Insmed Inc. Extends ARIKAYCE Intellectual Property Protection with Issuance of New U.S. Patent

BRIDGEWATER, N.J., Feb. 14, 2017 (GLOBE NEWSWIRE) -- Insmed Incorporated (Nasdaq:INSM), a global biopharmaceutical company focused on the unmet needs of patients with rare diseases, today announced that the United States Patent and Trademark Office (USPTO) issued U.S. Patent Number 9,566,234 for ARIKAYCE, the Company's liposomal amikacin for inhalation. The claims of the patent relate in part to systems and methods for treating pulmonary infections, including nontuberculous mycobacteria (NTM) infections. The systems each include a pharmaceutical formulation containing an aqueous dispersion of liposomal complexed aminoglycoside, which can be amikacin sulfate, with a nebulizer. The patent, the seventh U.S. patent to issue to Insmed for ARIKAYCE in NTM, is expected to provide patent coverage for ARIKAYCE in NTM into January 2034, thereby extending previously existing patent coverage by five years and five months. Insmed is currently evaluating ARIKAYCE in a global Phase 3 trial in patients with NTM lung disease.

"This new patent significantly extends our long-term intellectual property protection for ARIKAYCE in the U.S., and provides us with further protection at a time when we will have potentially reached a mature point in our commercial efforts for ARIKAYCE in NTM," said Will Lewis, president and chief executive officer of Insmed. "We will continue to pursue additional patents in the U.S. and other major markets worldwide to further strengthen our patent estate and enhance the value potential of ARIKAYCE."

About Insmed

Insmed Incorporated is a global biopharmaceutical company focused on the unmet needs of patients with rare diseases. The company is advancing a global phase 3 clinical study of ARIKAYCE (liposomal amikacin for inhalation) in nontuberculous mycobacteria (NTM) lung disease, a rare and often chronic infection that is capable of causing irreversible lung damage and can be fatal. There are currently no products indicated for the treatment of NTM lung disease in the United States or European Union (EU). Insmed's earlier-stage clinical pipeline includes INS1007, a novel oral reversible inhibitor of DPP1 with therapeutic potential in non-CF bronchiectasis, and INS1009, an inhaled nanoparticle formulation of a treprostinil prodrug that may offer a differentiated product profile for rare pulmonary disorders. For more information, visit www.insmed.com.

Forward-looking statements

This press release contains forward looking statements. "Forward-looking statements," as that term is defined in the Private Securities Litigation Reform Act of 1995, are statements that are not historical facts and involve a number of risks and uncertainties. Words herein such as "may," "will," "should," "could," "would," "expects," "plans," "anticipates," "believes," "estimates," "projects," "predicts," "intends," "potential," "continues," and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) identify forward-looking statements.

Forward-looking statements are based upon the company's current expectations and beliefs, and involve known and unknown risks, uncertainties and other factors, which may cause actual results, performance and achievements and the timing of certain events to differ materially from the results, performance, achievements or timing discussed, projected, anticipated or indicated in any forward-looking statements. Such factors include, among others, the factors discussed in Item 1A "Risk Factors" in the company's Annual Report on Form 10-K for the year ended December 31, 2016 and subsequent quarterly reports on Form 10-Q, and the following: the ability to complete development of, receive, and maintain regulatory approval for, and successfully commercialize ARIKAYCE, INS1007, and INS1009; the number of patients enrolled and the timing of patient enrollment in the company's global phase 3 clinical study of ARIKAYCE; the ability to successfully develop

INS1007 (formerly known as AZD7986) for the treatment of non-CF bronchiectasis; estimates of expenses and future revenues and profitability; status, timing, and the results of preclinical studies and clinical trials and preclinical and clinical data described herein; the sufficiency of preclinical and clinical data in obtaining regulatory approval for the company's product candidates; the timing of responses to information and data requests from the US Food and Drug Administration, the European Medicines Agency, and other regulatory authorities; expectation as to the timing of regulatory review and approval; estimates regarding capital requirements, including milestone payments and royalty obligations due to AstraZeneca, and the needs for additional financing, the ability to repay our existing indebtedness, estimates of the size of the potential markets for product candidates; selection and licensing of product candidates; the ability to attract third parties with acceptable development, regulatory and commercialization expertise; the benefits to be derived from corporate license agreements and other third party efforts, including those relating to the development and commercialization of product candidates; the degree of protection afforded to the company by its intellectual property portfolio; the safety and efficacy of product candidates; sources of revenues and anticipated revenues, including contributions from license agreements and other third party efforts for the development and commercialization of products; the ability to create an effective direct sales and marketing infrastructure for products the company elects to market and sell directly; the rate and degree of market acceptance of product candidates; the impact of any litigation the company is a party to, including, without limitation, the class action lawsuit filed against the company; the timing, scope and rate of reimbursement for product candidates; the success of other competing therapies that may become available; and the availability of adequate supply and manufacturing capacity and quality for product candidates.

The company cautions readers not to place undue reliance on any such forward-looking statements, which speak only as of the date they are made. Insmed disclaims any obligation, except as specifically required by law and the rules of the Securities and Exchange Commission, to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.