Insmed Reports Third Quarter 2015 Financial Results and Provides Business Update

BRIDGEWATER, N.J., Nov. 06, 2015 (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 third quarter and nine months ended September 30, 2015.

Business Update

- **Global Phase 3 ARIKAYCE™ study update.** 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 (CONVERT™ or INS-212 study). The company has secured health authority clearance in 12 countries with CONVERT study sites and 83 sites are open. Securing regulatory clearance for a few countries in Asia and Europe has taken longer than expected. In addition, while patient screening is going well at many sites, the ramp of enrollment at certain centers is slower than expected largely due to administrative delays. As a result, the company expects to achieve its enrollment objective six to 12 months later than its initial expectation of enrolling the study by the end of 2015. Insmed has taken a number of steps to accelerate enrollment, including enhancing its clinical operations team with new talent.
- **EMA regulatory review of ARIKAYCE is progressing.** The company remains on track to submit its responses to the European Medicine Agency's (EMA) 120-day questions before the end of 2015. The 120-day questions are part of EMA's review of the company's marketing authorization application (MAA) for ARIKAYCE.
- **INS1009 advancing toward clinical development.** Insmed recently submitted an Investigational New Drug (IND) application and remains on track to begin a phase 1 clinical study of INS1009 before the end of 2015. INS1009 is the company's nebulized treprostinil prodrug that is being developed as a treatment for pulmonary arterial hypertension (PAH).
- **Management team enhancements.** The company recently made key enhancements to its senior leadership team, including the recent hire of Reinilde Heyrman, MD, senior vice president, clinical operations and development, and the promotion of Drayton Wise to vice president of sales and marketing. Dr. Heyrman will have direct oversight over the development and registration-readiness of Insmed's pipeline. Dr. Heyrman has 24 years of global clinical development experience at companies such as Bellerophon Therapeutics, Ikaria, Inc. (Mallinckrodt Pharmaceuticals), Daiichi-Sankyo, and Pharmacia and Upjohn (Pfizer). Mr. Wise joined Insmed in 2014 and previously worked at Novartis, where he led the U.S. sales launch of the TOBI Podhaler®, Novartis' leading inhaled antibiotic for cystic fibrosis patients.
- **Patient-focused drug development meeting hosted by U.S. Food and Drug Administration (FDA) for NTM lung disease highlights unmet medical need.** As part of its patient-focused drug development program, the FDA recently conducted a public meeting for NTM lung disease in order to obtain patients' perspectives on the impact of NTM lung disease on daily life and treatment approaches. During the afternoon's scientific workshop, Insmed participated on a panel with academic experts and discussed the unique aspects of developing drugs to treat NTM lung disease.

"We are making important progress advancing our efforts to support the approval and commercial launch of ARIKAYCE," said Will Lewis, president and chief executive officer. "Across the globe we are supporting the cause of patients with NTM lung disease by progressing our landmark CONVERT study, raising disease awareness, and ensuring launch-readiness. We remain pleased with patient and physician receptivity to the CONVERT study and are working hard to augment the enrollment process of this trial. We continue to be encouraged by the commercial opportunity that will flow from treating eligible patients and believe our trial design will increase the probability of a successful outcome. We are also excited about our preclinical programs for PAH, including INS1009, which will soon enter the clinic, and the overall progress from our research team."

Financial Results

For the third quarter of 2015, Insmed posted a net loss of $31.0 million, or $0.50 per share, compared with a net loss of $24.0 million, or $0.54 per share, for the third quarter of 2014.

Research and development expenses were $19.2 million for the third quarter of 2015, compared with $15.2 million for the third 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 third quarter of 2015 were $11.0 million, compared with $8.2 million for the third quarter of 2014. The increase was primarily related to pre-commercial activities in Europe and non-cash stock-based compensation expense.

Balance Sheet Highlights and Cash Guidance

As of September 30, 2015, Insmed had cash and cash equivalents of $311.0 million. Insmed ended the third quarter of 2015 with $25.3 million in short-term debt and working capital of $272.6 million.

Insmed continues to expect its cash operating expenses for the second half of 2015 will be in the range of $50 million to $60 million. As previously reported, the company will continue to invest in the following activities for the remainder of 2015: (i) clinical development of ARIKAYCE, (ii) regulatory and pre-commercial initiatives for ARIKAYCE, and (iii) initiating a phase 1 clinical study of INS1009.

Conference Call

Insmed will host a conference call beginning today at 8:30 AM Eastern Time. Shareholders and other interested parties may participate in the conference call by dialing 877-698-3991 (domestic) or 817-522-1636 (international) and referencing conference ID number 67505047. The call will also be webcast live on the internet on the company's website at www.insmed.com.

A replay of the conference call will be accessible approximately two hours after its completion through November 20, 2015 by dialing 855-859-2056 (domestic) or 404-537-3406 (international) and referencing conference ID number 67505047. A webcast of the call will also be archived for 90 days under the Investor Relations section of the company's website at www.insmed.com.

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 can lead to progressive inflammation and lung damage. 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 pipeline includes INS1009, a nebulized prodrug formulation of treprostinil that the company is developing for the treatment of pulmonary arterial hypertension (PAH), a chronic, life-threatening disorder characterized by abnormally high blood pressure in the arteries between the heart and lungs. 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, Canadian, 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, 2014and its subsequent quarterly reports on Form 10-Q. 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