Insmed Incorporated Provides Update on Clinical Program for ARIKACE®

MONMOUTH JUNCTION, N.J., Feb. 10, 2012 /PRNewswire/ -- Insmed Incorporated (Nasdaq CM: INSM), a biopharmaceutical company, today announced that the Company is proceeding with a phase 2 clinical trial of ARIKACE® (liposomal amikacin for inhalation) in patients with non-tuberculous mycobacteria (NTM) lung disease, as well as the previously planned European registration phase 3 clinical study of ARIKACE in Cystic Fibrosis (CF) patients with Pseudomonas aeruginosa (Pa) lung infections. Simultaneously, Insmed continues its discussions with the U.S. Food and Drug Administration (FDA) regarding the clinical hold previously placed on the ARIKACE clinical study in CF patients with Pa lung infections.

"I am pleased to announce that we are moving forward with the ARIKACE clinical development program in NTM in the U.S., and with the European CF program," said Timothy Whitten, President and CEO of Insmed. "We look forward to continuing our dialogue with FDA regarding the CF clinical program in the U.S., and continue to believe that ARIKACE has the potential to be an important treatment option for CF and NTM patients."

The phase 2 clinical trial for ARIKACE in NTM patients will consist of a randomized, placebo-controlled study of approximately 100 adult patients with recalcitrant NTM lung disease. Patients who are NTM culture positive will continue with their antibiotic treatment regimen, and receive additionally, either ARIKACE 560 mg, delivered once daily via an optimized, investigational eFlow® Nebulizer System (PARI Pharma GmbH), or placebo once daily. The primary efficacy endpoint will be change in mycobacterial density from baseline to the end of 84 days of treatment. At the conclusion of the randomized portion of the study, eligible patients will receive ARIKACE 560 mg once daily for an additional 84 days in an open-label design, primarily to measure longer-term safety and efficacy. The clinical trial design was previously agreed upon by Insmed and FDA. The Company expects to begin enrolling patients in the phase 2 clinical trial in mid-2012.

The European study in CF patients with Pa lung infections will be a randomized, phase 3 trial comparing ARIKACE 560 mg, delivered once daily via an optimized, investigational eFlow Nebulizer System, to TOBI®(1) (inhaled tobramycin solution), which is a marketed inhaled antibiotic that is delivered twice daily. The Company anticipates that the study will be conducted in approximately 300 patients. The primary endpoint will be change in pulmonary function (FEV-1) measured after three 28 day on-treatment and three 28 day off-treatment cycles (about six months). A key secondary endpoint will be time to pulmonary exacerbation. The study design was previously agreed upon by Insmed and the European Medicines Agency. Eligible patients will have the option to participate in a longer term open-label safety study. The Company expects to begin enrolling patients in the phase 3 European clinical study in the second quarter of 2012.

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 high 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 eFlow® Technology and PARI Pharma

ARIKACE is delivered by an investigational eFlow® Nebulizer System developed by PARI Pharma and optimized specifically for ARIKACE. 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 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 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 our financial position, results of operations, the status and the results of preclinical studies and clinical trials and preclinical and clinical data described herein, the timing of responses to information and data requests from FDA, the development of our products, and 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. Our results may be affected by such factors as the receipt and timing of FDA and other regulatory reviews and approvals, if at all, competitive developments affecting our product development, delays in product development or clinical trials, and patent disputes involving currently developing products. The risks and uncertainties include, without limitation, we may experience unexpected regulatory actions, delays or requests, our future clinical trials may not be successful, 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 endedDecember 31, 2010 and our Quarterly Report on Form 10-Q for the quarter ended September 30, 2011. Investors 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.

(1) TOBI® is a Registered Trademark of Novartis Pharmaceuticals Corporation

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