



[Home](#) / [Investors](#) / [Press Releases](#)

Insmed Granted Key Composition of Matter Patent Allowance for ARIKACE in Europe

MONMOUTH JUNCTION, NJ -- (Marketwired) -- 05/14/13 -- Insmed Incorporated (NASDAQ: INSM), a biopharmaceutical company focused on developing and commercializing an inhaled anti-infective to treat patients battling serious lung diseases in orphan indications that are often life-threatening, today announced that the European Patent Office intends to grant E.U. Patent No. 1909759 for ARIKACE® (liposomal amikacin for inhalation). Once granted, the composition of matter patent provides exclusivity in any of the European Patent Office's member states where Insmed chooses to file at least through July 19, 2026. The Company's liposomal amikacin for inhalation is in clinical development to treat cystic fibrosis (CF) patients with *Pseudomonas aeruginosa* lung infections and patients with nontuberculous mycobacteria (NTM) lung infections.

The granted patent, entitled "Sustained release of anti-infective aminoglycosides," will provide protection for novel anti-infective formulations comprising an aminoglycoside and Insmed's liposomal delivery technology, and methods for making the formulations. Amikacin is one of the aminoglycosides covered by the patent. The patent also includes claims relating to the use of the aforementioned aminoglycoside/lipid formulations for treating pulmonary infections, including those caused by *Pseudomonas aeruginosa* and certain mycobacterial infections, among others.

The U.S. Patent and Trademark Office issued a composition of matter patent covering the Company's liposomal amikacin for inhalation in August 2012, with U.S. exclusivity extending until at least August 2028.

"This key European patent significantly expands and fortifies our intellectual property estate for ARIKACE® as we continue to advance through the final stages of clinical development. I would like to recognize my colleagues for their efforts in obtaining this patent allowance," commented Walter Perkins, PhD, Chief Technology Officer of Insmed.

Will Lewis, President and Chief Executive Officer of Insmed, commented, "This patent allowance underscores the strength of our technology development team and recognizes the technology's innovation. This expanded patent coverage supports our goal to tackle *Pseudomonas aeruginosa* in CF and NTM, conditions which are serious and often times fatal lung infections with limited current treatment options. ARIKACE®, with its novel liposomal delivery of amikacin, offers the potential to provide these patients with a safe and effective, once-daily therapy. Together, we believe that the U.S. and European patents will provide a strong foundation for our future commercial interests and global development of our liposomal amikacin for inhalation."

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 patient populations: cystic fibrosis (CF) patients with *Pseudomonas aeruginosa* lung infections and patients with nontuberculous mycobacteria (NTM) lung infections. Insmed's Phase 3 registrational study of ARIKACE in Europe and Canada has completed the patient treatment period and the Company expects top-line clinical results in mid-2013. Insmed's Phase 2 clinical trial in patients with NTM is 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's 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 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.

Investor Relations Contact:

LHA

Anne Marie Fields

Senior Vice President

212-838-3777

afields@lhai.com

Bruce Voss

Managing Director

310-691-7100

bvoss@lhai.com
