Insmed Reports First Quarter 2016 Financial Results

BRIDGEWATER, N.J., May 05, 2016 (GLOBE NEWSWIRE) -- Insmed Incorporated (Nasdaq:INSM), a global biopharmaceutical company focused on the unmet needs of patients with rare diseases, today reported financial results for the quarter ended March 31, 2016.

Business Update

- **Global Phase 3 CONVERT study advancing.** Patient enrollment continues to proceed on track in the company's global phase 3 study of ARIKAYCE (liposomal amikacin for inhalation or LAI) in nontuberculous mycobacteria (NTM) lung disease caused by Mycobacterium avium complex (MAC) (CONVERT™ or INS-212 study). The CONVERT study is taking place in 16 countries and at more than 130 sites. The company continues to expect to achieve its enrollment objective in the second half of 2016.
- **EMA regulatory review of ARIKAYCE progressing.** The company remains on track with previous guidance, having submitted its responses to the European Medicine Agency's(EMA) Committee for Medicinal Products for Human Use (CHMP) 180-day list of outstanding issues related to the company's Marketing Authorization Application (MAA) for ARIKAYCE. Insmed expects to participate in an oral explanation meeting in the second quarter of 2016 and the CHMP to render an opinion on its MAA around the middle of 2016.
- **Data accepted for presentation at ATS 2016.** Three ARIKAYCE-related abstracts and one treprostinil prodrug abstract have been accepted for presentation at the American Thoracic Society (ATS) 2016 International Conference taking place May 13-18 in San Francisco. The ATS presentations include (i) one-year follow-up data from the phase 2 112 study, (ii) lung distribution and retention data from a scintigraphy study in patients with NTM lung disease, (iii) a preclinical study of ARIKAYCE, and (iv) a preclinical study of a variety of treprostinil prodrugs.
- **Phase 1 clinical study of INS1009 submitted for presentation.** Insmed has completed a phase 1 study of INS1009 and submitted the results for presentation at a future medical meeting. This first-in-human study of INS1009 was designed to determine the maximum-tolerated dose of a single dose of INS1009 and to characterize the pharmacokinetic profile of free treprostinil and INS1009 in healthy volunteers. INS1009 is one of the company's nebulized treprostinil prodrugs, which may offer a differentiated product profile with therapeutic potential in rare pulmonary disorders such as pulmonary arterial hypertension (PAH), idiopathic pulmonary fibrosis (IPF), sarcoidosis, and severe refractory asthma.
- **Canadian patent strengthens global patent portfolio.** The Canadian Intellectual Property Office issued patent no. 2,838,111, which covers pharmaceutical formulations that include mixtures of liposomal quinolone antibiotics, together with free, unencapsulated quinolone antibiotics, such as ciprofloxacin. The patent also covers the use of such formulations for the treatment of various pulmonary disorders, for example, in bronchiectasis patients. The Canadian patent complements ARIKAYCE's global intellectual property estate. Counterpart patent applications to this Canadian patent are pending in other countries.

"2016 is off to a solid start with all of our clinical, regulatory, and commercial-readiness activities remaining on track with our previously stated timelines," said Will Lewis, president and chief executive officer of Insmed. "Our top corporate priority is our global phase 3 CONVERT study and we look forward to achieving our patient enrollment objective later this year. In parallel with our clinical activities, our team is advancing the regulatory process for ARIKAYCE in Europe. For INS1009, we completed the phase 1 study and submitted the results for presentation at an international respiratory congress in the third quarter. Lastly, our talented team of scientists remain focused on advancing a number of preclinical programs and identifying our next candidates for clinical development."

First Quarter Financial Results

For the first quarter of 2016, Insmed posted a net loss of $33.5 million, or $0.54 per share, compared with a net loss of $27.4 million, or $0.55 per share, for the first quarter of 2015.

Research and development expenses were $20.5 million for the first quarter of 2016, compared with $17.2 million for the first quarter of 2015. The increase was primarily due to the advancement of the company's global phase 3 CONVERT study of ARIKAYCE in NTM lung disease.

General and administrative expenses for the first quarter of 2016 were $12.5 million, compared with $9.5 million for the first quarter of 2015. The increase was primarily related to pre-commercial activities in Europe, namely the buildout of the company's infrastructure and NTM disease awareness activities, as well as an increase in headcount and related expenses.

Balance Sheet Highlights and Cash Guidance

As of March 31, 2016, Insmed had cash and cash equivalents of $253 million. Excluding depreciation and stock-based compensation expense, the company's cash operating expenses for the quarter ended March 31, 2016 were $28 million. Insmed ended the first quarter of 2016 with $25 million in debt and working capital of $233 million.

The company is investing in the following activities in 2016: (i) clinical development of ARIKAYCE, (ii) regulatory and pre-commercial initiatives for ARIKAYCE, and (iii) preclinical and clinical activities for its earlier-stage pipeline. Insmed continues to expect its cash-based operating expenses for the first half of 2016 to be in the range of $58 to $68 million.

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). In the EU, the company has filed a marketing authorization application seeking approval of ARIKAYCE for use in patients with NTM lung disease. Insmed's earlier-stage clinical pipeline includes INS1009, a nebulized prodrug formulation of treprostinil that the company believes may offer a differentiated product profile with therapeutic potential in rare pulmonary disorders such as pulmonary arterial hypertension (PAH), idiopathic pulmonary fibrosis (IPF) sarcoidosis, and severe refractory asthma. To complement its internal research, Insmed actively seeks in-licensing opportunities for a broad range of rare diseases. For more information, visit www.insmed.com.

"Insmed" and "ARIKAYCE" are the company's trademarks. All other trademarks, trade names or service marks appearing in this press release are the property of their respective owners.

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, 2015 and subsequent quarterly reports on Form 10-Q, and the following: the ability to complete development of, receive regulatory approval for, and successfully commercialize ARIKAYCE, or liposomal amikacin for inhalation (LAI), and INS1009, nebulized treprostinil prodrug; estimates of expenses and future revenues and profitability; plans to develop and market new products and the timing of these development programs; status, timing, and the results of preclinical studies and clinical trials and preclinical and clinical data described herein; the timing of responses to information and data requests from the US Food and Drug Administration, the European Medicines Agency, and other regulatory authorities; clinical development of product candidates; ability to obtain and maintain regulatory approval for product candidates; expectation as to the timing of regulatory review and approval; estimates regarding our capital requirements and the needs for additional financing; estimates of the size of the potential markets for product candidates; selection and licensing of product candidates; 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; 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 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.

Financial Statements to Follow