Insmed Provides Update on Follow-On Biologics and IPLEX(TM) Programs

RICHMOND, Va., April 29, 2008 /PRNewswire-FirstCall via COMTEX News Network/ -- Insmed Inc. (Nasdaq: INSM), a developer of follow-on biologics (FOBs) and biopharmaceuticals, today provided an update of the status of its initial FOB development candidates, INS-19 (a FOB of Neupogen(R)) and INS-20 (a FOB of Neulasta(R)) which represent combined 2007 sales of over $4 billion. The Company also reported recent progress made with its IPLEX(TM) development program.

Follow-On Biologics Program

Insmed recently received regulatory approval from the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA) to initiate a clinical trial for Insmed's most advanced FOB candidate, INS-19. Pre-clinical pharmacological, pharmacokinetic and toxicological studies have demonstrated that INS-19 and FDA-approved Neupogen(R) are comparable, and detailed analytical characterisation has also demonstrated that the products have a high degree of similarity. Screening for participants for the Phase 1 study has begun, with dosing of the first patient expected in May 2008. Data to support human similarity is expected in July 2008.

Insmed's second FOB product candidate, INS-20, has also completed pre- clinical pharmacological and pharmacokinetic studies, which have demonstrated that INS-20 and FDA-approved Neulasta(R) are comparable. Detailed analytical characterisation has also demonstrated that the products have a high degree of similarity. The Company intends to initiate clinical studies for INS-20 in the fourth quarter of 2008.

Insmed also has several other FOB products which are currently at an earlier stage of cell line development and product characterisation.

IPLEX(TM)

IPLEX(TM) is a complex of recombinant human insulin-like growth factor-I (rhIGF-I) and its predominant binding protein IGFBP-3 (rhIGFBP-3). The drug, approved in the United States in December 2005 for the treatment of children with growth failure due to severe primary IGF-I deficiency, is currently being investigated in Myotonic Muscular Dystrophy (MMD) and Amyotrophic Lateral Sclerosis (ALS), or Lou Gehrig's disease.

A Phase 2 trial of IPLEX(TM) in MMD is on-going and a substantial portion of the external costs associated with the study are expected to be covered by an approximately $2.1 million grant awarded to Insmed by the Muscular Dystrophy Association in late 2007.

IPLEX(TM) is also in use as part of an Expanded Access Program (EAP) in partnership with the Italian Ministry of Health for the treatment of ALS. Since early 2007, the EAP has grown to include 20 physicians, and approximately 90 subjects have been enrolled into the program to date with additional subjects being enrolled as the program progresses. IPLEX(TM) continues to be safe and well tolerated in the subject population. During the first quarter of 2008, the EAP generated $2.3 million in cost recovery revenue for Insmed, compared to $0.7 million during the same period last year, and $2.0 million in the fourth quarter of 2007.

"We are pleased with the development progress and results to date of IPLEX(TM) in both MMD and ALS, especially considering the level of investment these therapeutic programs currently require from Insmed," noted Dr. Geoffrey Allan, CEO of Insmed. "The market potential for MMD alone is estimated in excess of $800 million. Thus, we consider our current program for IPLEX(TM) one of minimal risk and high potential reward. Also, our substantial capabilities in the evolving, potential multi-billion dollar, follow-on biologics industry provide us with a unique growth driver not available to the vast majority of biotechnology companies our size. As evidenced by the initiation of the INS-19 clinical trial in the UK, we are committed to being at the forefront of the follow-on-biologics market. We remain confident that our company will be one of the few initial U.S. follow-

on-biologics market entrants upon the establishment of a regulatory pathway, and look forward to providing patients with cost-effective access to important biotechnology medications when the innovator products come off patent."

About INS-19

Recombinant human G-CSF is a protein that is produced in bacterial cells and is used to treat certain medical conditions where a person's neutrophils are too low (neutropenia), such as in cancer patients who are receiving certain chemotherapeutic regimens, patients receiving bone marrow transplants, or in patients who have chronically low neutrophils for other reasons. The FDA approved version of this drug is Neupogen(R). INS-19 is Insmed's follow-on biologic version of Neupogen(R).

About INS-20

Pegylated recombinant human G-CSF is a chemically modified version of G-CSF in which a water soluble polymer called polyethylene glycol is attached to the protein. The pegylated protein has a prolonged biological activity after it is injected into the patient. This allows less frequent dosing for the patient compared to recombinant human G-CSF. The FDA approved version of this drug is Neulasta(R). INS-20 is Insmed's follow-on biologic version of Neulasta(R).

About IPLEX(TM)

IPLEX(TM) was approved in the United States in December 2005 for the treatment of children with growth failure due to severe primary IGF-I deficiency (Primary IGFD). IPLEX(TM) (rhIGF-I/rhIGFBP-3), is a complex of recombinant human insulin-like growth factor-I (rhIGF-I) and its predominant binding protein IGFBP-3 (rhIGFBP-3). The drug is also being investigated for various other indications with unmet medical needs including Myotonic Muscular Dystrophy (MMD) and Amyotrophic Lateral Sclerosis (ALS).

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. 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, the FDA may not establish specific guidelines for the approval of FOB products, FOB products may not be accepted by consumers, 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 Capital Market and other risks and challenges detailed in our filings with the U.S. Securities and Exchange Commission, including our Annual Report on Form 10-K for the year ended December 31, 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.