Insmed Incorporated Announces Lifting of Clinical Hold by U.S. Food and Drug Administration on ARIKACE® in Cystic Fibrosis Patients With Pseudomonas Lung Infections

MONMOUTH JUNCTION, N.J., May 7, 2012 /PRNewswire/ -- Insmed Incorporated (Nasdaq CM: INSM), a biopharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA) has lifted the clinical hold previously placed on ARIKACE® (liposomal amikacin for inhalation) in Cystic Fibrosis (CF) patients with Pseudomonas lung infections.

Insmed has reached agreement with FDA on a revised CF clinical trial population consisting of adult patients who have chronic Pseudomonas lung infections and FEV-1 % predicted between 25% and 75%. The Company is continuing discussions with the Agency in an effort to finalize additional details of the phase 3 study protocol for the potential clinical trial. At the same time, the Company is evaluating possible next steps for the ARIKACE U.S. CF clinical program given the current progress and anticipated resource requirements of the ongoing ARIKACE CF (CLEAR-108) and U.S. non-tuberculous mycobacteria (NTM) clinical programs.

"We are pleased that FDA has lifted the clinical hold on the ARIKACE studies in both CF and, as previously disclosed, in patients with NTM lung disease," said Timothy Whitten, President and CEO of Insmed. "We believe that ARIKACE has the potential to be an important treatment option for CF patients who have Pseudomonas lung infections, and patients who have lung infections due to NTM."

As recently announced, Insmed has begun dosing patients in CLEAR-108, a European and Canadian registrational phase 3 clinical study of ARIKACE in CF patients, and is proceeding with CLEAR-110, a follow-on multi-cycle open-label study intended primarily to measure safety and tolerability for patients who complete CLEAR-108. The Company also previously announced it is initiating a U.S. phase 2 clinical trial of ARIKACE in NTM.

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 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.

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