Insmed Announces CLEAR-108 Phase 3 Clinical Study of ARIKACE® in Cystic Fibrosis Patients with Pseudomonas Lung Infections Has Completed Target Enrollment

MONMOUTH JUNCTION, N.J., Nov. 13, 2012 /PRNewswire/ -- Insmed Incorporated (Nasdaq CM: INSM), a biopharmaceutical company focused on developing inhaled therapeutics for serious diseases of the lung, today announced that the Company's CLinical Evaluation of ARIKACE (CLEAR-108) phase 3 European and Canadian registrational study of ARIKACE® (liposomal amikacin for inhalation) for Cystic Fibrosis (CF) patients with Pseudomonas aeruginosa (Pa) lung infections has now enrolled over 300 patients.

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) (tobramycin solution for inhalation), which is a commercially available inhaled antibiotic that is delivered twice daily. The study is being conducted in over 300 patients in Europe and Canada.

"The completion of enrollment in this pivotal phase 3 clinical trial represents an important milestone for Insmed as we advance ARIKACE closer to commercialization," said Will Lewis, President and CEO of Insmed. "We continue to expect top-line data from CLEAR-108 to be available in mid-2013."

About Insmed

Insmed Incorporated is a biopharmaceutical company dedicated to improving the lives of patients battling serious orphan lung diseases through the development and commercialization of novel, targeted inhalation therapies in orphan patient populations with critical unmet needs. Insmed's lead candidate, ARIKACE®, is engineered to deliver a proven and potent anti-infective directly to the site of serious lung infections to improve the efficacy, safety and convenience of treatment for at least two identified patient populations: cystic fibrosis (CF) patients with Pseudomonas lung infections and patients with nontuberculous mycobacteria lung infections (NTM). Following positive phase 2 results in CF patients, Insmed's phase 3 registrational study of ARIKACE (CLEAR-108) in Europe and Canada is well underway, as is the U.S. Phase 2 trial in NTM (TARGET-NTM). The Company expects to report clinical results from both the CF Phase 3 and NTM Phase 2 studies in 2013 and currently is preparing for regulatory filings and for commercialization, if and when regulatory approvals are obtained. 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. 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 results of pre-clinical studies and clinical trials and pre-clinical and clinical data and the anticipated benefits of Insmed's products, constitute forward-looking statements which 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, failure or delay of U.S. Food and Drug Administration and other regulatory reviews and approvals, competitive developments affecting our product development, delays in product development or clinical trials, patent disputes involving currently developing products, unexpected regulatory actions, delays or requests, the failure of future clinical trials, inability to successfully develop our product candidates or receive necessary regulatory approvals, inability to make product candidates commercially successful, changes in anticipated expenses, 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 and our Quarterly Report on Form 10-Q for the quarter ended September 30, 2012. 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 update these forward-looking statements to reflect events or circumstances or changes in our expectations.

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

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