ARIKACE to Receive Orphan Medicinal Product Designation in the European Union to Treat Lung Infections Caused by Nontuberculous Mycobacteria

MONMOUTH JUNCTION, NJ -- (Marketwired) -- 02/10/14 -- Insmed Incorporated (NASDAQ: INSM), a biopharmaceutical company focused on developing an inhaled anti-infective to treat patients battling serious lung diseases in orphan indications that are often life-threatening, today announced that the Committee for Orphan Medicinal Products of the European Medicines Agency (EMA) has issued a positive opinion on the Company's application for orphan designation for ARIKACE®, the Company's liposomal amikacin for inhalation, for the treatment of lung disease caused by nontuberculous mycobacteria (NTM). Orphan drug designation in the European Union (EU) is given to products that are designed for the diagnosis, prevention or treatment of rare diseases that are life-threatening or chronically debilitating.

NTM lung disease is a chronic condition that can lead to progressive inflammation and lung damage, and there is a 40% increase in mortality for patients over 65 years of age.1 Treatment usually involves multi-drug regimens that can be poorly tolerated and have limited effectiveness, especially in patients with severe disease or in those who have failed prior treatment attempts. There is no current treatment approved by the EMA or the U.S. Food and Drug Administration (FDA) for NTM lung disease.

"The EMA's orphan drug designation represents another step forward in our progress towards bringing this important therapy to the approximately 30,000 patients in the European Union in need of an effective therapy to treat NTM lung disease. We have already commenced the Scientific Advice Working Party process with the EMA to discuss a regulatory path forward for ARIKACE to treat NTM lung disease in Europe," noted Will Lewis, President and Chief Executive Officer of Insmed. "We are actively developing a strategy to commercialize ARIKACE globally in this uncontested orphan disease market, and the EMA's decision is an important milestone in support of these efforts."

Orphan designation from the EMA provides a number of incentives, including protocol assistance, scientific advice specific for designated orphan medicines, ten years of market exclusivity once the medicine is on the market and potential fee reductions. ARIKACE has also received Orphan Drug, Qualified Infectious Disease Product and Fast Track designations from the FDA for the treatment of NTM lung infections.

Insmed remains on track to report top-line data from a Phase 2 clinical trial of ARIKACE in the U.S. and Canada to treat NTM lung disease by the end of the first quarter 2014.

About Insmed
Insmed Incorporated is a biopharmaceutical company dedicated to improving the lives of patients battling serious lung diseases. Insmed is focused on the development and commercialization of ARIKACE®, or liposomal amikacin for inhalation, for at least two identified orphan patient populations: patients with non-tuberculous mycobacteria (NTM) lung infections and cystic fibrosis (CF) patients with Pseudomonas aeruginosa lung infections. For more information, please visit http://www.insmed.com.

Forward-looking Statements
This release contains forward-looking statements. Words, and variations of words, such as "intend," "expect," "will," "anticipate," "believe," "continue," "propose" and similar expressions are intended to identify forward-looking statements. Investors are cautioned that such statements in this release, including statements relating to the status, results and timing of clinical trials and clinical data, the anticipated benefits of Insmed's products,

the anticipated timing of regulatory submissions, and the ability to obtain required regulatory approvals, bring products to market and successfully commercialize products constitute forward-looking statements that involve risks and uncertainties that could cause actual results to differ materially from those in the forward-looking statements. Such risks and uncertainties include, without limitation, failure or delay of European, Canadian, U.S. Food and Drug Administration and other regulatory reviews and approvals, competitive developments affecting the Company's product candidates, delays in product development or clinical trials or other studies, patent disputes and other intellectual property developments relating to the Company's product candidates, unexpected regulatory actions, delays or requests, the failure of clinical trials or other studies or results of clinical trials or other studies that do not meet expectations, the fact that subsequent analyses of clinical trial or study data may lead to different (including less favorable) interpretations of trial or study results or may identify important implications of a trial or study that are not reflected in Company's prior disclosures, and the fact that trial or study results or subsequent analyses may be subject to differing interpretations by regulatory agencies, the inability to successfully develop the Company's product candidates or receive necessary regulatory approvals, inability to make product candidates commercially successful, changes in anticipated expenses, changes in the Company's financing requirements or ability raise additional capital, and other risks and challenges detailed in the Company's filings with the U.S. Securities and Exchange Commission, including its Annual Report on Form 10-K for the year ended December 31, 2012. Investors are cautioned not to place undue reliance on any forward-looking statements that speak only as of the date of this news release. The Company undertakes no obligation to update these forward-looking statements to reflect events or circumstances or changes in its expectations.

1 Adjemian et al. Prevalence of Pulmonary Nontuberculous Mycobacterial Disease among Medicare Beneficiaries, USA, 1997-2007

Contacts:
LHA
Anne Marie Fields
Senior Vice President
212-838-3777
afields@lhai.com

Bruce Voss
Managing Director
310-691-7100
bvoss@lhai.com