PRESS RELEASE

Milan - Italy, 25 July 2019

Zambon completes transformational acquisition of Breath Therapeutics

- *Zambon, a privately held long-established Italian multinational company, extends its presence in severe respiratory diseases through the acquisition of Breath Therapeutics, a biopharmaceutical company developing an innovative inhalation therapy for Bronchiolitis Obliterans Syndrome (BOS), a rare fatal respiratory disease currently in phase III.*
- *Acquisition reinforces Zambon's strategy to grow through further globalization and continued investment in Specialty Care.*
- *Highly synergistic combination of Breath Therapeutics' late-stage respiratory drug together with Zambon's established expertise and commercialization infrastructure.*
- *Zambon's severe respiratory disease business now includes two leading projects in phase III, both with broad geographic outreach, including USA.*
- *Price acquisition is €140 million with a total maximum up to €500 million subject to regulatory and sales milestones.*

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, announces the acquisition of Breath Therapeutics and its subsidiaries for € 140 million (up to total € 500 million subject to regulatory and sales milestones). The combination will improve both companies' ability to better serve patients and healthcare professionals in severe respiratory diseases, as well as accelerate the commercialization of these important new therapies.

Breath Therapeutics (BREATH), based in Munich, Germany and Menlo Park, California, US, is a biopharmaceutical company specializing in advanced and first-in-class inhalation therapies for severe respiratory diseases with high unmet medical need. BREATH's drug candidate is L-CsA-i, a novel proprietary liposomal formulation of Cyclosporine A, designed for inhaled administration with the drug-specific, investigational customized nebulizer from PARI. BREATH initiated two global phase III trials (BOSTON-1 and -2) in the US and Europe to evaluate L-CsA-i for the treatment of Bronchiolitis Obliterans Syndrome (BOS), a severe progressive lung disease with no approved therapies. It is estimated that there are over 30,000 people affected by BOS[1]. L-CsA-i has received orphan drug designation for the treatment of BOS from the US Food and Drug Administration (FDA) and European Medicines Agency (EMA), reflecting the high unmet need in addressing this disease. With financing in 2017 from its strong European investor syndicate, which includes Sofinnova Partners, Gimv and Gilde Healthcare, the BREATH team led L-CsA-i into global phase III trials, established a full commercial scale production for the drug and the device, and initiated commercial activities to prepare for and support future product launch.

BOS is a rapidly progressive disease that usually leads to respiratory failure and death within one to two years after diagnosis[2]. BOS is caused by an inflammatory process triggered by the immune system that irreversibly destroys the airways of the lungs. BOS most commonly affects people who have received lung or stem cell transplantation, although it is also associated with autoimmune disease and exposure to environmental contaminants. This disease is particularly

devastating to those who have undergone complex transplants, as nearly 50 percent of that patient population develops BOS within five years after transplantation[2].

Roberto Tascione, Chief Executive Officer at Zambon, commented:

“I am proud to announce the acquisition of Breath Therapeutics. This important deal, the largest in our history, reinforces Zambon’s commitment to serve severe respiratory diseases, enhancing and broadening our offering to the healthcare system, and complements our late-stage pipeline.

Bronchiolitis Obliterans Syndrome is an incredibly debilitating condition. Through the combination of our geographic footprint, R&D infrastructure and relationships with the scientific communities, we are well positioned to accelerate the development of an important new potential treatment and have the expertise in respiratory and the commercial capabilities to bring the product to patients and doctors as soon as possible.

As we want to identify, develop and offer innovative solutions for the treatment of severe life-altering diseases, this acquisition marks the start of a new phase for Zambon, not only for the great pipeline we’re acquiring but also for the scientific knowledge that the Breath Therapeutics team brings into our company.

I look forward to welcoming and working with our new colleagues, as together we can really maximise the potential of these life-changing products.”

Elena Zambon, President of Zambon, commented:

“It’s a pleasure to welcome in Zambon the Breath Therapeutics team. In a knowledge-based Company, as we are, with a long-term horizon, continuously focused on innovation, the most important asset are our people, their competences and expertise and, above all, their commitment to make patients’ lives better.
This acquisition is aligned to our core values and our vision to innovate cure and care. We are a “113 year old startup Company”, as I often say, with a strong heritage and tradition, aiming to enrich our pipeline with new relevant research projects to invest in the future for our patients and our people.”

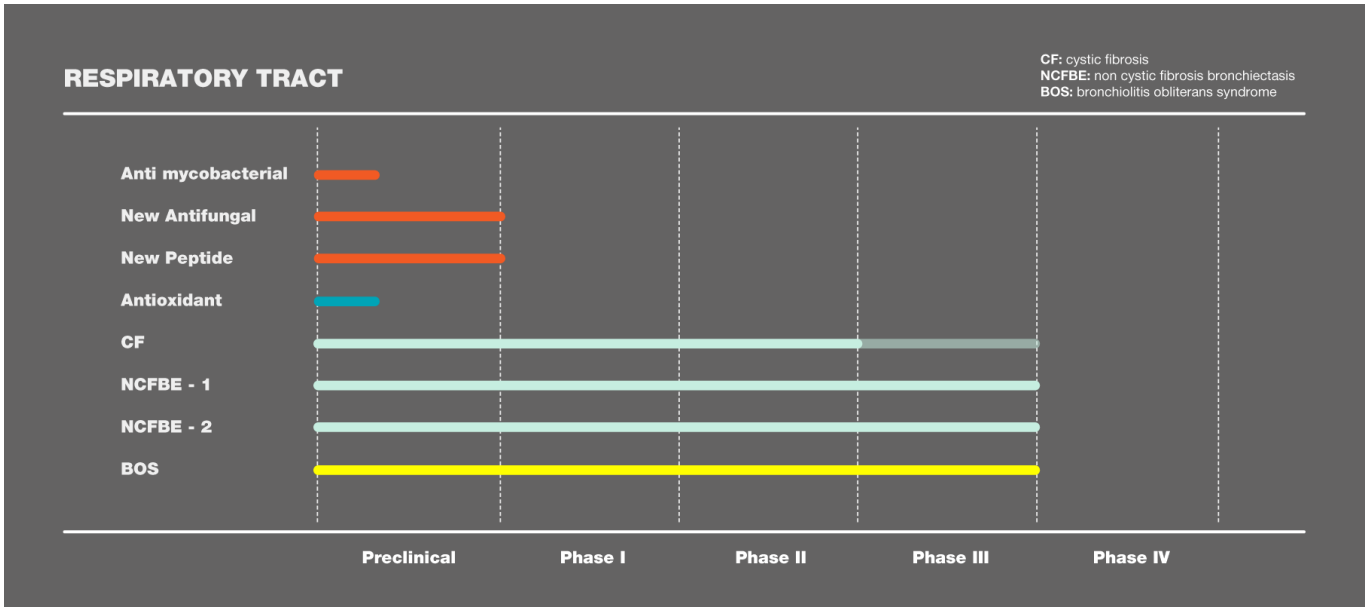
Jens Stegemann, Chief Executive Officer of Breath Therapeutics, commented:

“At Breath Therapeutics, we have established L-CsA-i as a promising therapy for the treatment of BOS, with potential to impact patient lives. In Zambon, an ethical company with a strong heritage of innovation and a genuine commitment to a patient-orientated approach, we have a partner who shares our vision and significantly strengthens our position through their infrastructure, expertise and commitment to R&D. Together with the leading international lung transplantation centers participating in our BOSTON pivotal studies, we are now in an excellent position to achieve advances in the treatment of BOS.”

Zambon expects data from the L-CsA-i phase III clinical trials in 2021 and is confident that the drug will be ready for commercialization by 2023, subject to FDA and EMA regulatory approvals. Zambon’s expertise and resources will complement the Breath Therapeutics’ team as they become part of Zambon. Together, they will work to create an environment in which scientists feel comfortable developing new solutions and are able to drive meaningful change.

The acquisition of BREATH and its phase III asset, L-CsA-i for the treatment of BOS, complements Zambon's existing pipeline in severe respiratory diseases and its presence in USA, which includes the treatment of Non-Cystic Fibrosis Bronchiectasis (NCFBE), extending the company's leadership in two rare respiratory conditions. Zambon recently received qualified infectious disease product (QIDP)[3] and "Fast Track"[4] designation from the FDA for colistimethate sodium powder for nebulizer solution via inhalation, in the prevention of pulmonary exacerbations in adult patients with NCFBE colonized with *Pseudomonas aeruginosa*. These important designations reinforce Zambon's commitment to continue to develop a treatment against this disabling disease, with the aim of offering new options to patients and physicians.

ZAMBON RESPIRATORY TRACT NEW PIPELINE



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[1] Breath Therapeutics market research

[2] The International Thoracic Organ Transplant Registry of the International Society for Heart and Lung Transplantation: Thirty-fifth adult lung and heart-lung transplant report—2018; Focus theme: Multiorgan Transplantation. Chambers DC, et al. J Heart Lung Transplant; Volume 37, Issue 10,1169 – 1183

[3] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/qualified-infectious-disease-product-designation-questions-and-answers

[4] https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track

L-CsA-i and colistimethate sodium powder for nebulizer solution are investigational drugs and their safety and efficacy have not been established for the respective use described here.

Notes to Editors

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 around 2,500 employees all over the world. For further information, please visit www.zambon.com

About Breath Therapeutics
Founded in 2016, Breath Therapeutics is a private, venture-backed clinical stage biopharmaceutical company specializing in advanced inhaled therapeutics for severe respiratory diseases with high unmet medical need. In 2017, the company completed a Series A financing of USD 46 million with leading European investors, Sofinnova Partners, Gimv and Gilde Healthcare. Breath Therapeutics' proprietary drug formulations have been specifically designed for inhaled administration with exclusively licensed, high performance nebulizer technology. L-CsA-i, Breath Therapeutics' lead asset, is advancing as the first therapy for BOS, a rare and devastating lung disease with no currently available treatment. Breath Therapeutics has offices in Munich, Germany and Menlo Park, CA. For more information, please visit www.breath-therapeutics.com.

Liposomal Cyclosporine A for Inhalation (L-CsA-i)
Breath Therapeutics' lead candidate, L-CsA-i, is a novel liposomal formulation of cyclosporine A designed for inhaled delivery to the lungs. Calcineurin inhibitors (CNIs), like cyclosporine A, are highly potent immunosuppressive drugs and a cornerstone of lung transplant medicine. Due to a narrow therapeutic window, mainly caused by nephrotoxicity, the systemic administration of CNIs cannot achieve sufficient drug levels in the bronchiolar tissue needed to treat BOS. L-CsA-i is administered via a customized drug-specific investigational eFlow® nebulizer from PARI Pharma (Germany). The drug-device combination is designed to deliver L-CsA-i to the site of disease in the lung while minimizing systemic exposure.

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

Leopoldo Zambeletti acted as exclusive financial advisor to Breath Therapeutics.

For more information, please contact:

Zambon Global Pharma Communications
Valentina Saffioti
valentina.saffioti@zambongroup.com
Tel. +39 02 6652 4508

FTI Consulting (media relations)
Brett Pollard/Victoria Foster Mitchell/Sam Purewal
Tel. +44 20 3727 1000