

Beyond Air[®] Receives Grant for Up to \$2.17 million from the Cystic Fibrosis Foundation to Advance the Clinical Development of Inhaled Nitric Oxide to Treat Nontuberculous Mycobacteria Pulmonary Disease

Award will help fund the development of high concentration nitric oxide (NO) for Nontuberculous Mycobacteria (NTM) pulmonary disease, which disproportionately affects cystic fibrosis (CF) patients

Beyond Air recently initiated a pilot study using LungFit[™] GO for at-home self-administration of up to 250 ppm NO to treat refractory NTM pulmonary disease in adult patients

GARDEN CITY, N.Y., Feb. 16, 2021 (GLOBE NEWSWIRE) -- Beyond Air, Inc. (NASDAQ: XAIR), a clinical-stage medical device and biopharmaceutical company focused on developing inhaled nitric oxide (NO) for the treatment of patients with respiratory conditions, including serious lung infections and pulmonary hypertension, and gaseous NO (gNO) for the treatment of solid tumors, today announced a funding agreement with the Cystic Fibrosis Foundation to advance the clinical development of high concentration NO for the treatment of NTM pulmonary disease.

Under the terms of the agreement, Beyond Air will receive up to \$2.17 million to help fund the Company's ongoing LungFit[™] GO NTM pilot study. The study is an at-home, 12-week, single arm, multi-center pilot trial in Australia, which is expected to enroll approximately 20 CF or non-CF bronchiectasis patients with refractory *Mycobacterium avium* complex (MAC) or *Mycobacterium abscessus* complex (MABSC) lung infections. Beyond Air expects to report interim data around the middle of calendar year 2021, which will be followed by topline data approximately six months later.

"We are grateful to receive funding support from the Cystic Fibrosis Foundation toward a shared goal of improving the lives of people living with cystic fibrosis. To date, our NTM program has produced data from four compassionate use patients and nine patients from a previous pilot study – all suffering from refractory MABSC infection with underlying CF. If our ongoing at-home pilot trial is successful, we believe that LungFit[™] GO has the potential to improve the lives of patients suffering with NTM lung infection by bringing high concentration nitric oxide to the home," said Steve Lisi, Chairman and Chief Executive Officer of Beyond Air.

"Understanding the true potential of nitric oxide in this patient population is our responsibility as physicians and researchers given the known benefits of NO. I am excited to be a part of

this groundbreaking study with a nitric oxide generator in the home setting,” added Andrew Colin, M.D., Batchelor Family Professor of Cystic Fibrosis and Pediatric Pulmonology Director, Division of Pediatric Pulmonology Miller School of Medicine University of Miami and principal investigator for this award.

Additionally, Beyond Air is collaborating with Charles Daley, MD, Chief of the Division of Mycobacterial and Respiratory Infections and Tasha Fingerlin, PhD, Professor and Vice Chair in the Department of Immunology and Genomic Medicine at National Jewish Health in Denver, CO on testing of patient sputum samples. “Chronic NTM lung infections are devastating to patient health and quality of life. I am happy to partner with Beyond Air on this important work, and I thank the Cystic Fibrosis Foundation for their support. We look forward to evaluating the effects of inhaled nitric oxide treatment on NTM bacteria in this patient population,” said Dr. Daley.

About the LungFit™ GO Pilot NTM Trial

The trial is a 12-week, single arm, multi-center pilot trial in Australia enrolling approximately 20 CF or non-CF bronchiectasis patients with refractory *Mycobacterium avium* complex (MAC) or *Mycobacterium abscessus* complex (MABSC) lung infections. After an initial run-in period that provides a baseline for efficacy endpoints, patients are titrated from 150 parts per million (ppm) up to a maximum of 250 ppm NO over several days in the hospital. During this phase, patients will receive NO for 40 minutes, four times per day. Patients will be trained to use LungFit™ GO in the hospital and subsequently discharged to complete the remaining portion of the initial two-week treatment phase at their home at the highest tolerated NO concentration. For the second treatment phase, a 10-week maintenance period, patients will self-administer the 40-minute treatments twice daily at home. The study will evaluate parameters including safety, quality of life, physical function, and bacterial load, as compared to baseline measurements. In addition, NO treatment-mediated changes in the antibiotic susceptibility and gene expression of NTM bacteria in patient sputum will be characterized.

About Beyond Air, Inc.

Beyond Air, Inc. is a clinical-stage medical device and biopharmaceutical company developing a revolutionary NO Generator and Delivery System, LungFit™, that uses NO generated from ambient air to deliver precise amounts of NO to the lungs for the potential treatment of a variety of pulmonary diseases. The LungFit™ can generate up to 400 ppm of NO, for delivery either continuously or for a fixed amount of time and has the ability to either titrate dose on demand or maintain a constant dose. The Company is currently applying its therapeutic expertise to develop treatments for pulmonary hypertension in various settings, in addition to treatments for respiratory tract infections that are not effectively addressed with current standards of care. Beyond Air is currently advancing its revolutionary LungFit™ for clinical trials for the treatment of severe lung infections such as SARS-CoV-2 and nontuberculous mycobacteria (NTM). Additionally, Beyond Air is using ultra-high concentrations of NO with a proprietary delivery system to target certain solid tumors in the pre-clinical setting. For more information, visit www.beyondair.net.

About LungFit™ GO

LungFit™ GO* is a portable device that weighs approximately 20 lbs and operates with a standard electrical outlet (120-240 volts). Since NO is generated from ambient air that flows through a reaction chamber, there is an unlimited supply. Beyond Air’s proprietary nitrogen

dioxide (NO₂) filters are required for the system to generate and safely deliver NO. Toxic levels of NO₂ can result from high concentrations of NO without proper filtration. The filter also programs the system, via an attached RFID chip, with respect to NO concentration, flow rate and duration of therapy while alarms monitor system performance. The Company believes this simple design provides maximum flexibility for NO administration, allowing for at-home use by patients. Filters are single administration use and there are no special requirements for disposal.

* Beyond Air's LungFit™ GO is not approved for commercial use. Beyond Air's LungFit™ GO is for investigational use only.

About Nitric Oxide (NO)

Nitric Oxide (NO) is a powerful molecule, naturally synthesized in the human body, proven to play a critical role in a broad array of biological functions. In the airways, NO targets the vascular smooth muscle cells that surround the small resistance arteries in the lungs. Currently, exogenous inhaled NO is used in adult respiratory distress syndrome, post certain cardiac surgeries and persistent pulmonary hypertension of the newborn to treat hypoxemia. Additionally, NO is believed to play a key role in the innate immune system and *in vitro* studies suggest that NO possesses anti-microbial activity not only against common gram-positive and gram-negative bacteria, but also against other diverse pathogens, including mycobacteria, viruses, fungi, yeast and parasites, and has the potential to eliminate multi-drug resistant strains.

About NTM

Nontuberculous mycobacteria (NTM) is a rare and serious bacterial infection in the lungs causing debilitating pulmonary disease associated with increased morbidity and mortality. NTM infection is acquired by breathing in aerosolized bacteria from the environment, and can lead to NTM lung disease, a progressive and chronic condition. Individuals with pre-existing lung disease, such as cystic fibrosis (CF), are at a higher risk for NTM. In fact, approximately 13% of CF patients test positive for NTM¹. NTM is an emerging public health concern worldwide because of its multi-drug antibiotic resistance. Current treatment guidelines suggest a combination of multiple antibiotics delivered continually for as long as two years. These complex, expensive and invasive regimens have a poor record in the treatment of *Mycobacterium abscessus* complex (MABSC) and refractory *Mycobacterium avium* complex (MAC) and have the potential for causing severe adverse events. Beyond Air's system is designed to effectively deliver 150 - 400 ppm NO to the lung, and early data indicate that this range of NO concentration may have a positive effect on patients infected with NTM.

Forward Looking Statements

This press release contains "forward-looking statements" concerning inhaled nitric-oxide and the Company's LungFit™ product, including statements with regard to potential regulatory developments, the potential impact on patients and anticipated benefits associated with its use. Forward-looking statements include statements about our expectations, beliefs, or intentions regarding our product offerings, business, financial condition, results of operations, strategies or prospects. You can identify such forward-looking statements by the words "anticipates," "expects," "intends," "impacts," "plans," "projects," "believes," "estimates," "likely," "goal," "assumes," "targets" and similar expressions and/or the use of future tense or conditional constructions (such as "will," "may," "could," "should" and the like)

and by the fact that these statements do not relate strictly to historical or current matters. Rather, forward-looking statements relate to anticipated or expected events, activities, trends or results as of the date they are made. Because forward-looking statements relate to matters that have not yet occurred, these statements are inherently subject to risks and uncertainties that could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements. These forward-looking statements are only predictions and reflect our views as of the date they are made with respect to future events and financial performance. Many factors could cause our actual activities or results to differ materially from the activities and results anticipated in forward-looking statements, including risks related to: our approach to discover and develop novel drugs, which is unproven and may never lead to efficacious or marketable products; our ability to fund and the results of further pre-clinical and clinical trials; obtaining, maintaining and protecting intellectual property utilized by our products; our ability to enforce our patents against infringers and to defend our patent portfolio against challenges from third parties; our ability to obtain additional funding to support our business activities; our dependence on third parties for development, manufacture, marketing, sales, and distribution of products; the successful development of our product candidates, all of which are in early stages of development; obtaining regulatory approval for products; competition from others using technology similar to ours and others developing products for similar uses; our dependence on collaborators; our short operating history and other risks identified and described in more detail in the “Risk Factors” section of the Company’s most recent Annual Report on Form 10-K and other filings with the SEC, all of which are available on our website. We undertake no obligation to update, and we do not have a policy of updating or revising, these forward-looking statements, except as required by applicable law.

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¹ Olivier KN et al; Nontuberculous Mycobacteria in Cystic Fibrosis Study Group. Nontuberculous mycobacteria. II: nested-cohort study of impact on cystic fibrosis lung disease. Am J Respir Crit Care Med. 2003 Mar 15;167(6):835-40. doi: 10.1164/rccm.200207-679OC. Epub 2002 Nov 14. PMID: 12433669.

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