

AIT Therapeutics' Adjuvant Nitric Oxide Treatment Shown to be Safe and Effective in the Compassionate Use Setting in Cystic Fibrosis Patients with Non-tuberculous Mycobacteria (NTM) Infection

Significant Reductions in Mycobacterium abscessus Load in Sputum Demonstrated

Manuscript Published in the Pediatric Infectious Disease Journal

REHOVOT, Israel and NEW YORK, Sept. 13, 2017 (GLOBE NEWSWIRE) -- AIT Therapeutics Inc. (OTC:AITB), a clinical-stage anti-microbial therapeutic company treating respiratory diseases with nitric oxide (NO), today announced publication of a manuscript of its compassionate use in cystic fibrosis patients with Mycobacterium abscessus complex (MABSC) in the peer-reviewed *Pediatric Infectious Disease Journal*. MABSC is one of the most antibiotic-resistant pathogens in cystic fibrosis patients, and both patients in the trial showed significant reductions in bacterial load, while also showing the treatment was safe and tolerable.

“We were pleased to see such dramatic results in these two patients with Mycobacterium abscessus complex,” said Steve Lisi, Chief Executive Officer of AIT Therapeutics. “This condition is very difficult to treat and these patients had exhausted all other treatment options. The encouraging results demonstrate our proprietary Nitric Oxide therapy could be a potential treatment for these patients.”

Two cystic fibrosis (CF) patients with MABSC received intermittent inhalations of nitric oxide at 160 parts per million. The treatments were well-tolerated with no safety issues. Both patients showed significant reductions in quantitative PCR results for Mycobacterium abscessus load in sputum during treatment, with the estimated colony forming unit (CFU) decreasing from 7000 to 550 for patient 1 and from 3000 to 0 or complete eradication for patient 2. Study authors recommended further trials be conducted in this patient population. A summary of the abstract can be found [here](#).

Current Ongoing NO Trials

The Company is currently conducting two trials in Nitric Oxide: a Phase 3 study in infants hospitalized due to bronchiolitis and a Phase 2 study in NTM abscessus. The prospective, randomized, double-blind, controlled Phase 3 Nitric Oxide in Bronchiolitis (NO-BRO) trial will compare the company's proprietary nitric oxide therapy plus current standard-of-care versus the current standard-of-care alone in 94 patients, aged 0-12 months, who are hospitalized due to bronchiolitis. Patients will receive 160 parts per million (ppm) NO treatment five times a day for up to 5 days. The primary endpoint will be hospital length-of-stay (LOS). Secondary endpoints are time required to achieve a clinical score of 5 or less on the

modified Tal score and time required to achieve oxygen saturation (SaO₂) of 92% or greater. Data from this trial are expected in the first half of 2018.

The single-arm, open-label Phase 2 Nitric Oxide in NTM abscessus (NO-NTM abscessus) trial will enroll 10 patients with MABSC, who are refractory to standard-of-care. Patients will be treated with inhaled NO at a concentration of 160 ppm for 30-minutes, in addition to treatment with standard-of-care. The inhaled NO treatment will be administered intermittently 5 times per day over a 14-day period, followed by a 7-day period with 3 treatments per day. The primary endpoint will be safety, as measured by NO-related serious adverse events (SAEs), over the 21-day treatment period. Secondary endpoints include a 6-minute walk test and *Mycobacterium abscessus* load in sputum. Data are expected to be announced in the fourth quarter of 2017.

About 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 their multi-drug resistant strains.

About AIT Therapeutics Inc.

AIT Therapeutics Inc. is a clinical-stage anti-microbial therapeutic 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 are not effectively addressed with current standards of care. AIT Therapeutics is advancing its revolutionary respiratory targeted system in clinical trials for the treatment of bronchiolitis (RSV) exacerbations, and nontuberculous mycobacteria (NTM). For more information, visit 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.

CONTACT

Steven Lisi, Chief Executive Officer
AIT Therapeutics, Inc.
Steve@AIT-Pharm.com

Bob Yedid
LifeSci Advisors, LLC
Bob@LifeSciAdvisors.com
(646) 597 6989



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