October 20, 2021

Beyond Air® Reports Positive Interim Results for LungFit® GO Pilot Study Using High Concentration Inhaled Nitric Oxide Self-Administered, At-Home for Nontuberculous Mycobacterial Lung Disease

Interim results show that 250 parts per million (ppm) nitric oxide (NO) was well-tolerated with no study discontinuations or treatment-related serious adverse events observed

At the time of data cutoff, 8 subjects were successfully titrated up to 250 ppm NO with none having titrated down while in the study

LungFit® GO is the first NO generator and delivery system safely used in a clinical trial in the home setting with patients self-administering high concentration NO treatment

GARDEN CITY, N.Y., Oct. 20, 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 positive interim data from the ongoing LungFit® GO pilot study in Australia. In this study, patients self-administered high concentration inhaled NO at home to treat severe nontuberculous mycobacterial (NTM) lung disease. The Company expects complete safety and efficacy results to be reported in 2022.

At the time of the data cutoff on September 6, 2021, a total of 8 subjects were enrolled in the pilot study. The mean age of subjects was 56.6 years (range: 22–73 years) with the majority female (87.5%), a distribution consistent with real-world NTM disease, and occurring at a higher rate in older adult women than men[1]. At baseline some subjects were diagnosed with more than one strain of NTM.

Interim data showed that high concentration inhaled NO was well tolerated with no study discontinuations and no treatment-related serious adverse events. All 8 subjects were successfully titrated to 250 ppm NO in the hospital setting, and none have required dose reductions during the subsequent at-home portion of the study. Methemoglobin and NO_2 concentrations remained within acceptable ranges in all subjects during NO treatment, and below the safety thresholds of 10% and 5 ppm, respectively. The study continues to enroll patients, and the totality of the data will be used to evaluate efficacy measures including quality of life, physical function, and sputum bacteria as compared to baseline measurements.

"We believe these data show that safe self-administration of nitric oxide at concentrations up to 250 ppm in the home setting is now a reality. This therapeutic advance was made possible by the Beyond Air engineering team's ability and dedication to produce the LungFit® system. We believe that LungFit® GO will ultimately offer freedom to NTM patients, and others suffering from chronic refractory severe lung infections, by allowing them to self-administer treatment in the comfort of their own homes or anywhere they choose with a standard electric outlet available," said Steve Lisi, Chairman and Chief Executive Officer of Beyond Air. "The Beyond Air team continues to work with our Australian colleagues, who have been outstanding in a difficult COVID-19 lockdown environment, to complete this study. We are encouraged by these interim data and look forward to reporting the complete efficacy and safety results, which are expected to be announced in 2022."

"I am very pleased with the safety profile of 250 ppm NO to date, as this is the highest concentration of inhaled NO that has ever been tested in a clinical trial with patient self-administration in the home. The bactericidal effects of high concentration NO on the *Mycobacterium abscessus* strain of NTM have been well documented in preclinical *in vitro* studies, along with its broad-spectrum activity against multiple bacterial and fungal pathogens at 200 ppm NO," commented 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. "Refractory NTM lung infection is notoriously difficult to treat, and patients often suffer side effects and require complex dosing schedules to complete the 6-to-18-month combination antibiotic regimens that are the current standard of care. Given these new interim safety and tolerability data, with methemoglobin and nitrogen dioxide levels remaining at acceptable levels, the future for the LungFit® GO device is promising. I look forward to the final analyses of the full data set and hope to see results to support a move to a larger, definitive study in NTM patients. If successful, such a study could prove transformative for the lives of NTM patients."

---

[1] Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration (FDA). The Voice of the Patient. Non-Tuberculous Mycobacterial (NTM) Lung Infection. Public Meeting: October 15, 2015. Report Date: April, 2016. accessed 10/4/2021 at http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM496941.p

LungFit® GO NTM Trial Design

The 12-week, multi-center, open-label clinical trial is taking place in Australia and will enroll approximately 20 adult subjects with chronic refractory NTM lung disease. The trial is enrolling both cystic fibrosis (CF) and non-CF subjects chronically infected with *Mycobacterium avium* complex (MAC), *Mycobacterium abscessus* complex (MABSC) or other strains of NTM. The trial consists of a run-in period followed by two treatment phases. The run-in period provides a baseline for the efficacy endpoints, such as patient physical function and bacterial load. The first treatment phase takes place over a two-week period and begins in the hospital setting where subjects are titrated from 150 ppm NO up to 250 ppm NO over several days. During this first treatment phase subjects receive NO for 40 minutes, four times per day while methemoglobin and nitrogen dioxide (NO_2) levels are monitored. Subjects are trained to use LungFit® GO and subsequently discharged to complete the remaining portion of this two-week treatment period at their home administering the highest tolerated NO concentration. For the second treatment phase, a 10-week maintenance phase, the inhalation treatments are administered twice daily. The study

evaluates safety, quality of life, physical function, and bacterial load among other parameters, as compared to baseline measurements.

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 acute viral pneumonia (including COVID-19) 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 the LungFit®*
Beyond Air's 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 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 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 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:

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

Source: Beyond Air™