PRESS RELEASE

Zambon Announces Attendance at American Thoracic Society (ATS) 2022 Annual Meeting

MILAN, Italy and **Boston, MA, May 12, 2022** — Zambon, a multinational pharmaceutical company focused on innovating cure and care to improve people's health and the quality of patients' lives, today announced the Company will attend the American Thoracic Society (ATS) 2022 Annual Meeting being held May 13 - 18, 2022 in San Francisco, CA. Zambon representatives will be at booth #10 in the ATS 2022 Clinical Trials Awareness Area to discuss advancements in the company's two Phase 3 development programs for the treatment of non-cystic fibrosis bronchiectasis (NCFB) and bronchiolitis obliterans syndrome (BOS), two severe respiratory diseases with high unmet medical needs.

The meeting comes as Zambon advances its Phase 3 PROMIS clinical program consisting of the PROMIS-I and PROMIS-II trials, both designed to evaluate the safety and efficacy of colistimethate sodium powder for nebulization solution (CMS I-neb®) in patients with NCFB who are chronically infected with *P. aeruginosa*. PROMIS-I evaluated 377 patients in Europe, Israel, Australia and New Zealand, and PROMIS-II is closed and evaluated 287 patients in 12 countries including Argentina, Australia, Canada, Germany, Greece, Israel, Italy, New Zealand, Poland, Portugal, France, and the United States.

A presentation highlighting the efficacy and safety of *colistimethate sodium* via CMS I-neb® in patients with NCFB and *P. aeruginosa* was selected by the ATS International Conference Committee and will be presented at the Clinical Trials Symposium by **Dr. Charles Haworth, Respiratory Physician at the Cambridge Centre for Lung Infection at Royal Papworth Hospital** and PROMIS Chief Investigator on May 16, 2022.

The company reported positive results from the PROMIS-I study at the 2021 European Respiratory Society Congress which showed that twice-daily treatment with CMS I-neb® significantly reduced the annual rate of exacerbations in patients with NCFB and *P. aeruginosa* chronic infection, the primary endpoint of the trial. In addition, the trial met important secondary endpoints, including reduction of severe exacerbations and prolongation of time to first exacerbation, and improvement in Quality of Life (QoL). The treatment was demonstrated to be well tolerated with adverse events similar between groups.

"We are excited for the opportunity to develop and bring innovative treatments like CMS I-neb® to patients who face tremendous unmet medical needs. Currently, there is no approved therapy for people with NCFB and *P. aeruginosa* chronic infection," said **Paola Castellani, CMO and Head of R&D at Zambon.** "The Phase 3 PROMIS-I and PROMIS-II trials will provide important evidence to help further characterize the potential clinical and quality of life benefits of CMS I-neb® as a treatment option for patients with this devastating disease if approved. With the PROMIS-II trial now complete, we look forward to reporting results from this important clinical program very soon."

CMS I-neb® has received U.S. Food and Drug Administration Qualified Infectious Disease Product, Fast Track, and Breakthrough Therapy designations for the reduction in the incidence of pulmonary exacerbations in adult patients with NCFB colonized with *P. aeruginosa*.

Details about the ATS 2022 Clinical Trials Symposium presentation are as follows:

Title: Efficacy and Safety of Colistimethate Sodium Delivered Via the I-Neb in Patients with Bronchiectasis and *Pseudomonas aeruginosa*
Presentation Time: May 16, 2022, 9:30 AM – 11:00 AM PDT
Presenter: Charles Haworth, M.D., Royal Papworth Hospital NHS Foundation Trust, Cambridge, United Kingdom
Location: Room 209-211 (South Building, Level 2), Moscone Center
Session B12: Breaking News: Clinical Trial Results in Pulmonary Medicine

To learn more about the Company's late-stage development programs for the treatment of rare and severe respiratory diseases, please visit **booth #10** in the ATS 2022 Clinical Trials Awareness Area in the South Lobby of the Moscone Center.

About the PROMIS Development Program
The PROMIS-I and PROMIS-II are multicenter, randomized, double-blind, placebo-controlled trials investigating the efficacy and safety of inhaled *colistimethate sodium* administered via the I-neb® Adaptive Aerosol Delivery System (CMS I-neb®) in adults with non-cystic fibrosis bronchiectasis chronically infected with *P. aeruginosa.* The primary objective of both trials was to investigate the annual rate of pulmonary exacerbations in patients receiving CMS I-neb® administered twice daily versus placebo.

Secondary endpoints included the time to first pulmonary exacerbation, annual rate of severe pulmonary exacerbations, time to first severe pulmonary exacerbation, quality of life measured by the St. George's Respiratory Questionnaire and the Quality of Life Questionnaire-Bronchiectasis (QOL-B), number of exacerbation-free days, *P. aeruginosa* density and susceptibility, any developing resistance, and overall safety and tolerability.

The PROMIS-I trial enrolled 377 patients in 12 countries including Australia, Belgium, Germany, Greece, Israel, Italy, Netherlands, New Zealand, Portugal, Spain, Switzerland, and United Kingdom. The PROMIS-II trial is closed and was conducted in 12 countries including Argentina, Australia, Canada, Germany, Greece, Israel, Italy, New Zealand, Poland, Portugal, France, and the United States.

About NCFB
Non-cystic fibrosis bronchiectasis (NCFB) is a chronic lung disease characterized by recurrent airway infection and inflammation, persistent cough, and sputum production. Its prevalence is increasing worldwide. NCFB has a progressive course that is primarily determined by the rate of pulmonary exacerbations, many of which are related to infection with *P. aeruginosa*. Consequently, research efforts directed to treat infection by *P. aeruginosa* and its associated acute exacerbations remain a clinical priority.

The objectives of treatment in bronchiectasis are to prevent exacerbations, reduce symptoms, improve quality of life, and stop disease progression. Cough and sputum

production, along with breathlessness are the most frequent symptoms but rhinosinusitis, fatigue, hemoptysis, and thoracic pain are also common.

About Colistimethate sodium (CMS)
Colistimethate sodium (CMS) is a pro-drug (the form used for inhalation therapy) of the antibiotic colistin. Colistin is a polymyxin antibiotic derived from *Bacillus polymyxa var. colistinus*. The polymyxin antibiotics are surface active agents and act by binding to and changing the permeability of the bacterial cell membrane, causing bacterial cell death.
Colistin is an active agent against aerobic Gram-negative pathogens that can cause life-threatening infections, an example being *P. aeruginosa*. Colistin remains one of the few active antimicrobial agents against multi drug resistant Gram-negative bacteria and is currently considered one of the last therapeutic options for infections such as carbapenem-resistant *P. aeruginosa*.

About I-neb®
The I-neb® is a third-generation nebulizer for Adaptive Aerosol Delivery (AAD). The I-neb® is a small, battery powered, lightweight and silent drug delivery device, delivering a precise and reproducible dose of the drug.

The AAD technology ensures optimal drug delivery by only delivering medication when the patient inhales, (not continuously as in other nebulizers). This gives the medication the best opportunity to reach deep into the lungs and greatly reduces waste to the environment. AAD delivers the right amount of medication, regardless of breath size or breathing pattern.

I-neb® generates a fine-particle low-velocity aerosol, by forcing the liquid medication through a fine mesh. Faster than conventional jet or ultrasonic nebulizers, I-neb® support shorter treatment times (usually 3 to 4 minutes) and precise drug delivery.

About Zambon S.p.A.
Zambon S.p.A. is a global pharmaceutical company established in 1906 in Vicenza, Italy, and built on the values of an Italian family committed to innovating cure and care to improve patients' lives. With innovative quality products commercialized in 87 countries, Zambon has a global presence with 2,400 employees across Europe, America, and Asia, including production facilities in Italy, Switzerland, China, and Brazil. Alongside its three historical therapeutic areas of focus, which are diseases of the respiratory system, urinary tract infections, and pain management, Zambon is also focused on developing treatments for Parkinson's Disease and Cystic Fibrosis. Additionally, Zambon is currently advancing its clinical development programs of potentially first-in-class treatments for Non-Cystic Fibrosis Bronchiectasis (NCFB) and Bronchiolitis Obliterans Syndrome (BOS). If approved by regulatory authorities, the Company intends to launch the NCFB and BOS treatments globally, including in the U.S., which is the latest market entry for Zambon as an organization. In Europe, Zambon also plans to market and distribute, upon regulatory approval, an innovative oral formulation of riluzole for patients suffering with Amyotrophic Lateral Sclerosis (ALS). For further information, please visit www.zambon.com.

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