

NON-CYSTIC FIBROSIS BRONCHIECTASIS (NCFB) FDA GRANTS “FAST-TRACK” AND “QIPD” TO ZAMBON FOR COLISTIMETHATE SODIUM POWDER FOR NEBULIZER SOLUTION DELIVERED BY THE I-NEB AAD SYSTEM.

- *Non-Cystic Fibrosis Bronchiectasis (NCFB) is a, chronic, progressive and irreversible disease, prevalent in Europe and the US.*
- *Fast track is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need.*
- *The Qualified Infectious Diseases Product (QIDP) designation is granted by FDA to provide incentives for the development of antibacterial and antifungal drugs for human use intended to treat serious and life-threatening infections.*

December 11, 2018 Zambon announced that *colistimethate sodium powder for nebulizer solution, delivered by the I-neb AAD system* obtained QIDP and “Fast Track” designation by the FDA for the indication “prevention of pulmonary exacerbations in adult patients with Non-Cystic Fibrosis Bronchiectasis (NCFB) colonized with *Pseudomonas aeruginosa*”.

Zambon’s Open Research and Development (Open R&D) has developed a clinical program evaluating the efficacy and safety of *colistimethate sodium powder for nebulizer solution* delivered by the I-neb AAD system for patients suffering from NCFB, who are colonized with a *Pseudomonas aeruginosa* lung infection. NCFB is a chronic disease that results in repeated serious pulmonary infections, which in turn can cause further inflammation and damage in the respiratory organs. Filing for registration is anticipated in the second half of 2021.

Colistimethate sodium is a polymixin antibiotic, and bactericidal against susceptible Gram-negative bacteria. The drug will be provided for the clinical trials by Xellia Pharmaceuticals ApS., Zambon’s long-standing partner, with which it shares the objective of bringing this formulation to patients with NCFB all over the world.

“With our Phase-III trial on Non-Cystic Fibrosis Bronchiectasis– so stated **Roberto Tascione, Zambon’s CEO** – we are among the very few companies committed to continue to develop a treatment against this disease with the aim of offering new prospects to the patients with the seriously disabling disease NCFB”

“As the world’s leading supplier of colistimethate sodium we are excited to expand our long-time partnership with Zambon to also provide to patients this important drug product for the new indication of Non-Cystic Fibrosis Bronchiectasis (NCFB)”, quoted **Gaël Bernard, President Xellia International**.

“In recent years – **Tascione** went on to say – Zambon has met major goals, which allow us to continue to pursue our mission to innovate cures and therapies aimed at improving the quality of life for patients worldwide. Therefore, we are supporting other ambitious research projects with 200 million euros worth of investments over 3 years. Our target areas are respiratory and neurodegenerative diseases, serious infection and rare diseases.”

Colistimethate sodium is one of the antibiotics against *Pseudomonas aeruginosa* infections, and the I-Neb AAD system is an inhalation system designed to deliver nebulised medications into the lung. Antibiotics given by inhalation deliver high drug concentrations to the airways, minimizing systemic exposure and potential side effects.

Notes for editors

THE PROMIS I AND PROMIS II CLINICAL TRIALS

Open R&D is conducting **two Phase-III pivotal trials** in the indication of prevention of pulmonary exacerbations in adult patients with Non-Cystic Fibrosis Bronchiectasis (NCFB) colonized with *Pseudomonas aeruginosa*.

PROMIS I is being carried out in Europe, Israel, Australia and New Zealand and **PROMIS II** in North and South America and in Europe. By the end of the first half of 2019, it is expected that overall the two studies will enroll 840 patients. CMS for the treatment of *P aeruginosa* infection has received **Qualified Infectious Disease Product™ (QIDP) and Fast Track designations**.

I-NEB

Neb is a medical device manufactured by Philips and in partnership with Zambon is currently used to treat lung infections for patients suffering from Cystic Fibrosis (CF).

NON-CYSTIC FIBROSIS BRONCHIECTASIS (NCFB)

This is a chronic and irreversible disease of the airways causing dilation of the airways, become scarred and inflamed with thick mucus, also called phlegm or sputum. The airways cannot be cleared of this thick mucus meaning it builds up and the airways can become infected by bacteria. The number of bacteria multiply, and proliferate, in particular **bacteria such as *Pseudomonas aeruginosa***, each new infection causes more damage to the respiratory tract, thus further exacerbating the disease itself. The recurrence of bronchopulmonary infections results in progressively reduced respiratory capacity and **deterioration in the patients' quality of life**.

About Zambon

Zambon is a multinational pharmaceutical and fine-chemical company that focuses on innovation and development with the aim to improve the quality of people's health and patients' lives. Based on a valuable heritage but strongly focused on the future, its goal is to improve people's health through the development of innovative and quality medicines. Zambon products are commercialized in 86 countries. The company has 20 subsidiaries in three different Continents – Europe, America and Asia – and owns manufacturing units in Italy, Switzerland, France, China and Brazil. The company today has a strong focus on the treatment of rare diseases and specialties, such as Parkinson's disease and Cystic Fibrosis, and it's well-established in 3 therapeutic areas: respiratory, pain and women's care. Zambon was established in 1906 in Italy and today counts around 2,700 employees all over the world. For details on Zambon please visit www.zambon.com

About Xellia Pharmaceuticals

Xellia Pharmaceuticals ("Xellia") is a specialty pharmaceutical company developing, manufacturing and commercializing anti-infective treatments against serious and often life-threatening bacterial and fungal infections. Headquartered in Copenhagen, Denmark, Xellia has a global footprint with R&D, manufacturing and commercial operations across Europe, Asia and North America and is investing significantly to expand its sales and manufacturing capabilities within the United States. Xellia is wholly owned by Novo Holdings A/S and employs a dedicated team of over 1,500 people. Further information about Xellia can be found at: www.xellia.com.

Press contacts

Zambon Global Pharma Communication

Valentina Saffioti

Valentina.saffioti@zambongroup.com

Tel +39 02 66524508