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## Insmed Receives Second Composition Of Matter Patent For ARIKACE®

MONMOUTH JUNCTION, N.J., Aug. 2, 2012 /<u>PRNewswire</u>/ -- Insmed Incorporated (Nasdaq CM: INSM), a biopharmaceutical company focused on developing inhaled therapeutics for serious diseases of the lung, today announced that the U.S. Patent and Trademark Office has issued a new composition of matter patent for ARIKACE® (liposomal amikacin for inhalation), U.S. Patent No. 8,226,975. Amikacin is one of the aminoglycosides covered by the patent. The patent describes a system for treating or providing prophylaxis against pulmonary infections, and includes both of the compound's lead indications, cystic fibrosis (CF) patients who have Pseudomonas lung infections and patients who have non-TB Mycobacteria (NTM) lung infections.

The patent claims a new and unique inhaled treatment system and formulation in which the aerosol delivered to the lung contains a combination of both free unencapsulated aminoglycoside drug that is present outside the liposomes and aminoglycoside drug encapsulated inside liposomes. When delivered, ARIKACE contains both the free and liposomal encapsulated amikacin, which could be beneficial to patients in two ways. The delivery of free amikacin provides immediate bactericidal activity against the initial load of organisms, and the liposome encapsulated amikacin provides sustained bactericidal activity against persistent organisms.

The new patent provides exclusivity at least through May 18, 2027.

"The issuance of this second composition of matter patent expands our already extensive intellectual property position around ARIKACE," said Renu Gupta, M.D., Insmed's Executive Vice President of Development and Chief Medical Officer. "Our ARIKACE development plan is progressing well in both CF and NTM, and we are projecting top-line results in mid-2013 and fourth quarter 2013, respectively."

## 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. Insmed's primary focus is on the development of inhaled antibiotic therapy delivered via proprietary advanced liposomal pulmonary technology in areas of high unmet need. For more information, please visit <u>http://www.insmed.com</u>.

## 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 pre-clinical studies and clinical trials and pre-clinical and clinical data described herein, the timing of and costs associated with pre-clinical studies and clinical trials, the development of our products, our estimates of the size of the potential markets for our product candidates, 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, 2011 and our Quarterly Report on Form 10-Q for the guarter ended March 31, 2012. 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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