Insmed Announces European Medicines Agency Acceptance of Its Pediatric Investigation Plan for ARIKACE™ in the Cystic Fibrosis Pseudomonas Indication

RICHMOND, Va., March 3, 2011 /PRNewswire/ -- Insmed Incorporated (Nasdaq: INSM), a biopharmaceutical company, announced today that the Pediatric Committee of the European Medicines Agency (EMA) has issued a positive opinion on the Company's Pediatric Investigation Plan (PIP) for ARIKACE™ (liposomal amikacin for inhalation), Insmed's Phase 3-ready compound for cystic fibrosis (CF) Pseudomonas and non-TB mycobacteria (NTM) lung infections. The PIP covers children from birth to 18 years of age with cystic fibrosis that suffer from Pseudomonas lung infections.

An accepted PIP is a pre-requisite for European approval of new drugs, according to legislation passed in Europe in January 2007. The aim of the legislation is to facilitate the development of new medicines for children without subjecting them to unnecessary clinical trials or delaying the authorization of those medicines for use in adults.

"The acceptance of our PIP by the EMA is an important milestone in Insmed's regulatory submission plan for ARIKACE in Europe," said Renu Gupta, M.D., Executive Vice President Development & Chief Medical Officer of Insmed. "As previously disclosed, we intend to initiate our Phase 3 clinical trials for ARIKACE in the CF indication, as well as in NTM, in the second half of this year. Data in both indications are expected during the first half of 2013."

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 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 the results of clinical trials, the development of our products, or 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. The risks and uncertainties include, without limitation, we may be unsuccessful in developing our product candidates, 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, 2009 and Quarterly Report on Form 10-Q for the fiscal quarters ended March 31, 2010, June 30, 2010 and September 30, 2010. Readers 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.