Insmed Announces Multiple Clinical and Scientific Presentations at European Respiratory Society's International Congress 2014

BRIDGEWATER, NJ -- (Marketwired) -- 09/03/14 -- Insmed Incorporated (NASDAQ: INSM) announces that the Company's novel inhalation technologies for the treatment of orphan pulmonary diseases will be highlighted in a variety of clinical and scientific presentations at the European Respiratory Society's (ERS) International Congress 2014, taking place September 6-10, 2014 at the Internationales Congress Center München in Munich, Germany.

There will be several presentations regarding the Company's lead product ARIKAYCE™, or liposomal amikacin for inhalation delivered by an investigational eFlow® Nebulizer System (PARI Pharma GmbH), for the treatment of both nontuberculous mycobacteria lung infections (NTM) and Pseudomonas aeruginosa in cystic fibrosis patients. In addition, the Company will present several posters regarding INS-1009 (treprostinil), the Company's novel inhalation formulation of a proven prostacyclin 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 INS-1009 with the goal of addressing current limitations of inhaled prostacyclin therapies in the treatment of PAH. INS-1009 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.

"We believe INS-1009 and its sustained-release inhaled formulation of prostacyclin may prolong duration of effect and provide greater consistency in the reduction of pulmonary arterial pressure over time. As a result, this may reduce the acute impact of drug treatment on heart rate, blood pressure and the severity and/or frequency of cough. Moreover, current inhaled prostacyclin therapies must be dosed four to nine times per day. Reducing dose frequency to once-daily would ease patient burden and may positively impact compliance," stated Walter Perkins, Ph.D., Chief Technology Officer of Insmed.

"We are particularly pleased to have the depth of data presented on ARIKAYCE in both NTM and Pseudomonas aeruginosa in cystic fibrosis patients as we move forward with plans to submit for licensure with the European Medicines Agency in both indications. In addition, the introduction of INS-1009 is testament to our innovative research and development team and underscores our commitment to new treatments for orphan lung diseases. We believe we can address the current limitations of inhaled prostacyclin therapies in PAH with our proven design, development and formulation expertise," noted Will Lewis, President and Chief Executive Officer of Insmed.

Information on the presentations is as follows (all times are local):

Session 109: Thematic Poster Session: The epidemiology of respiratory infections and lung cancer
Title: Comparison of treatment practices for nontuberculous mycobacterial pulmonary disease in Japan, Europe and United States
Day/Date: Sunday, September 7, 2014
Session Time: 12:50 p.m. - 2:40 p.m.
Poster Board: #P1066
Room: Hall B2-29

Session 109: Thematic Poster Session: The epidemiology of respiratory infections and lung cancer
Title: Annual prevalence and treatment estimates of nontuberculous mycobacterial pulmonary disease

in Europe: A NTM-NET collaborative study
Day/Date: Sunday, September 7, 2014
Session Time: 12:50 p.m. - 2:40 p.m.
Poster Board: #P1067
Room: Hall B2-29

Session 257: Thematic Poster Session: Pulmonary hypertension: novel targets and drugs
Title: Incorporation into lipid nanoparticles extends the duration of activity of treprostinil in an acute hypoxia rat model of pulmonary arterial hypertension
Day/Date: Monday, September 8, 2014
Session Time: 12:50 p.m. - 2:40 p.m.
Poster Board: #P2357
Room: Hall B2-19

Session 257: Thematic Poster Session: Pulmonary hypertension: novel targets and drugs
Title: Treprostinil prodrugs for pulmonary arterial hypertension evaluated in cAMP profiling studies in live CHO-K1 cells
Day/Date: Monday, September 8, 2014
Session Time: 12:50 p.m. - 2:40 p.m.
Poster Board: #P2358
Room: Hall B2-19

Session 257: Thematic Poster Session: Pulmonary hypertension: novel targets and drugs
Title: Prolonged activity of inhaled treprostinil prodrug-nanoparticles in a rat model of pulmonary arterial hypertension
Day/Date: Monday, September 8, 2014
Session Time: 12:50 p.m. - 2:40 p.m.
Poster Board: #P2356
Room: Hall B2-19

Session 257: Thematic Poster Session: Pulmonary hypertension: novel targets and drugs
Title: Treprostinil pharmacokinetics in rats are extended using inhaled prodrug formulations
Day/Date: Monday, September 8, 2014
Session Time: 12:50 p.m. - 2:40 p.m.
Poster Board: #P2367
Room: Hall B2-19

Session 381: Oral Presentation: Cystic fibrosis: assessment and treatment
Title: Interim data from a long-term safety, tolerability and efficacy study of liposomal amikacin for inhalation in cystic fibrosis patients with chronic Pseudomonas aeruginosa infection
Day/Date: Tuesday, September 9, 2014
Session Time: 10:45 a.m. - 12:45 p.m.
Publication Page: OP3445
Discussion: 11:15 a.m.
Room: Room 5

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 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 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 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. For more information, visit www.insmed.com.

Forward-Looking Statements

This release contains forward-looking statements. Words, and variations of words, such as "intend," "expect," "will," "anticipate," "believe," "continue," "propose" and similar expressions are intended to identify forward-looking statements. Investors are cautioned that such statements in this release, including statements relating to the status, results and timing of clinical trials and clinical data, the anticipated benefits of Insmed's products, the anticipated timing of regulatory submissions, and the ability to obtain required regulatory approvals, bring products to market and successfully commercialize products constitute forward-looking statements that involve risks and uncertainties that could cause actual results to differ materially from those in the forward-looking statements. Such risks and uncertainties include, without limitation, market conditions, failure or delay of European, Canadian, U.S. Food and Drug Administration and other regulatory reviews and approvals, competitive developments affecting the Company's product candidates, delays in product development or clinical trials or other studies, patent disputes and other intellectual property developments relating to the Company's product candidates, unexpected regulatory actions, delays or requests, the failure of clinical trials or other studies or results of clinical trials or other studies that do not meet expectations, the fact that subsequent analyses of clinical trial or study data may lead to different (including less favorable) interpretations of trial or study results or may identify important implications of a trial or study that are not reflected in Company's prior disclosures, and the fact that trial or study results or subsequent analyses may be subject to differing interpretations by regulatory agencies, the inability to successfully develop the Company's product candidates or receive necessary regulatory approvals, the inability to make product candidates commercially successful, changes in anticipated expenses, changes in the Company's financing requirements or ability to raise additional capital, and other risks and challenges detailed in the Company's filings with the U.S. Securities and Exchange Commission, including its Annual Report on Form 10-K for the year ended December 31, 2013 and its subsequent quarterly reports on Form 10-Q. Investors are cautioned not to place undue reliance on any forward-looking statements that speak only as of the date of this news release. The Company undertakes no obligation to update these forward-looking statements to reflect events or circumstances or changes in its expectations.

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