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Beyond Air Publishes New Data on Nitric Oxide to Treat M. Abscessus in the Peer-Reviewed Journal Access Microbiology

Heterogeneity in M. abscessus susceptibility to NO

Longer treatment regimens could be required to see reduction or eradication of more resistant pulmonary strains

GARDEN CITY, N.Y., Aug. 10, 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, today announced that the results from a compassionate use patient case study using NO to treat pulmonary *Mycobacterium abscessus* disease *(M. abscessus disease)* at the National Heart, Lung, and Blood Institute (NHLBI), part of the National Institutes of Health, was published in a scientific article, "*Antibacterial Activity of High-dose Nitric Oxide against Pulmonary Mycobacterium abscessus Disease*" in the August 2020 edition of Access Microbiology, a peer-reviewed journal published by the Microbiology Society, https://www.microbiologyresearch.org/content/journal/acmi/fasttrack.

The study evaluated the effect of inhaled NO therapy delivered via the LungFit™ System, with inhaled NO doses titrated up to 240ppm, as compassionate treatment in a 24-year-old, female cystic fibrosis (CF) patient with chronic and progressive pulmonary *M. abscessus* disease. The patient had an eight-year history of *M. abscessus* refractory to treatment with multiple drug combinations. The patient had progressive deterioration in lung function, functional status, and quality of life, and was denied lung transplantation consideration at multiple centers in the US and Canada due to chronic *M. abscessus* lung infection. In addition to treatment of the patient, the study examined the response of the patient's bacterial isolate to high-dose NO relative to other clinical *M. abscessus* isolates by performing *in vitro* susceptibility tests using an NO exposure chamber.

The patient completed the first three-week treatment course with no significant adverse effects noted. The course of treatment included 160 parts per million (ppm) inhaled NO for 30 minutes every three to four hours daily, five times a day, for 14 days, followed by three times per day for days 15-21. In general, the patient noted improved respiratory symptoms and quality of life and had small improvements in her lung function, six-minute walk distance, and inflammatory markers but no significant change in tests and cultures for *M. abscessus*.

Given the overall tolerability of the first treatment, the patient requested to repeat the treatment. A retreatment protocol was designed with an initial dose titration up to 240ppm over two days and similar dosing schedule to the initial treatment. However, dosing at 240ppm was stopped after day eight of the retreatment due to adverse symptoms, which did

not occur during administration of NO, and methemoglobin levels remained within safe thresholds at all times.

In vitro susceptibility tests showed a dose-dependent NO effect on *M. abscessus* susceptibility and significant heterogeneity in response among *M. abscessus* clinical isolates. The patient's isolate was found to be the least susceptible strain *in vitro*.

"This study reports the NHLBI's compassionate use of inhaled NO using the LungFit system to treat a CF patient with chronic and progressive pulmonary *M. abscessus* disease. Over the course of the follow-up period after the first course of treatment that included 160 ppm inhaled NO, the patient was able to lead a more active life. While this patient's second course of treatment at 240 ppm NO was stopped on day 8, we believe the reason for the stoppage was not related to NO. The heterogeneity in *M. abscessus* susceptibility to NO suggests that longer treatment regimens could be required to see reduction or eradication of more resistant pulmonary strains. These data are in line with our other preclinical and clinical studies," said Steve Lisi, Chairman and Chief Executive Officer of Beyond Air.

"These results demonstrate the potential clinical benefits of NO in the treatment of this patient population and we look forward to initiating a 12 week study later this year, in which patients will self-administer NO with LungFit at home," concluded Mr. Lisi.

"The potential of inhaled nitric oxide to treat the critical unmet medical need of nontuberculous mycobacterial (NTM) lung infections in patients with cystic fibrosis is encouraging," said study co-author Kenneth Olivier, MD, MPH, Chief of the NHLBI's Laboratory of Chronic Airway Infection and Pulmonary Branch. "The safety profile and clinical improvement seen in this patient after treatment with inhaled NO therapy combined with results of the in vitro studies allow for the possibility that ex vivo susceptibility of NTM to NO may predict effective clinical dose regimens."

This research is supported by Intramural Research Programs of the National Heart, Lung and Blood Institute (NHLBI/NIH) and the NIH Clinical Center and through the CRADA HL-CR-18-003.

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 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 bacteria, including both gram-positive and gram-negative, but also against other diverse pathogens, including mycobacteria, viruses, fungi, yeast and parasites, and has the potential to eliminate multi-drug resistant strains.

About the LungFit™ NO Generator and Delivery System*

Beyond Air's LungFit™ NO Generator and Delivery System is a cylinder-free, phasic flow nitric oxide delivery system and has been designated as a medical device by the US Food and Drug Administration (FDA). The ventilator compatible version of the device can generate NO from ambient air on demand for delivery to the lungs at concentrations ranging from 1 part per million (ppm) to 80 ppm. The LungFit™ system could potentially replace large, high-pressure NO cylinders providing significant advantages in the hospital setting, including greatly reducing inventory and storage requirements, improving overall safety with the elimination of NO2 purging steps, and other benefits. The LungFit™ can also deliver NO at concentrations at or above 80 ppm for potentially treating: COVID-19 in the hospital setting and chronic, refractory lung infections in the home setting. With the elimination of cylinders, Beyond Air intends to offer NO treatment in the home setting.

* Beyond Air's LungFit™ is not approved for commercial use. Beyond Air's LungFit™ is for investigational use only. Beyond Air is not suggesting NO use over 80 ppm nor use at home.

About NTM

Nontuberculous mycobacteria (NTM) infection 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 if ignored can lead to NTM lung disease, a progressive and chronic condition. 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 concentrations 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 devices and drugs, which is unproven and may never lead to 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 various 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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