Insmed Incorporated Provides Corporate Update

MONMOUTH JUNCTION, N.J., Jan. 20, 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 patients with non-tuberculous mycobacteria (NTM) lung disease. Insmed continues to engage in discussions with FDA regarding the clinical hold placed on ARIKACE in Cystic Fibrosis (CF) patients with Pseudomonas lung infections.

The clinical holds placed on the ARIKACE programs in NTM and CF were based on an initial review by FDA of the results reported by Insmed of a long-term rat inhalation carcinogenicity study of ARIKACE.

FDA previously requested that Insmed conduct a phase 2 clinical trial of ARIKACE in adult patients with NTM to provide proof-of-concept efficacy and safety data before proceeding with a phase 3 clinical trial. As part of its on-going assessment of the appropriate path forward for the ARIKACE program, including the phase 2 trial of ARIKACE in NTM patients, the Company is continuing communication with FDA regarding the CF clinical hold.

Insmed also announced that it will move ahead with the 9-month dog inhalation toxicity study of ARIKACE as previously requested by FDA to determine if the findings of the rat inhalation carcinogenicity study are observed in a non-rodent model.

"We are pleased that FDA has lifted the clinical hold on the ARIKACE development program in NTM," said Timothy Whitten, President and CEO of Insmed. "Insmed continues to work closely with regulatory authorities regarding the development program for ARIKACE. We are initiating the work required to begin the 9-month dog study during the second quarter and are continuing our dialogue with FDA regarding the CF clinical program."

Insmed also announced that IPLEX® inventory has now been fully depleted. At present, about 10 patients remain on drug. Regarding potential future IPLEX initiatives, the Company is currently evaluating possible out-licensing opportunities for the drug.

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, and has a proprietary protein platform aimed at niche markets with high unmet medical need. 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 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, 2010 and our Quarterly Report on Form 10-Q for the quarter ended September 30, 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.

Investor Relations Contact:
Brian Ritchie — FTI Consulting
212-850-5683
brian.ritchie@fticonsulting.com

Media Contact:
Irma Gomez-Dib — FTI Consulting
212-850-5761
irma.gomez-dib@fticonsulting.com