious Diseases and Vaccines (now Johnson & Johnson Innovative Medicine), as a scientist in charge of pharmaceutical product development, before moving to Noxopharm (Sydney, Australia) in 2018 as Director of Manufacturing (CMC, Chemistry, Manufacturing and Controls).

At NFL Biosciences, she has been recruited to lead the deployment and management of the NFL-101 production line for the Phase 3 batches, equivalent to commercial batches. She will help put in place an organization that will be able to manage the change of scale (transition from producing several thousand doses to millions), from suppliers to CDMOs (Contract Development Manufacturing Organizations) and the Good Manufacturing Practices (GMP) process. She is responsible for defining and ensuring compliance with the quality control criteria throughout the chain. Across her activities, she will be able to count on the support of the Company's network of experts, especially in the analytical and regulatory fields. For NFL-301, her mission will cover the operational management of relations with ATHENA Pharmaceutiques to develop the manufacturing of the drug candidate NFL-301 for producing the Phase 1 batches.

Lara Babich's arrival takes the total headcount up to five people, with gender parity progressing and three different nationalities represented. Her recruitment follows the €3m of funds raised on April 11 to anticipate the Phase 3 requirements for NFL-101, while moving forward with the development of NFL-301.

NFL Biosciences, firmly committed to the fight against addictions with innovative and natural solutions

NFL-101 is a clinically developed, nicotine-free botanical drug candidate from Institut Pasteur, comprising natural proteins extracted from tobacco leaves. It is protected by three international patent families through to 2047. In 2023, NFL-101 achieved promising results with the PRECESTO clinical trial: they established the efficacy of the drug candidate NFL-101 for reducing smoking satisfaction compared with a placebo. A further study on the mechanism of action conducted by the French Alternative Energies and Atomic Energy Commission (CEA) demonstrated the ability of NFL-101 to restore normal activity in the area of the brain associated with smoking craving in a cessation situation, which represents innovative progress for the treatment of tobacco addiction. These good results confirm NFL Biosciences' success with CESTO II, its Phase 2 trial involving 318 smokers that is currently being finalized in nine clinical investigation centers in France. The main CESTO II results are expected for July 2024.

NFL-301 is a natural drug candidate for the reduction of alcohol consumption, which is being developed jointly with ATHENA Pharmaceutiques. At the end of 2023, NFL-Biosciences submitted a pre-IND application to the FDA in the United States. Following a discussion in March 2024, the FDA is expected to issue its report soon. Following this, NFL-Biosciences will put in place the first stages aiming to develop NFL-301 at least to the point of demonstrating its efficacy against placebo. The development plan will be set out in more detail after obtaining the FDA report and could for instance concern: the finalization of the product's development, the pre-clinical studies and/or the Phase 1 clinical trial.



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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