PRESS RELEASE

Milan - April 28, 2020

A new FDA Fast Track designation for Zambon

The designation is for L-CsA-i for the treatment of bronchiolitis obliterans syndrome, developed by Breath Therapeutics, a Zambon company.

Zambon, a multinational pharmaceutical company that focuses on innovation and development with the aim to improve the quality of people's health and patients' lives, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to Liposomal Cyclosporine A for Inhalation (L-CsA-i), in late-stage clinical development for the treatment of Bronchiolitis Obliterans Syndrome (BOS). L-CsA-i, developed by Breath Therapeutics which was acquired by Zambon in 2019, previously received orphan drug designation from the FDA and European Medicines Agency for the treatment of BOS.

"Zambon is committed to its mission of innovating cure and improving the quality of life for people living with severe respiratory diseases worldwide. The FDA's Fast Track designation for L-CsA-i represents an important recognition of its potential to address the unmet medical need of patients with BOS, a devastating rare disease with currently no approved treatment," said **Roberto Tascione**, **Zambon's CEO**.

The FDA Fast Track program facilitates the development and review of potential new drugs intended to treat serious conditions with unmet medical need, allowing important new drugs, if requisite criteria are met, to become more quickly available to people suffering from serious conditions.

"*We believe Fast Track designation provides an opportunity for frequent interactions with the FDA which may potentially expedite the development and registration of L-CsA-i*," said **Paola Castellani, CMO** at Zambon. "*We will work closely with the FDA to advance the BOSTON clinical program and accelerate our efforts to develop an effective therapy for the treatment of BOS*."

Fast Track Designation may allow a therapy to be eligible for several benefits including enhanced interaction with the FDA and the potential for Accelerated Approval and Priority Review at the time of a New Drug Application (NDA) filing, if relevant criteria are met. Additional information about FDA Fast Track designation is available at https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track.

Bronchiolitis Obliterans Syndrome (BOS)

Bronchiolitis Obliterans Syndrome (BOS), also known as obliterative bronchiolitis (OB), is caused by T-cell mediated inflammation that leads to blockage of bronchioles, the small and medium airways in the lungs, resulting in respiratory failure and death. BOS most commonly affects people who have received lung transplant or allogeneic hematopoietic stem cell transplant (alloHSCT), although it is also associated with autoimmune disease and exposure to environmental contaminants. Based on 2019 company market research, an estimated 30,000 lung transplant and alloHSCT recipients worldwide are affected by BOS.

Liposomal Cyclosporine A for Inhalation (L-CsA-i)
Liposomal Cyclosporine A for Inhalation (L-CsA-i) is a novel liposomal formulation of cyclosporine A developed for inhaled delivery to the lungs. Calcineurin inhibitors (CNIs), like cyclosporine A, are highly potent immunosuppressive drugs and a cornerstone of lung transplant medicine. L-CsA-i is administered via a drug-specific Investigational eFlow® Technology nebulizer system (PARI Pharma GmbH). The investigational drug-device combination is designed to deliver L-CsA-i to the site of disease in the lung.

BOSTON Clinical Development Program
L-CsA-i is being evaluated for the treatment of BOS in patients age six and older. Five clinical trials are currently ongoing or planned. BOSTON-1 and BOSTON-2 are pivotal Phase 3 studies of adults with BOS following lung transplantation. BOSTON-3 is an open-label extension study for eligible study participants who complete BOSTON-1 or BOSTON-2. BOSTON-4 is a safety and exploratory efficacy study and is the first trial of L-CsA-i in adults with BOS following allogeneic hematopoietic stem cell transplant. BOSTON-5 is a planned safety study in pediatric patients with BOS.

About Zambon S.p.A.
Zambon is a multinational pharmaceutical company that focuses on innovation and development with the aim to improve patients' lives. Based on a valuable heritage and strongly focused on the future, its goal is to improve people's health through the development of innovative and quality healthcare solutions.
Zambon products are commercialized in 87 countries. The company has 20 subsidiaries in three different continents – Europe, America and Asia – and owns manufacturing units in Italy, Switzerland, China and Brazil. The company today has a strong focus on the treatment of rare diseases and specialties, on top of respiratory, pain management and women's care. Zambon was established in 1906 in Italy and today counts 2,500 employees all over the world. For further information, please visit www.zambon.com

About Breath Therapeutics, a Zambon company
Founded in 2016, Breath Therapeutics is a biopharmaceutical company specializing in advanced inhaled therapeutics for severe respiratory diseases with high unmet medical need. The company's proprietary drug formulations have been specifically designed for inhaled administration with exclusively licensed, high performance nebulizer technology. L-CsA-i is advancing in clinical trials as the first potential therapy for BOS, a rare and devastating lung disease with no currently approved treatments. In July 2019, Breath Therapeutics was acquired by Zambon S.p.A, a multinational pharmaceutical company that focuses on innovation and development with the aim to improve patients' lives. For more information, please visit www.breath-therapeutics.com.

L-CsA-i and the eFlow® for L-CsA-i are investigational and their safety and efficacy have not been established for the uses described here.

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