Insmed Announces FDA Clearance of IND for Pivotal Phase 3 Trial of ARIKACE™ in Nontuberculous Mycobacteria Indication

RICHMOND, Va., March 21, 2011 /PRNewswire/ -- Insmed Incorporated (Nasdaq: INSMD), a biopharmaceutical company, announced today that the Company's Investigational New Drug Application (IND) to conduct a pivotal Phase 3 clinical trial of ARIKACE™ (liposomal amikacin for inhalation) in nontuberculous mycobacteria (NTM) lung infections has been cleared by the U.S. Food and Drug Administration (FDA).

In 2010, Insmed initially submitted a regulatory filing to FDA requesting clearance to proceed with a Phase 2 clinical trial for ARIKACE in NTM. FDA responded by suggesting that the Company could change the proposed Phase 2 trial to a primary efficacy study. Based on this feedback, Insmed submitted its IND seeking FDA clearance to initiate a Phase 3 clinical trial of ARIKACE in NTM earlier in the first quarter of this year.

Development of the clinical program aimed at NTM infections was done in partnership with the National Institute of Allergy and Infectious Diseases (NIAID) at the National Institutes of Health. According to Kenneth Oliver, M.D., M.P.H., staff pulmonologist in the NIAID Laboratory of Clinical Infectious Diseases, current NTM treatment requires lengthy multi-drug regimens that can be poorly tolerated and are often not very effective, especially in patients with severe disease or in those who have failed prior treatment attempts.

No new drugs have been assessed for NTM in a significant number of years. The sustained-release formulation of ARIKACE allows for targeting of the drug to the lungs and the site of disease.

"FDA clearance of our IND to conduct a pivotal Phase 3 clinical trial for ARIKACE in NTM is a critical step in continuing to advance our development plan for this compound," said Renu Gupta, M.D., Executive Vice President Development & Chief Medical Officer of Insmed. "We continue to expect that patient accrual will begin in our Phase 3 clinical trials of ARIKACE in NTM, as well as in the cystic fibrosis Pseudomonas lung infections indication, in the second half of this year. Data in both indications are expected during the first half of 2013."

About Insmed

Insmed Incorporated is a biopharmaceutical company focused on the development of innovative inhaled pharmaceuticals for the site-specific treatment of serious lung diseases, and has a proprietary protein platform aimed at niche markets with unmet medical need. Insmed's primary focus is on the development of inhaled antibiotic therapy delivered via proprietary advanced pulmonary liposome technology in areas of high unmet need in lung diseases. For more information, please visit http://www.insmed.com.

About ARIKACE™

ARIKACE™ 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 that enable penetration of the biofilm. ARIKACE is administered once daily using an optimized, investigational eFlow® Nebulizer System (PARI Pharma GmbH), a novel, highly efficient and portable aerosol delivery system enabling more effective distribution in the lungs.

ARIKACE has been granted orphan drug status in the United States by the FDA, and has received an orphan drug designation in Europe by the European Medicines Agency for the treatment of Pseudomonas infections in patients with CF. The Company intends to file for orphan drug designation for NTM lung infections in both the

United States and the European Union by the end of 2011.

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. NTM lung disease is often a chronic condition that can lead to progressive inflammation and lung damage, characterized by bronchiectasis and cavitary disease. NTM infections often require lengthy hospital stays for medical management. Treatment usually involves lengthy multi-drug regimens that can be poorly tolerated and with limited effectiveness, especially in patients with severe disease or in those who have failed prior treatment attempts. According to a proprietary SDI Healthcare Database, in the U.S. in 2008, there were approximately 32,000 patients who had a physician office visit for a primary diagnosis of NTM, and about 14,400 patients who had a hospital visit with an NTM diagnosis.

About eFlow® Technology and PARI Pharma

ARIKACE is delivered by an optimized, investigational eFlow® Nebulizer System developed by PARI Pharma and optimized specifically for ARIKACE. The optimized, investigational eFlow Nebulizer System 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 to 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 it 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. PARI Pharma focuses on the development of aerosol delivery devices and comprehensive inhalation drug development to advance aerosol therapies where drug and device can be optimized together. Online at www.paripharma.com.

Forward-Looking Statements

This release contains forward-looking statements which are made pursuant to provisions of Section 21E of the Securities Exchange Act of 1934. Investors are cautioned that such statements in this release, including statements relating to the results of clinical trials, the development of our products, or the business strategies, plans and objectives of management, constitute forward-looking statements which involve risks and uncertainties that could cause actual results to differ materially from those anticipated by the forward-looking statements. The risks and uncertainties include, without limitation, we may be unsuccessful in developing our product candidates or receiving necessary regulatory approvals, we may experience delays in our product development or clinical trials, our product candidates may not prove to be commercially successful, our expenses may be higher than anticipated and other risks and challenges detailed in our filings with the U.S. Securities and Exchange Commission, including our Annual Report on Form 10-K for the year ended December 31, 2010. Readers are cautioned not to place undue reliance on any forward-looking statements which speak only as of the date of this release. We undertake no obligation to publicly release the results of any revisions to these forward-looking statements that may be made to reflect events or circumstances that occur after the date of this release or to reflect the occurrence of unanticipated events.

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