

NFL BIOSCIENCES VALIDATES THE INDUSTRIALIZATION OF NFL-101 FOR SMOKING CESSATION

Establishment of a robust industrial organization to meet the demands of a mass market: NFL-101 goes from a manufacturing capacity of a few thousand doses per year to several million.

Enhanced attractiveness of the project in ongoing discussions with laboratories interested in in-licensing.

Another key step towards securing substantial non-dilutive financing

Potential to generate additional future revenues from the sale of manufactured doses to laboratories

NFL BIOSCIENCES (Euronext Growth Paris – FR0014003XT0 – ALNFL), a biopharmaceutical company developing botanical drugs for the treatment of addictions, validated the key stages in the industrialization of NFL-101, an advanced drug candidate in the field of smoking cessation, paving the way for GMP (Good Manufacturing Practice) batch production scheduled for early 2025. This advance confirms the transition from a manufacturing capacity of a few thousand doses per year to several million, reinforcing NFL-101's attractiveness to pharmaceutical companies interested in licensing the product, as well as to non-dilutive financing organizations.

A robust industrial organization to meet the demands of a mass market

Thanks to subcontracting agreements with international CDMOs, Fareva for the manufacture of the active ingredient and Synerlab Group for the manufacture of doses, NFL Biosciences now has production capacity for Phase 3 and the marketing of NFL-101 for smoking cessation.

As part of these agreements, NFL Biosciences has:

- Transferred its know-how to new production sites,
- Resized and optimized the manufacturing process, relying on two complementary subcontractors capable of absorbing the increase in production volumes,
- Manufactured test and engineering batches with a view to GMP batches by early 2025, and on December 4 received the Certificate of Analysis attesting to the quality control of NFL-101 manufacturing.

This industrial organization makes it possible to anticipate growing demand for Phase 3 clinical trials and future marketing, with a production capacity of up to several million doses per year.

Fareva is one of the world's leading subcontractors in the industrial and pharmaceutical sectors. Fareva employs over 13,000 people at more than 41 sites worldwide.

Synerlab Group is a European leader in pharmaceutical development and manufacturing, employing 1,300 people at 6 sites in France and one in Spain.

NFL Biosciences strengthens its attractiveness in ongoing discussions and creates new licensing opportunities

The validation of this industrial stage comes at a time when NFL Biosciences is in discussions with several pharmaceutical companies as part of its in-licensing strategy. This development demonstrates NFL Biosciences' ability to meet the demands of a mass market, and is viewed very positively by the laboratories.

This industrialization reinforces the opportunities offered by the licensing strategy. By relying on a robust production line, NFL Biosciences could retain responsibility for manufacturing and supply doses directly to

licensed laboratories. This organization also meets the needs of laboratories that do not plan to invest in setting up an industrial infrastructure to produce the drugs they market. This model also enhances the value of agreements by generating additional revenues from the sale of doses produced at a profit margin.

A key step towards securing substantial non-dilutive financing

The validation of the pivotal stages in the industrialization of NFL-101 is a major asset in obtaining substantial non-dilutive financing. These require not only a solid demonstration of the prospects for obtaining marketing authorization, based on the results of the studies carried out to date (Phase I, Phase 2, Mechanism of Action), but also a demonstration of NFL Biosciences' ability to meet the needs of a mass market. By demonstrating that it can produce millions of doses thanks to a robust and reliable industrial organization, NFL Biosciences is strengthening its credibility with non-dilutive funding bodies and maximizing its chances of securing these resources, both nationally and internationally.

Driven by its commitment to innovation, scientific and industrial excellence, and its societal impact on the health and environmental consequences of tobacco use, NFL Biosciences has reached a new milestone in its development strategy for NFL-101. NFL Biosciences continues to validate the clinical development plan with regulatory agencies. At the same time, NFL Biosciences continues to advance its financing strategy, with both pharmaceutical companies and non-dilutive financing organizations, in a position strengthened by the validation of its production capacities.

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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