

October 19, 2020



# **Beyond Air® Presents In Vivo Solid Tumor Data Confirming In Situ Cancer Vaccination with a Single Injection of Gaseous Nitric Oxide at the AACR Conference on Tumor Immunology and Immunotherapy**

*New in vivo data for colon cancer show anti-tumor immunity in 100% of mice*

*In vivo breast cancer data show a significant delay in challenge tumor uptake*

**Garden City, NY, October 19, 2020** – 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 and tumor metastases, today announced additional preclinical data that further suggest exogenous high concentration gNO (>10,000 ppm) administered directly to solid tumors may trigger a systemic anti-tumor immune response, a concept that could serve as the basis for an effective immunotherapy. These data were included in a presentation by Hila Confino, PhD of Beyond Air, at the AACR Conference on Tumor Immunology and Immunotherapy, which is being held from October 19<sup>th</sup> to 20<sup>th</sup>.

Steve Lisi, Chairman and Chief Executive Officer of Beyond Air, stated, “To our knowledge, ours is the first and only program testing the concept of injecting high concentration NO gas into solid tumors. If successful, this approach has the potential to elicit a paradigm shift in the standard of care for solid tumors and their metastases, which are responsible for approximately 90% of all cancer-related deaths.”

In the studies, colon and breast tumor-bearing mice (CT26 and 4T1 models, respectively) received a single treatment with high concentration gNO intratumorally. The CT26 study mice received either 20,000 or 50,000 ppm gNO for five minutes and the 4T1 study mice received 50,000 ppm gNO for ten minutes. Naïve mice, inoculated with the same cancer cells, served as an internal control for each study, with the 4T1 study having an additional control arm of mice treated with nitrogen gas. Up to 21 days after gNO administration to the primary tumor, all mice were inoculated with a challenge tumor and growth of that tumor was tracked.

At day 45 in the CT26 study, challenge tumor uptake was observed in 100% of naïve mice, 27% of 20,000 ppm gNO mice, and 0% of 50,000 ppm gNO mice, suggesting dose-dependence. With respect to CT26 related mortality at day 45, 25% of naïve mice, 73% of

20,000 ppm gNO mice and 100% of 50,000 ppm gNO mice were alive. In the 4T1 study, while tumor take was observed in all mice, tumor take was delayed in the gNO-treated mice compared to both control groups.

Professor Ido Wolf, the head of the oncology division at Sourasky Medical Center in Tel Aviv, commented, "I find this data very encouraging and, coupled with previously reported data, strongly suggests the clinical use of gNO for the treatment of primary tumors and their metastases should be further explored. I look forward to the development of this program and the initiation of a first in human study as soon as possible."

### **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](http://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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