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# AIT Therapeutics Reports Positive Top Line Results from its Nitric Oxide in Bronchiolitis (NO-BRO) Pilot Study in Infants

*Pivotal study expected to commence in the fourth quarter of calendar year 2019*

NEW YORK, June 13, 2018 (GLOBE NEWSWIRE) -- AIT Therapeutics, Inc. (OTC:AITB), 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, today announced positive top line results from its Nitric Oxide in Bronchiolitis (NO-BRO) Pilot study. Given these positive results, a pivotal study is expected to commence in the fourth quarter of calendar year 2019.

"Nitric oxide has once again been shown to improve the condition of patients with lung infections when delivered at a high concentration," said Steven Lisi, Chairman and Chief Executive Officer of AIT Therapeutics. "Our pivotal study in bronchiolitis patients, anticipated to start in the fourth quarter of calendar year 2019 and to complete in the second quarter of calendar year 2020 in the United States, will be performed using our proprietary nitric oxide generator and delivery system. Reducing length of hospital stay in bronchiolitis patients benefits not only the patient and the parents, it reduces cost to the hospital as well."

David Greenberg, M.D., Chairman of Pediatrics, and Head of the Pediatric Infectious Disease Unit at Soroka University Medical Center, and Principal Clinical Consultant of the study, stated, "today is a promising day for physicians and parents combatting bronchiolitis, which can lead to near-term and long-term respiratory complications. Releasing infants from the hospital a day earlier is a huge relief for parents and caregivers, plus it allows the hospital to provide optimal care for more patients during the busy winter season." Dr. Greenberg further added, "I am looking forward to the day we can use inhaled nitric oxide for all of our bronchiolitis patients."

## **NO-BRO Study Design**

The trial was a prospective, double blind, randomized, multi-center (6 sites), placebo-controlled study in 67 infants hospitalized with bronchiolitis. All patients received standard-of-care (SOC) which consisted of oxygen, hydration and other typical treatments for bronchiolitis at the physician's discretion. In addition to SOC, the treatment arm received NO 160 ppm for 30 minutes five times per day for up to five days delivered via a breathing mask.

Patients enrolled into the study were required to have a trial entry composite score of 7 – 10 using the modified Tal (mTal) score. The mTal score has four components: 1) respiratory rate, 2) oxygen saturation (SaO<sub>2</sub>), 3) accessory muscle use and 4) wheezing. Each component is scored on a scale of 0-3. Other enrollment criteria included: age <12 months, gestation period of at least 28 weeks and acute bronchiolitis when admitted to the hospital, with an expected stay of at least 24 hours.

The primary endpoint of the study was hospital length-of-stay (LOS) as measured from the time of enrollment to the time of hospital discharge. Secondary endpoints were safety, tolerability, time to mTal score <5 and time to SaO<sub>2</sub> >92%. With respect to the primary endpoint, to be discharged from the hospital a patient had to achieve an mTal score <5, have SaO<sub>2</sub> >92% and have the physician sign the hospital discharge order.

## **NO-BRO Study Results**

Table 1 shows the primary endpoint of hospital length of stay (LOS). The mean difference in LOS between the NO treated patients v. control was 17.4 hours on an intent-to-treat (ITT) basis. Using an adjusted intent to treat (aITT) analysis, the mean difference in LOS was 21.0 hours. LOS for patients in the control arm was 35% longer than NO treated patients.

There were protocol deviations for two patients: 1) an infant with a feeding tube was incorrectly enrolled in the study in the NO treatment arm, and 2) LOS was significantly increased in one patient in the control arm after treatment had been completed. These two patients represent the only difference between the ITT and aITT analyses. This study was not powered to show statistical significance.

**Table 1: Hospital Length of Stay (LOS)**

Arm	ITT		aITT	
	NO	Control	NO	Control
Number of Patients	33	34	32	34
Mean LOS (hours)	66.8	84.2	60.4	81.4
NO Benefit (hours)	17.4		<b>21.0</b>	
p value (Welch's t-test)	0.20*		<b>0.11*</b>	

ITT = Intent to Treat

aITT = adjusted Intent to Treat

\*not significant p<0.05

There were no serious adverse events (SAEs) related to NO therapy. NO treatment was well tolerated with no patient discontinuing treatment due to elevations in methemoglobin or nitrogen dioxide levels.

Further data on the NO-BRO study will be presented at a future medical meeting.

### About Nitric Oxide (NO)

Nitric Oxide (NO) is a powerful molecule proven to play a critical role in a broad array of biological functions. In the airways, NO is believed to play a key role in the innate immune system at concentrations of approximately 200 ppm. In vitro studies suggest that NO possesses anti-microbial activity not only against common bacteria, both gram-positive and gram-negative, but also against other diverse organisms including mycobacteria, 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. AIT's system is designed to effectively deliver 160 ppm NO, which has been proven to eliminate bacteria, viruses, fungi and other microbes from the lungs.

### About AIT Therapeutics Inc.

AIT Therapeutics Inc. is a clinical-stage medical device and biopharmaceutical company using nitric oxide (NO) to treat respiratory and other diseases. The Company is currently applying its therapeutic expertise to treat lower respiratory tract infections that are not effectively addressed with current standards of care, as well as pulmonary hypertension, in various settings. AIT Therapeutics is currently advancing its revolutionary NO Generator and Delivery System in clinical trials for the treatment of bronchiolitis and severe lung infections such as nontuberculous mycobacteria (NTM). For more information, visit [www.AIT-Pharm.com](http://www.AIT-Pharm.com).

### Forward-Looking Statement

This press release contains "forward-looking statements." 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 "expects," "intends," "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 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; and our short operating history. 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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