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Beyond Air® Approved to Initiate Clinical Study at 150 ppm Nitric Oxide with LungFit™ for the Treatment of Acute Viral Pneumonia Including COVID-19

Patients with pneumonia caused by any virus, including SARS-CoV-2, will be considered for enrollment

Study scheduled to start in November 2020

GARDEN CITY, N.Y., Oct. 21, 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 plans to initiate a clinical study of the LungFit™ system for evaluation of the safety and efficacy of high concentration inhaled NO given intermittently to adults hospitalized with acute viral pneumonia, including SARS-CoV-2.

The study will take place in Israel and be a multi-center, open-label, randomized clinical trial with approximately 90 adult patients. The enrolled patients will be randomized in a 1:1 ratio to receive inhalations of 150 ppm NO given intermittently for 40 minutes four times per day for up to seven days in addition to standard supportive treatment (NO+SST); or standard supportive treatment alone (SST). Endpoints related to safety, oxygen saturation, fever and ICU admission, among others, will be assessed.

“Initiating this pilot study in patients hospitalized with acute viral pneumonia is another important step towards establishing the broad-spectrum anti-microbial activity of nitric oxide,” said Steve Lisi, Chairman and Chief Executive Officer of Beyond Air. “The study will enroll subjects with any virus, with an emphasis on SARS-CoV-2 infections. Our LungFit™ system is poised to transform the way we treat lung infections by generating nitric oxide from ambient air and safely delivering it to patients’ lungs.”

“As the COVID-19 pandemic is nowhere near its end, the scientific and medical communities are fearful of the upcoming winter, and the possibility of patients with co-infections of SARS-COV-2 with the flu or RSV,” said Prof. Talya Wolak, head of Internal Medicine Department D and head of the COVID-19 unit at Shaare Zedek Medical Center (Jerusalem, Israel). ”We are eager for a treatment to minimize the effect of co-infection, and to treat our patients safely and effectively. Beyond Air’s upcoming trial, with previously announced positive safety and efficacy data in other viral infections, could be efficient in the treatment of those patients.”

The ***LungFit™*** system 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. The LungFit™ system is designed to accommodate simultaneous oxygen delivery for patients who require it via a dedicated port in the rear of the device. 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 NO concentration, flow rate and duration. The Company believes this provides flexibility for NO administration. The Company is confident that respiratory therapists (RTs) can easily be trained to use and manage the system. If multiple patients are treated in the same facility, one RT could manage multiple systems simultaneously, with each system potentially treating up to four patients per day. Filters are single patient use and there are no special requirements for disposal. Alarms monitor system performance.

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™ system 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 Acute Viral Pneumonia

In adults, viruses have been identified as the causative agents in approximately 100 million cases of community-acquired pneumonia per year. While viral pneumonia in adults is most commonly caused by rhinovirus, respiratory syncytial virus (RSV) and influenza virus, newly emerging viruses (including SARS-CoV-1, SARS-CoV-2, avian influenza A, and H1N1 viruses) have been identified as pathogens contributing to the overall burden of adult viral

pneumonia. Patients aged 65 years or older are at particular risk for death from the disease, as are patients with other underlying health conditions or weakened immune systems. There is no consensus regarding the use of antiviral drugs to treat viral pneumonia, and specific preventative measures are currently limited to the influenza vaccine. Given that current treatment recommendations are largely limited to supportive care, there is an unmet medical need for effective treatment options.

About the LungFit™*

Beyond Air's LungFit™ is a cylinder-free, phasic flow nitric oxide generator and 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 NO_2 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 October 19, 2020, more than 40.2 million confirmed cases of COVID-19 and more than 1.12 million 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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