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Beyond Air® Initiates Patient Screening for LungFit™ GO Pilot Study for At-Home, Self-Administration of Inhaled Nitric Oxide in Nontuberculous Mycobacteria Lung Disease

Expect to dose first patient in January 2021 and report interim data mid-2021

Success in nontuberculous mycobacteria (NTM) at-home study paves the way to enter the much broader market treating severe lung infections in the home

GARDEN CITY, N.Y., Dec. 07, 2020 (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 for the treatment of solid tumors and tumor metastases, today announced that it initiated screening patients for its at-home pilot trial with LungFit™ GO for the treatment of NTM lung disease.

The 12-week, multi-center, open-label clinical trial is taking place in Australia and will enroll approximately 20 adult patients with chronic refractory NTM lung disease. The trial will enroll both cystic fibrosis (CF) and non-CF patients infected with *Mycobacterium avium* complex (MAC) or *Mycobacterium abscessus* complex (MABSC). The Company expects to dose the first patient in January 2021, report interim data mid-2021, and release the full data set approximately six months later.

The trial consists of a run-in period followed by two treatment phases. The run-in period will provide a baseline for the efficacy endpoints, such as patient physical function and bacterial load. The first treatment phase will take place over a two week period and begin in the hospital setting where patients will be titrated from 150 parts per million (ppm) NO up to 250 ppm NO over several days. During this phase patients will receive NO for 40 minutes, four times per day while methemoglobin and nitrogen dioxide (NO_2) levels are monitored. Patients will be trained to use LungFit™ GO then subsequently discharged to complete the remaining portion of the two week treatment period at their home at the highest tolerated NO concentration. For the second treatment phase, a 10-week maintenance phase, the administrations will be twice daily. The study will evaluate safety, quality of life, physical function, and bacterial load among other parameters, as compared to baseline measurements.

“The Beyond Air team continues to execute with the initiation of this trial, which brings us one step closer to being able to offer an at-home treatment option for difficult-to-treat patients who continue to experience a high level of unmet medical need despite recent

progress in the field of NTM," said Steve Lisi, Chairman and Chief Executive Officer of Beyond Air. "Our goal for this pilot study is to obtain a clean safety profile at the higher NO concentration while demonstrating the benefit for NTM patients self-administering NO with LungFit™ GO in a home setting. With success in this trial we will be able to show that NO therapy can be delivered in the home and potentially target other severe lung infections, given NO's broad antimicrobial properties. There are an estimated 1.1 million[1] annual hospitalizations due to acute exacerbations in chronic obstructive pulmonary disease (COPD) patients in the U.S. alone, with a three month mortality rate ranging from 16% to 19%[2] following hospitalization."

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[1] Jinjuvadia C et al. Trends in Outcomes, Financial Burden, and Mortality for Acute Exacerbation of Chronic Obstructive Pulmonary Disease (COPD) in the United States from 2002 to 2010. COPD. 2017 Feb;14(1):72-79. doi: 10.1080/15412555.2016.1199669.

[2] Raherison C, Girodet PO. Epidemiology of COPD. Eur Respir Rev. 2009 Dec;18(114):213-21. doi:10.1183/09059180.00003609. PMID: 20956146.

LungFit™ * is a portable device that weighs only 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 (NO_2) filters are required for the system to generate and safely deliver NO. Toxic levels of NO_2 can result from high concentrations of NO without proper filtration. The filters also program the system, via an attached RFID chip, with respect to NO concentration, flow rate and duration of therapy. The Company believes this design provides maximum flexibility for NO administration. Filters are single patient use and there are no special requirements for disposal. Alarms monitor system performance.

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

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 of ventilated and non-ventilated patients for the potential treatment of a variety of pulmonary diseases. 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 innovative LungFit™ in clinical trials for the treatment of severe lung infections such as SARS-CoV-2 and nontuberculous mycobacteria (NTM). Additionally, Beyond Air is performing preclinical testing of the use of ultra-high concentrations of NO with a proprietary delivery system, separate from LungFit™, to target certain solid tumors. For more information, visit www.beyondair.net.

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 antimicrobial 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) infection is a rare and serious bacterial infection in the lungs causing debilitating pulmonary disease associated with high morbidity and mortality. NTM infection is acquired by inhaling aerosolized bacteria from the environment, and if ignored can lead to NTM lung disease, a progressive and chronic condition. According to the Cystic Fibrosis Foundation, 13% of U.S. cystic fibrosis patients had a positive culture for a NTM species in 2017. NTM is an emerging public health concern worldwide because of its multi-drug antibiotic resistance. Current treatment guidelines suggest a combination of multiple antibiotics dosed chronically 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 to cause 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 concentrations could 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.

CONTACTS:

Steven Lisi, Chief Executive Officer
Beyond Air, Inc.
slisi@beyondair.net

Maria Yonkoski, Head of Investor Relations
Beyond Air, Inc.
myonkoski@beyondair.net

Corey Davis, Ph.D.
LifeSci Advisors, LLC
cdavis@lifesciadvisors.com
(212) 915-2577

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