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Insmmed Incorporated Provides Regulatory Update on ARIKACE® in Non-Tuberculous Mycobacteria Indication

MONMOUTH JUNCTION, N.J., Oct. 14, 2011 /[PRNewswire](#)/ -- Insmmed Incorporated (Nasdaq CM: INSM), a biopharmaceutical company, today announced that the Company has been notified by the U.S. Food and Drug Administration (FDA) that it is continuing the clinical hold previously placed on Insmmed's phase 3 clinical trial for ARIKACE® (liposomal amikacin for inhalation) in patients with non-tuberculous mycobacterial (NTM) lung disease.

As announced on August 1, 2011, the clinical holds placed on ARIKACE in NTM and Cystic Fibrosis (CF) patients with Pseudomonas lung infections were based on an initial review by FDA of the interim results of a long-term rat inhalation carcinogenicity study reported to the Agency by Insmmed with ARIKACE. At that time, FDA requested additional information on ARIKACE and data from the rat study. Insmmed submitted its complete response to this request before the end of August.

Insmmed has been informed by FDA that, based on its review of the information provided to date, including the rat inhalation carcinogenicity study results, the Agency has insufficient information to assess the risks of ARIKACE in NTM patients in the planned phase 3 clinical trial. FDA is requiring that Insmmed conduct a phase 2 clinical trial in adult NTM patients intended to provide proof-of-concept efficacy and safety data for ARIKACE in NTM before the Company can proceed with a phase 3 clinical trial. In addition, Insmmed will also need to further revise the assessment of the rat carcinogenicity study findings in the investigator brochure.

"Now that we have responses from FDA with respect to both clinical holds, we are seeking further input from the Agency in order to gain a better understanding of their requests regarding CF and NTM," said Timothy Whitten, President and CEO of Insmmed. "Once we have received clarifications from FDA on their requests, and have sufficient opportunity to evaluate potential next steps, we will provide a further update to the market."

About Insmmed

Insmmed 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. Insmmed'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 June 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.

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