March 16, 2020

Beyond Air Submits Investigational Device Exemption (IDE) to the United States Food and Drug Administration (FDA) for the Treatment of COVID-19 Patients

LungFit™ BRO system to be used in proposed study to treat COVID-19 patients

Grant applications have been submitted to the Biomedical Advance Research and Development Authority (BARDA), a division of Health and Human Services (HHS)

Second trial design being vetted to investigate use in patients exposed to severe acute respiratory syndrome 2 (SARS-CoV-2), but not infected

Company to host a conference call today at 8:30 am ET to discuss these developments

GARDEN CITY, N.Y. and REHOVOT, Israel, March 16, 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 submission of an Investigational Device Exemption (IDE) to the U.S. Food and Drug Administration (FDA) for use of its ***LungFit™ BRO*** system in the treatment of COVID-19 patients. Typically, the FDA responds within 30 days of an IDE submission.

“There is a mounting body of evidence that inhaled NO, including NO generated and delivered by our ***LungFit™ BRO*** system, is safe and well-tolerated in animals and in human subjects at concentrations of 150 ppm and higher. In vitro evidence[1] points to inhibition of viral replication in a variety of viruses, including coronaviruses, as well as anti-inflammatory properties of nitric oxide,” said Steve Lisi, Chairman and Chief Executive Officer of Beyond Air. “We believe that our ***LungFit™ BRO*** system may, given the three completed pilot clinical studies in bronchiolitis, be a significant tool in the battle against this coronavirus that has reached global pandemic status. In response to the unprecedented nature of the COVID-19 situation, Beyond Air is taking all necessary steps to make this potential solution available as quickly as possible to ensure that clinicians have access to NO therapy as a treatment option.”

“Nitric oxide therapy at high concentrations is an innovative and potentially ground breaking treatment option against COVID-19. The ***LungFit™ BRO*** system is a practical and effective mode of delivery of nitric oxide for both patients and medical teams,” added 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. “Combatting this pandemic is of crucial importance and having the ***LungFit™ BRO*** system tested and

available as expeditiously as possible should be a priority for all parties."

COVID-19 trial design highlights

Subject to FDA approval of our IDE, the Company plans to test the ***LungFit™ BRO*** for use in the treatment of patients suffering from COVID-19 in an open label study of 75 patients between the ages of 22 and 75 years confirmed with COVID-19 that require hospitalization. Subjects would be randomized 2:1 and treated with 150 ppm NO administered over 40 minutes, 4 times per day, in addition to standard of care (SOC) or SOC alone. The primary endpoint is time to clinical improvement based on key parameters such as fever and oxygen support. Other endpoints include reduction in viral load, fever resolution, oxygen support, hospital length of stay, requirement of mechanical ventilation, mortality, and various biomarkers. Final trial design is subject to FDA approval of our IDE.

Other protocols targeting people exposed to SARS-CoV-2, the virus that causes COVID-19, are being designed to show that treatment with NO may prevent infection. This can potentially result in a significant decline in the current standard quarantine time of 14 days, protect medical staff treating those with COVID-19 or allow flexibility for the military. Beyond Air will evaluate the path forward for these potential trial design after completion of the first IDE study.

Beyond Air has already generated relevant data in humans, as shown at its Analyst Day held on March 5, 2020 (replay available at www.beyondair.net). Specifically, in a bronchiolitis study from 2014, 4 out of 43 patients in the study tested positive for coronavirus. The trial was a randomized, double blind, placebo-controlled study designed to compare NO therapy plus SOC versus SOC alone. The study looked at hospital length of stay (LOS) as its primary endpoint. Of the four non-COVID-19 coronavirus patients, two were in the control arm and two were in the treatment arm, allowing for a post-hoc comparison of the results. The LOS for the 2 patients in the control arm was 60 hours compared to a LOS of 30 hours for the 2 patients in the treatment arm. We believe these results represent a clinically meaningful reduction in LOS. Additionally, Beyond Air has reported efficacy data from two bronchiolitis studies, and anticipates reporting data from a third study in approximately 8 weeks. The data reported to date show an approximate one day reduction in LOS. All infants suffering from bronchiolitis have viral infections.

Safety data from the bronchiolitis studies mentioned above, coupled with other high concentration NO studies, show no NO related serious adverse events (SAEs) with more than 2,000 NO administrations to more than 100 patients. Additionally, Beyond Air has completed three studies in rats and one in dogs. There were no macroscopic or microscopic observations in any of these studies. Two studies lasted 12 weeks and the animals were treated with 250 ppm NO intermittently on a daily basis. One study lasted 30 days with the top NO concentration of 400 ppm dosed intermittently on a daily basis. The fourth study provided a clean report for genotoxicity.

***LungFit™ BRO* profile**

The ***LungFit™ BRO*** system weighs 20 lbs and is easy to transport. All that is required to power the unit is an electrical outlet. The system is designed to handle up to 240 volts. Since NO is generated from ambient air, there is an unlimited supply. For patients who may need supplemental oxygen, the system is designed to accommodate this with a port in the rear of the device. Nitrogen dioxide (NO_2) filters are needed for the system to generate and

deliver NO for safety reasons. Toxic levels of NO_2 can be a consequence of high concentration NO without proper filtration. The filters also program the system. We believe this provides flexibility for NO administration. The Company is confident that patients can easily be trained to self-administer or if multiple patients are treated in the same facility, one respiratory therapist (RT) can manage at least 10 systems at the same time and each system could treat 4 patients per day. Each patient would receive 4 administrations of NO per day each lasting 40 minutes separated by 4 hours. Alarms monitor system performance. Filters are single-use and there are no special requirements for disposal. Each patient would use their own breathing circuit to avoid contamination.

Beyond Air has ample ***LungFit™ BRO*** systems, filters and other equipment necessary to perform the study included in our IDE as well as the second protocol described above.

Conference Call Details
The management team will host a conference call for investors today, March 16 at 8:30 am ET to answer any questions. Conference call details are as follows:

Domestic Dial-in: 877-407-0784
International Dial In: 201-689-8560
Conference ID: 13700395

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 lower 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 bronchiolitis and severe lung infections such as 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 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 and is used in adult respiratory distress syndrome and persistent pulmonary hypertension of the newborn. 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 organisms, 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 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™ 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 above 80 ppm for which intended treatments are: bronchiolitis in the hospital setting, and chronic, refractory lung infections in the home setting. For the first time, Beyond Air intends to offer NO treatment in the home setting with the elimination of cylinders.

* Beyond Air's LungFit™ is not approved for commercial use and Beyond Air is not suggesting use over 80 ppm or use at home. Beyond Air's LungFit™ is for investigational purposes only.

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 developfever, 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. The fatality rate is currently estimated at between 1% and 3%. 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. As of March 15, 2020, more than 160,000 cases of COVID-19 and more than 6,400 deaths have been reported in more than 140 countries.

About Bronchiolitis

The majority of hospital admissions of infants with bronchiolitis are caused by respiratory syncytial virus (RSV). RSV is a common and highly transmissible virus that infects the respiratory tract of most children before their second birthday. While most infants with RSV present with minor respiratory symptoms, a small percentage develop serious lower airway infections, termed bronchiolitis, which can become life-threatening. The absence of treatment options for bronchiolitis limits the care of these sick infants to largely supportive measures. Beyond Air's system is designed to effectively deliver over 80 ppm NO, for which preliminary studies indicate may eliminate bacteria, viruses, fungi and other microbes from the lungs.

Forward-Looking Statement

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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[1] *Tripathi et al, FEMS Immunology and Medical Microbiology, December 2017: Saura, M., et al., An antiviral mechanism of nitric oxide: inhibition of a viral protease. Immunity, 1999. 10(1): p. 21-8: Akerström S et al. Nitric oxide inhibits the replication cycle of severe acute respiratory syndrome coronavirus. J Virol. 2005; 79(3):1966-9.*

Source: Beyond Air™