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Beyond Air® Presents Data in Hospitalized Patients with Viral Lung Infections (including COVID-19) from LungFit® PRO Programs at ATS 2021

Interim analysis from the ongoing, open-label, randomized acute viral pneumonia (including COVID-19) pilot study shows 150 ppm nitric oxide (NO) administered with LungFit® PRO is well-tolerated with no treatment-related adverse events, and demonstrates encouraging efficacy signals

Further analysis of 3 previously reported pilot studies in bronchiolitis at 150-160 ppmNO demonstrates a favorable safety profile and consistent efficacy across multiple endpoints

Entirety of data at 150-160 ppm NO in both adult and infant patient populations supports further development of LungFit® PRO in patients hospitalized with viral pneumonia

GARDEN CITY, N.Y., May 13, 2021 (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 (gNO) for the treatment of solid tumors, today announced the presentation of data at the American Thoracic Society (ATS) International Conference 2021, which is being held virtually from May 14 – May 19. The data from both LungFit® PRO programs, acute viral pneumonia (including COVID-19) and bronchiolitis, show a favorable safety profile and encouraging efficacy trends using high concentration inhaled NO for the treatment of acute viral lung infections in hospitalized patients.

“We have now demonstrated a consistently favorable safety profile at high concentrations of nitric oxide in both adult and infant populations with acute viral lung infections,” said Steve Lisi, Chairman and Chief Executive Officer of Beyond Air. “The new data from the acute viral pneumonia pilot trial in adults, taken together with our three previously completed pilot clinical trials in bronchiolitis, enable Beyond Air to prepare for a pivotal study for high concentration NO in a viral indication.”

“The interim analysis of patients in the acute viral pneumonia (including COVID-19) pilot study shows a favorable safety profile and encouraging efficacy signals in this adult patient population treated with 150 ppm NO generated and delivered by LungFit® PRO,” commented 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. “Given these current data, I believe the results support the continued development of high concentration inhaled NO that can be delivered with ease by LungFit® for the treatment of viral pneumonia including COVID-19. LungFit® PRO is a revolutionary device that can allow for the treatment of this diverse patient population on a large scale”.

Summary of Interim Results of Acute Viral Pneumonia (including COVID-19) Pilot Trial

The ongoing acute viral pneumonia pilot study is a multi-center, open-label, randomized clinical trial in Israel with an emphasis on enrolling patients infected with SARS-CoV-2. Patients are 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, control group). At the time of the cut off for these data, a total of 23 COVID-19 subjects were enrolled. The intent-to-treat (ITT) analysis population included 19 patients (9 NO + SST vs 10 SST).

Safety and Tolerability

- 150 ppm NO treatment administered via LungFit® PRO was safe and well tolerated.
- NO_2 levels were below 4 ppm at all timepoints (safety threshold is 5 ppm).
- MetHb levels were below 4% at all times (safety threshold is 10%).
- A total of 15 adverse events were reported in 8 subjects (5 NO + SST vs. 3 SST) and two serious adverse events were reported in the NO + SST group – both were related to the underlying condition of the subject and were assessed to be unrelated to study treatment.
- There were no treatment-related, or possibly related, adverse events or severe adverse events.

Effect on Duration of Hospital Stay
Intent to Treat Population

		LungFit 150 ppm NO + SST	SST
Duration of hospital stay (days)	N	9	10
	Mean	2.7	3.1
	Median	2.2	2.1
	Min	1.2	0.1
	Max	4.9	7.9

Intent to Treat Population with Exclusion of Extreme Values*

		LungFit 150 ppm NO + SST	SST*
Duration of hospital stay (days)	N	9	8
	Mean	2.7	3.8
	Median	2.2	2.2
	Min	1.2	1.0
	Max	4.9	7.9

*2 subjects discharged from hospital within 6 hours of study enrollment were excluded from analysis.

Effect on Oxygen Support Requirements

		LungFit 150 ppm NO + SST	SST
Duration of Oxygen Support (days)	N	9	10
	Mean	3.2	5.2
	Median	1.9	4.9
	Min	0.0	0.0
	Max	12.0	16.7

- In the ITT population (n=19), 22.2% of subjects in the NO + SST group required oxygen support beyond their hospital stay, compared with 40% of control subjects.

Additional detailed study results will be submitted for presentation at an upcoming scientific meeting.

Summary of Analysis of 3 Completed Bronchiolitis Pilot Trials

“To date, over 90 patients hospitalized with a viral lung infection have received 150-160 ppm inhaled NO, dosed intermittently, without any reported treatment-related serious adverse events,” said Asher Tal, M.D. Professor Emeritus, Pediatrics, Soroka University Medical Center; Faculty of Health Sciences, Ben-Gurion University of the Negev, Beer-Sheva, Israel. “Overall, the data show that 150 ppm NO given intermittently via inhalation is effective in the treatment of patients with bronchiolitis, while data at the lower concentration of 85 ppm show no benefits. I look forward to further development of the program using a minimum concentration of 150 ppm NO, noting that a reduction in time spent in the hospital by these patients would be clinically meaningful.”

Beyond Air has assessed inhaled NO in three pilot clinical trials in bronchiolitis. 198 infants (43% females; 57% males) participated across the three programs, with a mean age of 3.9 months (range 0.3 – 11.9 months). Inhaled NO treatments were given intermittently for 30 to 40 minute durations, from 4 to 5 times daily for up to 5 days. Data from patients in the SST group were pooled across the 3 studies for safety analysis.

Studies Included in the Analysis

	Trial 1	Trial 2	Trial 3
Treatment groups	160 ppm NO + SST SST alone (control)	160 ppm NO + SST SST alone (control)	150 ppm NO + SST 85 ppm NO + SST SST alone (control)
Total Intent to Treat (ITT) Subjects Enrolled & Evaluated as the Safety Population	43	68	87
Study Treatment Protocol	Inhaled NO was given for 30 minutes, 5 times per day for up to 5 days	Inhaled NO was given for 30 minutes, 5 times per day for up to 5 days	Inhaled NO was given for 40 minutes, 4 times per day for up to 5 days

Primary objective	Safety	Efficacy (Length of Stay)	Efficacy (Time to Fit for Discharge)

Safety and Tolerability

	SST (N=82)		85 ppm NO + SST (N=32)		150 ppm NO + SST (N=29)		160 ppm NO + SST (N=55)		All (N=198)	
	N	%	N	%	N	%	N	%	N	%
Any AE	45	54.9%	20	62.5%	18	62.1%	25	45.5%	108	54.5%
Any SAE	10	12.2%	1	3.1%	3	10.3%	11	20.0%	25	12.6%

- NO treatment administered intermittently was generally safe and well tolerated across the three pilot trials, with the adverse event rates similar among treatment groups.

Efficacy Conclusions

	Trial 2	Trial 3
	Comparison Hazard Ratio[1] (p value)	Comparison Hazard Ratio[1] (p value)
Dose	160 ppm NO vs. SST	150 ppm NO vs. SST
Time to Fit for Discharge	N/A[2]	2.32 (0.049)*
Hospital Length of Stay (LOS)	1.92 (0.048)*	2.28 (0.043)*
Time to Oxygen Saturation of ≥ 92%	2.23 (0.057)	2.62 (0.039)*

*Met statistical significance ($p<0.05$)

[1]A hazard ratio estimate greater than one represents a higher probability of achieving success on each endpoint in the NO group relative to SST.

[2]Time to fit for discharge was not measured in Trial 2

- Analysis across the studies demonstrated that a short course of treatments with intermittent high concentration inhaled NO (150 – 160 ppm) was effective in shortening hospital length of stay and accelerating time to fit for discharge – a composite endpoint of clinical signs and symptoms to indicate readiness to be evaluated for hospital discharge.
- Inhaled NO (150 -160 ppm) was also effective in accelerating time to stable oxygen saturation without supplemental oxygen – measured as SpO_2 ≥ 92% in room air.
- In Trial 3, NO at a dose of 85 ppm NO showed no difference compared to control for all efficacy endpoints, while 150 ppm NO showed statistical significance when compared to control. Statistical significance was seen on time to fit for discharge and LOS when 150 ppm NO was compared to 85 ppm NO, while the p value for time to oxygen saturation was 0.055.
- By reducing the times to improvement in hospital length of stay, fit for discharge, and SpO_2, 150 – 160 ppm NO given intermittently via inhalation demonstrates clinically

meaningful efficacy for the treatment of infants with bronchiolitis.

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. 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 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. 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. 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 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 150 - 400 ppm NO, for which preliminary studies indicate may eliminate bacteria, viruses, fungi and other microbes from the lungs.

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 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 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 May 12, 2021 more than 160 million confirmed cases of COVID-19 and more than 3.3 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.

CONTACTS:
Steven Lisi, Chief Executive Officer
Beyond Air, Inc.
Slisi@beyondair.net

Maria Yonkoski, Head of Investor Relations
Beyond Air, Inc.
Myonkoski@beyondair.net

Corey Davis, Ph.D.
LifeSci Advisors, LLC
Cdavis@lifesciadvisors.com
(212) 915-2577

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