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Insmed Announces First Patient Dosed in TARGET-NTM Phase 2 Clinical Trial of ARIKACE® in Patients with Non-Tuberculous Mycobacteria (NTM) Lung Disease

MONMOUTH JUNCTION, N.J., June 27, 2012 [/PRNewswire/](#) -- Insmed Incorporated (Nasdaq CM: INSM), a biopharmaceutical company, today announced that the first patient has been dosed in the Company's U.S. phase 2 clinical study of ARIKACE® (liposomal amikacin for inhalation) in patients with non-tuberculous mycobacterial (NTM) lung disease entitled TARGET-NTM (Treatment with ARIKACE to Realize Greater Efficacy Trial).

"The prevalence of this debilitating chronic disease continues to grow, and the current NTM treatment paradigm lacks acceptable treatment options," said Mark Rolfe, M.D. FCCP, President of New Lung Associates P.A., Medical Director of the Lung Transplant and Adult Cystic Fibrosis Programs at Tampa General Hospital, where the first patient in the trial was dosed. "Many of these patients are treated with combinations of antibiotics which have shown limited efficacy and are poorly tolerated, especially when given long term. It has been many years since we had a promising new treatment to study in these patients, and I believe that if ARIKACE is successful in clinical trials, such as this one, then it has the potential to become an important treatment option for patients suffering from NTM lung infections."

The Principal Investigator of the study is Kenneth N. Olivier, M.D., M.P.H., staff pulmonologist in the Laboratory of Clinical Infectious Diseases at the National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health.

"The dosing of the first patient in this clinical trial is an important step in the development of ARIKACE," said Timothy Whitten, President and CEO of Insmed. "Individuals who have NTM lung infections are part of a substantially underserved patient population, and if ARIKACE is shown effective in this indication, it could prove to be a significant advancement in the treatment of this orphan disease."

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>.

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 pre-clinical studies and clinical trials and pre-clinical and clinical data described herein, the timing of and costs associated with pre-clinical studies and clinical trials, the development of our products, our estimates of the size of the potential markets for our product candidates, 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 and our Quarterly Report on Form 10-Q for the quarter ended March 31, 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 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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