Insmed Incorporated Announces Clinical Hold on ARIKACE® Phase 3 Clinical Trials

MONMOUTH JUNCTION, N.J., Aug. 1, 2011 /PRNewswire/ -- Insmed Incorporated (Nasdaq CM: INSM), a biopharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA) has notified the Company that the agency has placed a clinical hold on Insmed's phase 3 clinical trials for ARIKACE® (liposomal amikacin for inhalation) in Cystic Fibrosis (CF) patients with Pseudomonas lung infections and patients with non-tuberculous mycobacterial (NTM) lung disease. A clinical hold is a notification issued by FDA to the sponsor to delay a proposed clinical trial or suspend an ongoing clinical trial. The Company has been informed by FDA that this decision was based on an initial review of the interim results of a long-term rat inhalation carcinogenicity study, recently reported to the agency by Insmed, with ARIKACE. In this study, rats received daily doses of ARIKACE by inhalation for up to two years.

FDA has requested additional information on ARIKACE and data from the rat study. Insmed anticipates being able to supply the currently requested information and data within the next 30 days.

As a result of the clinical hold, the Company has suspended initiation of the ARIKACE phase 3 clinical trial programs, including the recruitment and enrollment of patients. To date, no patients have been dosed in the pending clinical trials. The clinical hold will remain in effect at least until FDA reviews the information and data that is provided by Insmed.

"We will work closely with FDA to provide the agency with all appropriate information and data required to expedite their review and evaluation," said Timothy Whitten, President and CEO of Insmed. "Once FDA has completed its review, we can better assess the impact this clinical hold might have on our phase 3 clinical programs for ARIKACE in CF and 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 pulmonary liposome technology in areas of high unmet need in lung diseases. 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 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 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, 2010. 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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