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Beyond Air to Initiate Clinical Study Evaluating High Concentration Nitric Oxide for the Treatment of COVID-19 Patients in the United States

Food and Drug Administration (FDA) agrees to a trial using the LungFit™ system to treat COVID-19 patients

Applications pending with Health Canada and the Israel Ministry of Health to allow studies to be conducted using high concentration nitric oxide to treat COVID-19 patients

GARDEN CITY, N.Y., April 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 that the U.S. Food and Drug Administration (FDA) agreed with the initiation of a clinical study in the U.S. using its ***LungFit™*** system to treat COVID-19 patients. Applications for funding are pending with the Biomedical Advance Research and Development Authority (BARDA), a division of Health and Human Services (HHS).

“We are pleased with the rapid action taken by the FDA to allow this first step in providing high concentration nitric oxide therapy to COVID-19 patients,” said Steve Lisi, Chairman and Chief Executive Officer of Beyond Air. “The Beyond Air team is working tirelessly to initiate this important study, into which we expect to begin enrolling patients within weeks.”

COVID-19 trial design highlights (United States)

The ***LungFit™*** will be used in an open-label study, to treat 20 patients between the ages of 22 and 65 years hospitalized with COVID-19. Subjects will be randomized 1:1 and treated with 80 ppm NO administered over 40 minutes, 4 times per day, in addition to standard of care (SOC) or treated with SOC 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.

COVID-19 trial design highlights (Canada and Israel)

These studies, pending respective approvals, will resemble the U.S. study with the NO concentration at 150 ppm.

***LungFit™* profile**

The ***LungFit™*** system is portable, weighing only 20 lbs. The system operates with a standard electrical outlet (120-240 volts). Since NO is generated from ambient air that flows

through a reaction chamber, there is potential unlimited supply. The system is designed to accommodate simultaneous oxygen delivery for patients who need 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 respect to NO concentration, flow rate and duration. We believe 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, each system treating up to 4 patients per day. Each patient would receive 4 administrations of NO daily at 4-5 hour intervals, each lasting 40 minutes. Filters are single-use and there are no special requirements for disposal. Each patient would use their own breathing circuit, which can be attached/detached in seconds, to avoid contamination. 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, 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 NO_2 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 purposes 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 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. 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 April 15, 2020, more than 2 million confirmed cases of COVID-19 and more than 125,000 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 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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