Insmed Launches National Awareness Campaign Surrounding Follow-On Biologics

RICHMOND, Va., Feb 05, 2008 /PRNewswire-FirstCall via COMTEX News Network/ -- Insmed Inc. (Nasdaq: INSM), a developer of follow-on biologics and biopharmaceuticals, today announced that it has launched a broad education campaign on the importance of establishing a regulatory pathway in the U.S. for large molecule protein-based drugs, known as follow-on biologics (FOBs), which are also commonly referred to as biosimilars or biogenerics.

The scientific, regulatory, and legal framework for the approval of small-molecule generic drugs is well developed, and a regulatory system for approving FOBs was established in Europe in 2006. However, no regulatory pathway currently exists for FOBs in the U.S.

Insmed has launched a number of public initiatives to promote awareness of the need for Congress to establish a pathway for approval of FOBs, which would enhance patient access to and reduce costs for expensive biotech drugs. Following Insmed CEO Geoffrey Allan's recent testimony before the U.S. Congress, Insmed has initiated multiple efforts to enhance awareness of this important issue, including:

"We hope that this renewed attention and the inception of these initiatives will shed some light onto the significant need for Congress to adopt legislation so patients can receive affordable access to life-saving biotech drugs," said Geoffrey Allan, Ph.D., CEO of Insmed. "Given Europe's previously established regulatory pathway for FOBs, the U.S. is clearly lagging behind other nations in responding to this critical healthcare issue."

"Insmed is very much at the forefront of the evolving FOB industry," continued Dr. Allan. "We have the capacity and intellectual capital to successfully develop FOBs, and are determined to continue working diligently to ensure an effective regulatory pathway is established as soon as possible, and are prepared to enter the market as soon as this becomes a reality."

Insmed is currently developing a portfolio of FOBs and intends to initiate clinical trials for its first two FOBs in 2008. Members of Insmed's skilled biologics team have worked on over 50 therapeutic proteins. Their focused protein-based drug development backgrounds, coupled with the Company's FDA-approved protein manufacturing facility, and clinical and regulatory expertise, positions Insmed, upon the establishment of a regulatory pathway, to be an initial entrant into the U.S. FOBs market with a broad range of medicines following the expiration of patents covering the innovator products.

According to published reports, an estimated $10 billion worth of biologic drugs are expected to come off patent by 2010 (with an additional $10 billion by 2015). FOBs would provide safe and effective therapies at a reduced cost following the expiration of the original product's patent.

About Insmed

Insmed Inc. is a biopharmaceutical company with unique protein process development and manufacturing experience and a proprietary protein platform aimed at niche markets with unmet medical needs. Insmed has a state-of-the-art, FDA-approved biologic commercial manufacturing facility in Boulder, Colorado and a Corporate office in Richmond, Virginia. For more information, please visit www.insmed.com.

Forward-Looking Statements

This release contains forward-looking statements which are made pursuant to provisions of Section 21E of the Securities Exchange Act of 1934. Investors are cautioned that such statements in this release, including statements relating to planned clinical study design, regulatory and business strategies, plans and objectives of management and growth opportunities for existing or proposed products, constitute forward-looking statements which involve risks and uncertainties that could cause actual results to differ materially from those anticipated by the forward-looking statements. The risks and uncertainties include, without limitation, risks that product candidates may fail in the clinic or may not be successfully marketed or manufactured, we may lack financial resources to complete development of product candidates, the FDA may interpret the results of studies differently than us, competing products may be more successful, demand for new pharmaceutical products may decrease, the biopharmaceutical industry may experience negative market trends, our entrance into the follow on biologics market may be

unsuccessful, our common stock could be delisted from the Nasdaq Global Market and other risks and challenges detailed in our filings with the U.S. Securities and Exchange Commission, including our Quarterly Report on Form 10-Q for the quarter ended September 30, 2007. Readers are cautioned not to place undue reliance on any forward-looking statements which speak only as of the date of this release. We undertake no obligation to publicly release the results of any revisions to these forward-looking statements that may be made to reflect events or circumstances that occur after the date of this release or to reflect the occurrence of unanticipated events.
