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MONMOUTH JUNCTION, NJ -- (Marketwire) -- 03/28/13 -- Insmed Incorporated (NASDAQ: INSM), a biopharmaceutical company focused on developing and commercializing inhaled therapies for patients battling serious lung diseases in orphan indications that are often life-threatening, today announced that ARIKACE®, the Company's liposomal amikacin for inhalation, has received orphan drug designation from the U.S. Food and Drug Administration(FDA) Office of Orphan Products Development for the treatment of infections caused by non-tuberculous mycobacteria (NTM).

Orphan drug designation provides certain exclusivity benefits, tax credits for certain research and a waiver of the New Drug Application user fee. According to a recent company-sponsored patient chart study conducted by Clarity Pharma Research, approximately 50,000 cases of NTM lung disease were treated by physicians in the U.S. during 2011. There is no current FDA-approved treatment for NTM lung infection.

"The FDA's timely approval of our request for orphan drug designation for ARIKACE to treat non-tuberculous mycobacteria is a key milestone that supports our broader strategy for this potentially life-saving therapy," stated Will Lewis, President and Chief Executive Officer of Insmed. "NTM is a chronic, debilitating disease, and currently available treatments have shown limited efficacy and tolerability. We continue to enroll patients in our phase 2 clinical trial of ARIKACE to treat NTM patients in the U.S. and Canada and look forward to having top-line data by the end of this year."

About Insmed

Insmed Incorporated is a biopharmaceutical company dedicated to improving the lives of patients battling serious lung diseases through the development and commercialization of inhalation therapies in orphan patient populations with critical unmet needs. Insmed's lead candidate, ARIKACE® or liposomal amikacin for inhalation, is engineered to deliver a proven and potent anti-infective directly to the site of serious lung infections to improve the efficacy, safety and convenience of treatment for at least two identified patient populations: cystic fibrosis (CF) patients with Pseudomonas aeruginosa lung infections and patients with non-tuberculous mycobacteria lung infections (NTM). Insmed's phase 3 registrational study of ARIKACE in Europe and Canadacompleted enrollment and the Company expects top-line clinical results in mid-2013. Insmed's phase 2 clinical trial in patients with NTM is well under way in the U.S. and Canada with clinical results expected in late 2013. For more information, please visit http://www.insmed.com.

Forward-Looking Statements

This release contains forward-looking statements that are made pursuant to provisions of Section 21E of the Securities Exchange Act of 1934. 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 results of preclinical studies and clinical trials and preclinical and clinical data and the anticipated

benefits of Insmed'sproducts, 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 U.S. Food and Drug Administration and other regulatory reviews and approvals, competitive developments affecting our product candidates, delays in product development or clinical trials or other studies, patent disputes and other intellectual property developments relating to our 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, inability to successfully develop our product candidates or receive necessary regulatory approvals, inability to make product candidates commercially successful, changes in anticipated expenses, 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, 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. We undertake no obligation to update these forward-looking statements to reflect events or circumstances or changes in our expectations.