Insmed Announces Upcoming Data Presentations at the American Thoracic Society 2015 International Meeting

BRIDGEWATER, N.J.--(BUSINESS WIRE)-- Insmed Incorporated (Nasdaq:INSM), a global biopharmaceutical company focused on developing orphan treatments for rare pulmonary diseases, today reported that three ARIKAYCE™ abstracts and three INS1009 abstracts will be presented at the American Thoracic Society (ATS) 2015 International Conference taking place in Denverfrom May 15 - 20. ARIKAYCE, or liposomal amikacin for inhalation, is in late-stage development for the treatment of adult patients with nontuberculous mycobacterial (NTM) lung infections caused by Mycobacterium avium complex (MAC). INS1009, an inhaled prodrug formulation of treprostinil, is the company's clinical candidate for pulmonary arterial hypertension.

Summarized below are the poster titles and presentation times. The ATS abstracts are available online at the conference website at http://conference.thoracic.org/2015/.

Poster Session: Preclinical Trials in Pulmonary Hypertension Models: Novel Targets and Delivery

Date: Sunday, May 17, 2015
Session Time: 9:30 AM-4:15 PM
Poster Viewing: 11:30-1:15

Abstract Title: A 14-Day Assessment of the Tolerability and Pharmacokinetics (Pk) with a Nanoparticle Formulation of Hexadecyl-Treprostinil, a Long-Acting Pulmonary Vasodilator, In Rats
Lead Author: V. Malinin, PhD
Poster Board: #P496
Publication Number: A1948

Abstract Title: Prolonged Pharmacokinetic Profile of a Prodrug Lipid Nanoparticle Formulation of Treprostinil in Dogs
Lead Author: F.G. Leifer, PhD
Poster Board: #P499
Publication Number: A1951

Abstract Title: Effect of a Lipid Nanoparticle Prodrug Formulation of Treprostinil on the Cough Reflex in Guinea Pigs
Lead Author: R.W. Chapman, PhD
Poster Board: #P500
Publication Number: A1952

Poster Session: Diagnosis and Management of Nontuberculous Mycobacteria Infections

Date: Wednesday, May 20, 2015
Session Time: 1:30 PM-3:30 PM
Poster Viewing: 1:30-2:15

Abstract Title: Subgroup Analyses of Baseline Demographics and Efficacy in Patients with Refractory Nontuberculous Mycobacteria (NTM) Lung Infection Treated with Liposomal Amikacin for Inhalation (LAI)
Lead Author: K.L. Winthrop, MD
Poster Board: #610
Publication Number: A6294

Abstract Title: Efficacy of Liposomal Amikacin for Inhalation (LAI) in Achieving Nontuberculous Mycobacteria (NTM) Culture Negativity in Patients Whose Lung Infection is Refractory to Guideline-Based Therapy
Lead Author: J.A. Biller, MD
Poster Board: #611
Publication Number: A6295

Abstract Title: Analysis of Functional Exercise Capacity (Via the Six-Minute Walk Test [6MWT]) and Culture Negativity in Patients with Nontuberculous Mycobacteria (NTM) Lung Infection Refractory to Guideline-Based Therapy Treated with Liposomal Amikacin for Inhalation (LAI)
Lead Author: S.J. Ruoss, MD
Poster Board: #612
Publication Number: A6296

About ARIKAYCE

ARIKAYCE is a form of the antibiotic amikacin, which is enclosed in nanocapsules of lipid called liposomes. This advanced pulmonary liposome technology prolongs the release of amikacin in the lungs while minimizing systemic exposure. The treatment uses biocompatible lipids endogenous to the lung that are formulated into small (0.3 micron), charge-neutral liposomes. 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 eFlow® Technology and PARI Pharma

ARIKAYCE is delivered by an investigational eFlow® Nebulizer System developed by PARI Pharma and optimized specifically for ARIKAYCE. The optimized device uses eFlow Technology to enable highly efficient aerosolization of medication including liposomal formulations via a vibrating, perforated membrane that includes thousands of laser-drilled holes. Compared with other nebulization technologies, eFlow Technology produces aerosols with a very high density of active drug, a precisely defined droplet size and a high proportion of respirable droplets delivered in the shortest possible period of time. eFlow Technology is not an ultrasonic nebulizer technology and is not a general purpose electronic aerosol generator nebulizer technology. Combined with its quiet mode of operation, small size, light weight and battery use, eFlow Technology reduces the burden of taking daily, inhaled treatments.

About Nontuberculous Mycobacteria (NTM)

Nontuberculous mycobacteria (NTM) are organisms found in the soil and water that can cause serious lung disease in susceptible individuals, for which there are currently limited effective treatments and no approved therapies. The prevalence of NTM disease is reported to be increasing, and according to reports from the American Thoracic Society is believed to be greater than that of tuberculosis in the U.S. According to the National Center for Biotechnology Information, epidemiological studies show that presence of NTM infection is increasing in developing countries, perhaps because of the implementation of tap water. Women with characteristic phenotype are believed to be at higher risk of acquiring NTM infection along with patients with defects on cystic fibrosis transmembrane conductance regulators.

NTM lung disease is often a chronic condition that can lead to progressive inflammation and lung damage, and is characterized by bronchiectasis and cavitary disease. NTM infections often require lengthy hospital stays for medical management. Treatment usually involves multi-drug regimens that can be poorly tolerated and have limited effectiveness, especially in patients with severe disease or in those who have failed prior treatment attempts. According to a company-sponsored patient chart study conducted by Clarity Pharma Research, approximately 50,000 patients suffering from NTM lung disease visited physician offices in the U.S. during 2011.

About INS1009

INS1009, the company's inhaled treprostinil prodrug for the treatment of pulmonary arterial hypertension (PAH), a chronic, life-threatening disorder characterized by abnormally high blood pressure in the arteries between the heart and lungs. Insmed has applied its product design, drug development and sustained-release formulation expertise to advance INS1009 with the goal of addressing current limitations of inhaled prostacyclin therapies in the treatment of PAH. INS1009 is expected to be delivered once-daily via inhalation. It is designed to provide consistent, effective drug levels and may also reduce the acute systemic effects of current treatment options.

About Pulmonary Arterial Hypertension (PAH)

Pulmonary arterial hypertension, or PAH, is a chronic, life-threatening form of pulmonary hypertension that is characterized by abnormally high blood pressure in the arteries between the heart and lungs. Pulmonary

arteries carry blood from the heart to the lungs, where it picks up oxygen to be delivered throughout the body. In PAH, the pulmonary arteries constrict abnormally. This forces the heart to pump harder to maintain adequate blood flow, which causes blood pressure within the lungs to rise. Common early symptoms include shortness of breath, fatigue, weakness, chest pain and syncope (fainting), particularly during physical activity. PAH worsens over time and is life-threatening because the pressure in a patient's pulmonary arteries rises to dangerously high levels, which strains the heart and may lead to heart failure. The one-year mortality rate among patients with PAH is 15% despite currently available treatments. The cause of some cases of PAH is unknown and there is no cure. PAH is considered an orphan disease, afflicting 30,000 to 40,000 people in the U.S. and 200,000 people globally.

There are several prescription medications approved by the U.S. Food and Drug Administration (FDA) to treat the symptoms of PAH and patients typically are treated with combination therapy including endothelin receptor antagonists, PDE-5 inhibitors and prostacyclin agonists. With annual sales exceeding $1 billion, prostacyclins are the preferred choice for treating late-stage disease. Prostacyclin formulations used to treat PAH include oral, intravenous, subcutaneous and inhaled formulations. All existing prostacyclin compounds have the limitation of a short half-life in the body and require multiple dosing sessions per day for inhaled and oral formulations, or the invasiveness of continuous infusion for injectable formulations.

About Insmed

Insmed Incorporated is a biopharmaceutical company dedicated to improving the lives of patients battling serious lung diseases. Insmed is focused on the development and commercialization of ARIKAYCE, or liposomal amikacin for inhalation, for at least two identified orphan patient populations: patients with nontuberculous mycobacteria (NTM) lung infections and cystic fibrosis (CF) patients with Pseudomonas aeruginosa lung infections. Insmed is also focused on the development of INS1009, the company's inhaled treprostinil prodrug for the treatment of pulmonary arterial hypertension (PAH), a chronic, life-threatening disorder characterized by abnormally high blood pressure in the arteries between the heart and lungs.

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