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Beyond Air® Presents Positive New Preclinical Data for the Use of a Single Injection of Gaseous Nitric Oxide as a Novel In situ Cancer Vaccination

GARDEN CITY, N.Y., Oct. 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 (gNO) for the treatment of solid tumors, today announced new *in vitro* and *in vivo* preclinical data that suggest the Company's innovative gNO-based treatment may treat lung cancer locally and its metastases systemically, potentially via stimulation of an anti-tumor immune response. These data were included in a presentation by Hila Confino, PhD of Beyond Air at the International Association for the Study of Lung Cancer's (IASLC) North America Conference on Lung Cancer 2020 (NACLC 2020), which is being held from October 16th to 17th.

In a series of *in vitro* experiments, the mouse lung cancer cell line LLC1 was exposed to gNO at 10,000-50,000 ppm for up to 15 minutes. Compared with air controls, NO-treated lung cancer cells demonstrated dose- and time-dependent reductions in viability at gNO doses up to 20,000 ppm and dose-dependent apoptosis at doses up to 50,000 ppm, indicating a potential direct anticancer effect of gNO in this *in vitro* model.

In the *in vivo* study, mice with LLC1 tumors received a single 50,000 ppm intratumoral gNO treatment over 10 minutes. Up to 14 days after the gNO treatment, a metastasis model was induced in all gNO-treated tumor-bearing mice after treatment by challenging the mice with a second LLC1 cancer cell inoculation. For comparison, a group of naïve mice also received the LLC1 inoculation. At day 5 all naïve mice showed uptake of the challenge tumor while at day 9, none of the NO-treated mice showed uptake of the challenge tumor. No unanticipated mortality or signs indicating distress were noted in the animals.

Steve Lisi, Chairman and Chief Executive Officer of Beyond Air, stated, "We are excited by the positive results of these studies, in which *in vitro* data indicate a cytotoxic effect of gNO on LLC1 lung cancer cells, and *in vivo* data demonstrated that 100% of gNO-treated tumor bearing mice rejected a subsequent tumor challenge, while 100% of the control group had challenge tumor uptake. We believe these promising data support the continued development of gNO as a novel treatment for primary and metastatic lung cancer."

The final version of the e-poster along with an accompanying audio presentation of the data will be available on the NACLC website at <https://naclc2020.iaslc.org/> and on the Company's website ([click here](#)).

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 Solid Tumors

Cancer is the second leading cause of death globally, with tumor metastases responsible for approximately 90% of all cancer-related deaths. Current cancer treatment modalities generally include chemotherapy, immunotherapy, radiation, and/or surgery. Nitric oxide at high concentrations has been reported to show anticancer properties and to serve as a chemosensitizer and radiotherapy enhancer. Based on its current findings, Beyond Air is developing treatment protocols using ultra-high nitric oxide concentrations to ablate primary tumors and treat metastatic disease.

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 devices and drugs, which is unproven and may never lead to 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 various 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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