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Zambon: innovating cure and care to improve lives

Life-threatening respiratory diseases remain a key therapeutic area of focus for multinational company Zambon. The company has two phase 3 development programs underway for the treatment of bronchiolitis obliterans syndrome (BOS) and non-cystic fibrosis bronchiectasis (NCFB).

Rare and severe respiratory diseases have devastating effects for patients and healthcare systems. Zambon, a family-owned Italian chemical and pharmaceutical company, is committed to delivering solutions to enhance the lives of underserved patients with debilitating conditions.

Founded in 1906, Zambon has more than 2,800 employees worldwide and four manufacturing facilities in Brazil, China, Switzerland and Italy. Zambon is a fully integrated company, from early-stage R&D to commercialization, and has a presence in 87 countries. Previously focused mainly on respiratory, women's health and pain therapeutic areas, over the past several years Zambon has been pioneering in drug development to treat severe life-threatening respiratory diseases.

Zambon is currently conducting phase 3 global clinical trials for the treatment of bronchiolitis obliterans syndrome (BOS) and non-cystic fibrosis bronchiectasis (NCFB), both life-threatening conditions with no approved treatments.

Z-LIFE, designed by Michele De Lucchi and Carlo Ratti, is the practical representation of Zambon, a company that faces important global challenges while keeping its family ethos and a unique 'human touch' in taking care of people.

Phase 3 development programs

BOS, also known as 'popcorn lung', is a rare, rapidly progressive inflammatory disease that destroys the lungs, usually leading to respiratory failure and death within 2–4 years of diagnosis. Affecting an estimated 30,000 patients worldwide, BOS commonly affects patients after lung transplant or allogeneic hematopoietic stem cell transplantation (alloHSCT), although it is also associated with autoimmune disease and exposure to environmental contaminants. Zambon broadened its programs with BOS after the acquisition of Breath Therapeutics in 2019.

NCFB is characterized by chronic inflammation, wall thickening and dilatation of the airways, resulting in chronic cough, increased sputum production, breathlessness, fatigue and high susceptibility to frequent lung infections. Chronic *Pseudomonas aeruginosa* lung infection in NCFB patients is associated with accelerated decline in lung function, and increased hospitalization and risk of death. This severe disease is often related to pre-existing chronic obstructive pulmonary disease, asthma and primary ciliary dyskinesia disease, but an estimated 50–80% of cases have no clear cause.

In addition to being devastating for patients, BOS and NCFB impose a significant burden on healthcare systems.

Phase 3 development programs for the treatment of BOS and NCFB are currently underway globally:

- The BOSTON program is evaluating a novel liposomal formulation of the immunosuppressant, cyclosporine, with targeted inhalation via a drug-specific nebulizer system for the treatment of BOS in patients following lung transplantation.
- The PROMIS program, involving more than 800 patients, is evaluating the inhaled antibiotic, colistin, delivered by a hand-held breath-actuated nebulizer to reduce the frequency of pulmonary exacerbations in NCFB patients with *Pseudomonas aeruginosa* infection.
- The BOSTON program has received Orphan Drug Designation from the US Food and Drug Administration (FDA) and European Medicines Agency and the NCFB program has received Qualified Infectious Disease Product designation. Both programs have been granted FDA Fast Track designation.

In both cases, Zambon's approach combines a novel formulation of an existing drug with innovative inhalation delivery technology. The rationale of inhaled therapies is to deliver sufficient concentrations of the drug directly to the lungs while minimizing overall systemic drug exposure.

Broad reach

Meanwhile, Zambon remains committed to identifying, developing and delivering innovative healthcare solutions to help patients with other debilitating conditions, including neurodegenerative diseases. In 2019, for instance, the company finalized a deal with USA-based Aquestive Therapeutics for the distribution in Europe of a new oral film formulation of riluzole for the treatment of amyotrophic lateral sclerosis (ALS). The innovative formulation allows intake of the medication without the need for water and swallowing.

Zambon has also been committed to the treatment of Parkinson disease since 2015, when it introduced Xadago (safinamide), first in Europe and later in North America, South America and Australia. Owing to its dual action, safinamide combines a dopaminergic and non-dopaminergic action, thus acting on the motor and non-motor symptoms in patients with this debilitating disease. More than 60,000 people have been treated with safinamide to date. Geographic expansion is one of Zambon's key objectives, and in 2020 there are plans to launch safinamide in Brazil, Israel and the United Arab Emirates, with many more countries to follow over the next few years.

Partnering with Zambon

Zambon has proven leadership and specialized skills in inhaled drug formulation, manufacturing, pulmonary drug delivery, clinical development and global commercialization. The company collaborates at all stages, particularly in its core therapeutic areas of severe respiratory diseases and the central nervous system. The business development activities remain fundamental and integral to Zambon's commitment to innovating cure and care to improve patients' lives.

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