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Beyond Air Announces First Patient Enrolled in its U.S. Study of Nitric Oxide Therapy Using the LungFit™ System in COVID-19 Patients

GARDEN CITY, N.Y., June 15, 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 the first patient has been enrolled in the U.S. clinical study using the LungFit™ system to treat COVID-19 with NO therapy. The patient was enrolled at the Baptist Health Center for Clinical Research in Little Rock, Arkansas.

“The Beyond Air team continues to execute with this most recent accomplishment. The global need to discover a safe and effective treatment for this virus is painfully apparent. We look forward to keeping everyone abreast of the study’s progress over the coming weeks,” said Steve Lisi, Chairman and Chief Executive Officer of Beyond Air. “We believe our LungFit™ system is the conduit for nitric oxide to be a potential practical solution to this pandemic.”

“The Baptist Health Center team and I have been on the frontlines combatting COVID-19 over these past couple of months, and we are excited to participate in this study of nitric oxide as a possible therapy for patients. I believe the potential of an agent such as NO with both antiviral and anti-inflammatory properties, delivered to the lungs, is great and we hope for a positive outcome,” stated Richard G. Pellegrino MD, PhD, President and CEO of Baptist Health Center for Clinical Research.

The US trial is an open-label study of 20 adult patients hospitalized with COVID-19. Subjects will be randomized 1:1 and treated intermittently with 80 ppm NO administered over 40 minutes, 4 times per day, in addition to standard supportive therapy (SST) or treated with SST alone. The primary endpoint is time to clinical deterioration as measured by the need for: 1) non-invasive ventilation: or 2) high flow nasal cannula; or 3) intubation. Other endpoints include reduction in viral load, need for supplemental oxygen, hospital length of stay, mortality, safety and various biomarkers.

About Beyond Air, Inc.

Beyond Air, Inc. is a clinical-stage medical device and biopharmaceutical company developing a revolutionary NO Generator and Delivery System, the 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. 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™ in clinical trials for the treatment of severe lung infections such as SARS-CoV-2, bronchiolitis and nontuberculous mycobacteria (NTM). Additionally, Beyond Air is using ultra-high concentrations of NO with a proprietary delivery system, separate from the Lungfit, 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 severe acute lung infections in the hospital setting (e.g. COVID-19, bronchiolitis) and chronic, refractory lung infections in the home setting (e.g. NTM). 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 or use at home.

About COVID-19

COVID-19 (coronavirus disease 2019) is an [infectious disease](#) caused by the severe acute respiratory syndrome [coronavirus 2](#) (SARS-CoV-2). COVID-19 first emerged in Wuhan, [China](#) in December of 2019. Those affected develop [fever](#), cough, shortness of breath and/or difficulty breathing. While the majority of cases result in mild symptoms, some can progress to [pneumonia](#) and [multi-organ failure](#). Older adults and people who have serious chronic medical conditions are at an increased risk of developing severe complications from COVID-19. There is no specific treatment approved for COVID-19 and patients are managed with [supportive care](#). NO may prove to be a treatment as the impact on the lung should result in bronchodilation, reduction in inflammation and inhibition of the viral replication process^{1,2,3}. As of June 14, 2020, more than 7.6 million confirmed cases of COVID-19 and

more than 424,000 deaths have been reported globally.

[1] Tripathi et al, FEMS Immunology and Medical Microbiology, December 2017

[2] Saura, M., et al., An antiviral mechanism of nitric oxide: inhibition of a viral protease. Immunity, 1999. 10(1): p. 21-8.

[3] Akerström S et al. Nitric oxide inhibits the replication cycle of severe acute respiratory syndrome coronavirus. J Virol. 2005; 79(3):1966-9.

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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