Insmed Announces First Patient Dosed in Pivotal European Phase 3 Clinical Study of ARIKACE® in Cystic Fibrosis Patients with Pseudomonas Lung Infections

MONMOUTH JUNCTION, N.J., April 16, 2012 /PRNewswire/ -- Insmed Incorporated (Nasdaq CM: INSM), a biopharmaceutical company, today announced the initiation of the Company's CLinical Evaluation of ARIKACE phase 3 study (CLEAR-108) of ARIKACE® (liposomal amikacin for inhalation) in Europe for Cystic Fibrosis (CF) patients with Pseudomonas aeruginosa (Pa) lung infections.

"The initiation of this clinical trial represents an important milestone for Insmed as we advance our ARIKACE program," said Timothy Whitten, President and CEO of Insmed. "Even with currently available treatments, chronic Pa lung infections remain a significant medical issue for CF patients, and we believe ARIKACE has the potential to be an important treatment option for these patients. In our randomized, placebo controlled phase 2 clinical study, ARIKACE demonstrated statistically significant improvement in lung function over the course of one complete 28-day on-treatment and 28-day off-treatment cycle in CF patients with Pa lung infections. Our goal is to confirm the benefits of ARIKACE in this phase 3 trial."

CLEAR-108 is a randomized, phase 3 trial comparing ARIKACE 560 mg, delivered once daily via an optimized, investigational eFlow® Nebulizer System (PARI Pharma GmbH), to TOBI®(1) (inhaled tobramycin solution), which is a commercially available 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, called CLEAR-110. The study's Principal Investigator is Diana Bilton, M.D., Director of Adult CF Centre at the Royal Brompton Hospital in London, England.

Top-line data from CLEAR-108 are currently expected to be available in the second 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. Insmed's primary focus is on the development of inhaled antibiotic therapy delivered via proprietary advanced liposomal pulmonary technology in areas of high unmet need. 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 and costs associated with pre-clinical studies and clinical trials, 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 ended December 31, 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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