News Releases

Insmed Initiates Clinical Study for Follow-on Biologic Version of Neupogen(R)

RICHMOND, Va., April 16, 2008 /PRNewswire-FirstCall via COMTEX News Network/ -- Insmed Inc. (Nasdaq: INSM), a developer of follow-on biologics and biopharmaceuticals, today announced that it has received approval from the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA) to initiate the Company's first clinical study for a follow-on biologic (FOB) product candidate. Insmed's INS-19, which is a recombinant form of human G-CSF, is a follow-on biologic of the FDA-approved product Neupogen(R), which had U.S. sales of approximately $0.9 billion in 2007.

Pre-clinical studies demonstrate that INS-19 and FDA-approved Neupogen(R) are comparable in both their pharmacological and toxicological profile. Detailed analytical characterisation also demonstrates that the products have a high degree of similarity. Data from these initial evaluations have been used, in part, to support the Phase I study, which will be initiated immediately. The Phase I study will be conducted in the UK and will compare the safety and establish the bioequivalence of INS-19 to Neupogen(R). Results from the trial are expected in the second half of 2008, and are planned to be used as part of a submission to the FDA to establish a protocol with the agency for a Phase III trial in the U.S.

"By utilizing Insmed's unique protein drug development capabilities and technical expertise, the Company has been able to advance a follow-on biologic product candidate from project initiation to human testing in less than one year, a significant achievement," said Geoffrey Allan, CEO of Insmed. "We intend to utilize the data generated from the Phase I trial, in combination with the positive preclinical results previously garnered, as the basis for discussions with the FDA in an effort to establish a Phase III development path for INS-19."

The initiation of this follow-on biologic trial is the first of two planned for 2008 as part of Insmed's development of a portfolio of FOBs. 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 approval 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. The patent covering Neupogen(R) expires in 2013.

The Follow-on Biologics Market

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. A recent econometric study by economist Dr. Robert J. Shapiro, former Under Secretary of Commerce in the Clinton Administration, found that "...generic versions of the top 12 categories of biologic treatments with patent protections that have expired or that are due to expire in the near future could save Americans $67 billion to $108 billion over 10 years and $236 billion to $378 billion over 20 years."

About INS-19

Recombinant human G-CSF is a synthetic version of a human G-CSF that is produced in bacteria. The G-CSF mimics the biological effects of naturally occurring G-CSF and is used to treat certain medical conditions were 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. Pre-clinical studies demonstrate that INS-19 and FDA-approved Neupogen(R) are comparable in both their pharmacological and toxicological profile. Detailed analytical characterisation also demonstrates that the products have a high degree of similarity.

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, 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.