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# Beyond Air Achieves Primary Endpoint in Pilot Bronchiolitis Study

*High concentration nitric oxide (150 ppm) is statistically significantcompared to both low concentration nitric oxide (85 ppm) and control arms on both the primary endpoint and the key secondary endpoint*

*No serious adverse events related to NO therapy*

*Third consecutive successful pilot study in bronchiolitis*

GARDEN CITY, N.Y., May 20, 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 positive top-line results from its third pilot study in bronchiolitis patients that showed, on an intent-to-treat (ITT) basis, 150 parts per million (ppm) NO is statistically significant compared to both the 85 ppm NO and control arms of the study.

The randomized, double blind, controlled study was performed at eight sites in Israel and enrolled 89 patients under the age of 12 months. The patients were randomized equally across three arms: standard supportive therapy (SST); 85 ppm NO + SST and 150 ppm NO + SST. Study treatment was delivered to patients intermittently four times per day for 40 minutes for up to five days. The primary endpoint was time to fit-to-discharge (FTD), a composite of the modified TAL score and sustained oxygen saturation on room air.

For the primary endpoint, on an ITT basis, a comparison of relative hazards is displayed in the table below, which shows statistical significance of the 150 ppm NO arm compared to the other two arms. For the key secondary endpoint of hospital length of stay (LOS), on an ITT basis, the results are also displayed in the table and show statistical significance of the 150 ppm NO arm compared to the other two arms. There was no statistical difference between the 85 ppm NO arm and SST on either endpoint.

| | **150 ppm vs. 85 ppm** | **150 ppm vs. SST** | **85 ppm vs. SST** |
|---|---|---|---|
| **Primary endpoint** | | | |
| Time to Fit-to-Discharge (FTD) | | | |
| Hazard Ratio | 2.11 | 2.32 | 0.90 |
| 95% CI | 1.03, 4.31 | 1.01, 5.33 | 0.44, 1.81 |
| P-value | 0.041 | 0.049 | NS |
| | | | |
| **Secondary endpoint** | | | |

| Hospital Length of Stay (LOS) | | | |
|---|---|---|---|
| Hazard Ratio | 2.01 | 2.28 | 0.77 |
| 95% CI | 1.01, 3.99 | 1.03, 5.06 | 0.40, 1.48 |
| P-value | 0.046 | 0.043 | NS |

NO therapy was generally well tolerated. There were no serious adverse events related to NO therapy, with no adverse events leading to discontinuation of NO therapy.

“Considering this study was designed to observe trends in efficacy, we believe the results are compelling given the statistical significance of the high NO concentration arm. We believe these data clearly show 150 ppm NO is safe and the minimum concentration necessary for efficacy when treating patients with viral lung infections,” said Steve Lisi, Chairman and Chief Executive Officer of Beyond Air. “These results bode well for our upcoming studies in patients with COVID-19.”

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 commented, “Bronchiolitis, a serious infantile respiratory disease, usually caused by respiratory syncytial virus (RSV), causes severe morbidity and is the leading cause of hospitalization at this age. To date no therapy has been found that effectively hastened recovery. The compelling results of this study point to a therapeutic effect of a higher concentration of NO that could be attributed to the established anti-inflammatory, vasodilator and bronchodilator effects of the gas. However, it also raises the possibility of affecting the invasiveness or viability of the virus, and with that, potentially opening a new horizon in therapies for respiratory viral infections.”

**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 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.

**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 use only. Beyond Air is not suggesting NO use over 80 ppm or use at home.

**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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