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AIT Therapeutics' Inhaled Nitric Oxide Therapy Granted Orphan Drug Designation by the U.S. Food and Drug Administration for Treating Infections Caused by Nontuberculous Mycobacteria (NTM)

REHOVOT, Israel and NEW YORK, Oct. 03, 2017 (GLOBE NEWSWIRE) -- AIT Therapeutics Inc. (OTC:AITB), a clinical-stage biopharmaceutical company focused on developing inhaled Nitric Oxide (NO) for the treatment of patients with serious lung infections, today announced that the U.S. Food and Drug Administration (FDA) has granted orphan drug designation to the Company for its novel NO formulation for the treatment of infections caused by NTM.

The FDA's Office of Orphan Drug Products grants orphan drug designation to support the development of medicines for underserved patient populations, or rare disorders, that affect fewer than 200,000 people in the United States. Orphan drug designation will provide AIT Therapeutics with certain exclusivity benefits, tax credits for certain research, and a waiver of the New Drug Application user fees.

"Receiving orphan drug designation is an important regulatory milestone," said Steve Lisi, Chairman and Chief Executive Officer of AIT Therapeutics. "NTM infection is a rare and debilitating pulmonary disease associated with increased morbidity and mortality. We are currently developing our nitric oxide therapy for two indications, and look forward to announcing data from our Phase 2 study in NTM abscessus during the fourth quarter of this year."

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 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. AIT Therapeutics is advancing its revolutionary NO respiratory targeted system in clinical trials for the treatment of bronchiolitis 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.

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