May 3, 2016

Insmed Announces Upcoming Presentations at the American Thoracic Society 2016 International Meeting

BRIDGEWATER, N.J., May 03, 2016 (GLOBE NEWSWIRE) -- Insmed Incorporated (Nasdaq:INSM), a global biopharmaceutical company focused on the unmet needs of patients with rare diseases, today reported that three ARIKAYCE™-related abstracts and one treprostinil prodrug abstract were accepted for presentation at the American Thoracic Society (ATS) 2016 International Conference taking place in San Francisco May 13 to 18. ARIKAYCE, or liposomal amikacin for inhalation, is in late-stage development for the treatment of adult patients with nontuberculous mycobacteria (NTM) lung disease, a rare and often chronic infection that is capable of causing irreversible lung damage and can be fatal. The company's earlier-stage pipeline includes a number of treprostinil prodrugs, which may offer a differentiated product profile with therapeutic potential in rare pulmonary disorders such as pulmonary arterial hypertension (PAH), idiopathic pulmonary fibrosis (IPF), sarcoidosis, and severe refractory asthma.

Summarized below are the abstract titles and presentation times. The ATS abstracts are available online at the conference website at http://conference.thoracic.org. The ATS presentations are embargoed for release at the date/time the data are presented at the conference. Once the posters are public, they will be available on Insmed's website at http://www.insmed.com.

Session: B49 - Non-tuberculous mycobacterial disease and case reports
Date: Monday, May 16, 2016
Session time: 9:00 AM - 4:15 PM PT
Poster 11396: 12-month follow-up data from a phase 2 trial of liposomal amikacin for inhalation (LAI) in patients with refractory nontuberculous mycobacterial (NTM) lung infection
Lead author: Kenneth N. Olivier, MD

Session: B49 - Non-tuberculous mycobacterial disease and case reports
Date: Monday, May 16, 2016
Session time: 9:00 AM - 4:15 PM PT
Poster 5105: Airway deposition and retention of liposomal amikacin for inhalation in patients with pulmonary nontuberculous mycobacterial disease
Lead author: Kenneth N. Olivier, MD

Session: C57 - Cellular/molecular mechanisms and translational aspects of respiratory infections
Date: Tuesday, May 17, 2016
Session time: 9:00 AM - 4:15 PM PT
Poster 8799: Biodistribution and clearance of liposomal amikacin for inhalation and free amikacin after a single-dose inhalation in rats
Lead author: Vladimir Malinin

Session: D52 - Molecular insight into pulmonary hypertension
Date: Wednesday, May 18, 2016
Session time: 9:00 AM - 4:15 PM PT
Poster 10405: Structure dependent PK profiles of alkyl ester treprostinil prodrugs (TPD) administered via metered dose inhaler to rats
Lead author: Adam Plaunt

About Insmed

Insmed Incorporated is a global biopharmaceutical company focused on the unmet needs of patients with rare diseases. The company is advancing a global phase 3 clinical study of ARIKAYCE™ (liposomal amikacin for inhalation) in nontuberculous mycobacteria (NTM) lung disease, a rare and often chronic infection that is capable of causing irreversible lung damage and can be fatal. There are currently no products indicated for the treatment of NTM lung disease in the United States or European Union (EU). In the EU, the company has filed a marketing authorization application seeking approval of ARIKAYCE for use in patients with NTM lung disease. Insmed's earlier-stage clinical pipeline includes INS1009, a nebulized prodrug formulation of treprostinil that the company believes may offer a differentiated product profile with
therapeutic potential in rare pulmonary disorders such as pulmonary arterial hypertension (PAH), idiopathic pulmonary fibrosis (IPF) sarcoidosis, and severe refractory asthma. To complement its internal research, Insmed actively seeks in-licensing opportunities for a broad range of rare diseases. For more information, visit www.insmed.com.

“Insmed” and “ARIKAYCE” are the company’s trademarks. All other trademarks, trade names or service marks appearing in this press release are the property of their respective owners.

About Nontuberculous Mycobacteria Lung Disease

NTM is a rare and serious disorder associated with increased morbidity and mortality. There is an increasing rate of lung disease caused by NTM and this is an emerging public health concern worldwide. Patients with NTM lung disease may experience a multitude of symptoms such as fever, weight loss, cough, lack of appetite, night sweats, blood in the sputum, and fatigue. Patients with NTM lung disease frequently require lengthy hospital stays to manage their condition. There are no products specifically indicated for the treatment of NTM lung disease in the US, Europe and Canada. Current guideline-based approaches involve multi-drug regimens that may cause severe side effects and treatment can be as long as two years or more.

The prevalence of human disease attributable to NTM has increased over the past two decades. In a decade long study (1997 to 2007), researchers found that the prevalence of NTM in the US is increasing at approximately 8% per year and that NTM patients on Medicare over the age of 65 are 40% more likely to die over the period of the study than those who did not have the disease. A 2015 publication with co-authors from several US government departments projected 181,037 national annual cases in 2014 costing the US healthcare system approximately $1.7 billion.

For more information about NTM lung disease, visit NTMfacts.com.

About ARIKAYCE

ARIKAYCE, or liposomal amikacin for inhalation, is a novel, once daily formulation of amikacin that is in late stage clinical development for patients with NTM lung disease. Amikacin solution for parenteral administration is an established drug that is effective against a variety of NTM; however, its use is limited by the need to administer it intravenously and by toxicity to hearing, balance, and kidney function. Insmed’s advanced pulmonary liposome technology uses charge neutral liposomes to deliver amikacin directly to the lung where it is taken up by the lung macrophages where the NTM infection resides. This prolongs the release of amikacin in the lungs while minimizing systemic exposure thereby offering the potential for decreased systemic toxicities. ARIKAYCE’s ability to deliver high levels of amikacin directly to the lung distinguishes it from intravenous amikacin. ARIKAYCE is administered once daily using an optimized, investigational eFlow® Nebulizer System manufactured by PARI Pharma GmbH, a novel, highly efficient and portable aerosol delivery system.

About PARI Pharma and the eFlow® Electronic Nebulizer

Arikayce is delivered by a novel, inhalation device, the eFlow® Electronic Nebulizer, developed by PARI Pharma GmbH. eFlow is a quiet, portable nebulizer that enables efficient aerosolization of liquid medications, including liposomal formulations such as Arikayce, via a vibrating, perforated membrane. Based on PARI's 100-year history working with aerosols, PARI Pharma is dedicated to advancing inhalation therapies by developing innovative platforms and new pharmaceutical formulations that work together to improve patient care.

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Source: Insmed Incorporated