Insmed Reports Fourth Quarter 2015 Financial Results

BRIDGEWATER, N.J., Feb. 25, 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 fourth quarter and year ended December 31, 2015.

Business Update

- **Global Phase 3 ARIKAYCE™ study advancing.** Patient enrollment continues 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 more than 115 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 submitted its responses to the European Medicine Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) 120-day questions in December 2015 and expects to receive the CHMP's 180-day list of outstanding issues (LOI) in the first quarter of 2016. Insmed anticipates responding to the LOI and participating in an oral hearing with the CHMP in the second quarter of 2016 to address the LOI on the company's marketing authorization application (MAA) for ARIKAYCE. The company continues to expect the CHMP to render an opinion on its MAA around the middle of 2016.
- **Phase 1 clinical study of INS1009 underway.** Insmed is conducting a phase 1 study of INS1009 in healthy subjects. INS1009 is the company's nebulized treprostinil prodrug. The company believes INS1009 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.
- **INS1009 patent issued.** The U.S. patent and trademark office issued U.S. patent no. 9,255,064 (the '064 patent) on February 9, 2016. The ‘064 patent, entitled "Prostacyclin compounds, compositions and methods of use thereof" is the first patent to issue with claims reciting INS1009. Other treprostinil prodrugs are also claimed and described in the patent. Methods of using treprostinil prodrugs, including INS1009, are described in the patent. The ‘064 patent provides exclusivity for INS1009 until October 24, 2034.

"Last year, Insmed made important progress advancing our clinical and regulatory activities and establishing the foundation of our commercial infrastructure for ARIKAYCE in Europe," said Will Lewis, president and chief executive officer of Insmed. "We enhanced our global team and managed our resources, ending the year with $283 million in cash. In 2016, our priorities include completing patient enrollment in the phase 3 CONVERT study, advancing the European regulatory review of ARIKAYCE, and reporting new data from our internal research programs."

Fourth Quarter Financial Results

For the fourth quarter of 2015, Insmed posted a net loss of $31.2 million, or $0.51 per share, compared with a net loss of $17.6 million, or $0.36 per share, for the fourth quarter of 2014.

Research and development expenses were $19.6 million for the fourth quarter of 2015, compared with $14.8 million for the fourth quarter of 2014. The increase was primarily due to the company's global phase 3 CONVERT study of ARIKAYCE in NTM lung disease.

General and administrative expenses for the fourth quarter of 2015 were $12.9 million, compared with $8.3 million for the fourth quarter of 2014. The increase was primarily related to pre-commercial activities in Europe and personnel-related expenses, including non-cash stock-based compensation expense.

Balance Sheet Highlights and Cash Guidance

As of December 31, 2015, Insmed had cash and cash equivalents of $283 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. As a result, Insmed expects its cash-based operating expenses for the first half of 2016 will 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.

Forward-looking statements

This release contains forward-looking statements. 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 clinical trials and clinical data, the anticipated benefits of Insmed's products, the anticipated timing of regulatory submissions, and the ability to obtain required regulatory approvals, bring products to market and successfully commercialize 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, market conditions, failure or delay of European, U.S. Food and Drug Administration and other regulatory reviews and approvals, competitive developments affecting the company's product candidates, delays in product development or clinical trials or other studies, patent disputes and other intellectual property developments relating to the company's 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, the fact that subsequent analyses of clinical trial or study data may lead to different (including less favorable) interpretations of trial or study results or may identify important implications of a trial or study that are not reflected in the company's prior disclosures, and the fact that trial or study results or subsequent analyses may be subject to differing interpretations by regulatory agencies, the inability to successfully develop the company's product candidates or receive necessary regulatory approvals, the inability to make product candidates commercially successful, changes in anticipated expenses, changes in the company's financing requirements or ability to raise additional capital, and other risks and challenges detailed in the company's filings with the U.S. Securities and Exchange Commission, including its Annual Report on Form 10-K for the year ended December 31, 2015. Investors are cautioned not to place undue reliance on any forward-looking statements that speak only as of the date of this news release. The company undertakes no obligation to update these forward-looking statements to reflect events or circumstances or changes in its expectations.

Financial Statements to Follow