Insmed Incorporated Provides Regulatory Update

MONMOUTH JUNCTION, N.J., Oct. 10, 2011 /PRNewswire/ -- Insmed 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 Insmed's phase 3 clinical trials for ARIKACE® (liposomal amikacin for inhalation) in Cystic Fibrosis (CF) patients with Pseudomonas lung infections. Insmed has not yet received a response from FDA regarding the clinical hold previously placed on Insmed's phase 3 clinical trials for ARIKACE in patients with non-tuberculous mycobacterial (NTM) lung disease.

As announced on August 1, 2011, the clinical holds placed on ARIKACE in CF and NTM 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 Insmed with ARIKACE. At that time, FDA requested additional information on ARIKACE and data from the rat study. Insmed submitted its complete response to this request before the end of August.

Insmed 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 for ARIKACE in CF patients. FDA has requested additional information from the Company, including that Insmed conduct a dog inhalational 9-month toxicity study of ARIKACE to determine if the findings of the rat inhalation carcinogenicity study are also demonstrated in a non-rodent model, and to propose a CF patient population/disease state where the risk-benefit profile of ARIKACE may be more favorable.

"Insmed is in the process of assessing the impact that FDA's recent requests and the continuation of the clinical hold will have on our phase 3 clinical trials for ARIKACE in CF," said Timothy Whitten, President and CEO of Insmed. "Once we have a better understanding of the FDA's requests and their implications, we will provide a further update to the market."

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 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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