INSMED Incorporated

Insmed Announces First Human Bioequivalence Data for a Follow-on Biologic by a U.S. Company

Company Intends to Request Meeting with FDA Regarding Possible Phase III Trial Based on Human Data Demonstrating Bioequivalence of INS-19 to Neupogen(R)

RICHMOND, Va., July 10, 2008, 2008 /PRNewswire-FirstCall via COMTEX News Network/ -- Insmed Inc. (Nasdaq: INSM), a developer of follow-on biologics and biopharmaceuticals for unmet medical needs, today announced that it has demonstrated the bioequivalence of INS-19, the company's recombinant human granulocyte colony stimulating factor (G-CSF), compared to Neupogen(R), an FDA-approved G-CSF product for the treatment of neutropenia that recorded 2007 sales of approximately $1 billion.

Human bioequivalence studies utilize well-established, FDA-recognized methodology with rigorous standards. Results of this clinical study demonstrated bioequivalence between INS-19 and Neupogen(R). G-CSF concentration profiles for the two products were identical. Absolute neutrophil count, the primary pharmacodynamic marker for G-CSF products, exhibited the same response profile to dosing with INS-19 as with Neupogen(R). These human INS-19 and Neupogen(R) data complement Insmed's extensive analytical testing and comparative data from pre-clinical assessments.

"These results are very exciting, as they represent Insmed's ability to replicate a protein product, to bring that product rapidly through the clinic and to demonstrate clear bioequivalence to the innovator drug," said Dr. Geoffrey Allan, President and CEO of Insmed. "To our knowledge, we are the first U.S. company to report human bioequivalence data for a follow-on biologic product, validating the idea that follow-on biologics can be a scientific reality in the U.S. and that Insmed is well positioned to be a leader in the field. Demonstration of bioequivalence is typically the sole clinical requirement to support FDA approval of generic drugs today. Thus, based on these data, Insmed intends to request a meeting with the FDA to discuss potentially initiating a Phase III clinical trial program for INS-19."

Insmed has one of the most robust follow-on biologics pipelines in the industry. Building upon the success of INS-19, the Company has also completed pre- clinical pharmacological and pharmacokinetic studies for its second follow-on biologic product, INS-20, which has demonstrated comparability to FDA-approved Neulasta(R). Based on these data, Insmed intends to initiate a Phase I bioequivalence study of INS-20 in humans in the fourth quarter of 2008. Insmed intends to seek approval of both products in the U.S. and launch the products on expiration of the relevant innovator patents.

Study Design

The study was a single-center, randomized, double-blind, two-way, crossover bioequivalence design in healthy volunteers. Thirty-two volunteers enrolled, and all completed the study as planned. Each volunteer received a single dose of either INS-19 or Neupogen(R), underwent a wash-out period, and returned to the clinic for a single dose of the alternate product. Blood samples were collected to characterize the pharmacokinetic and pharmacodynamic responses to each dose administration. Point estimates and 90% confidence intervals (CI) for the mean ratios of the products' maximum G-CSF concentrations (Cmaxs) and areas under the G-CSF concentration curves (AUCs) were calculated, and bioequivalence was assessed.

Study Results

Results of this clinical study demonstrated bioequivalence between INS-19 and Neupogen(R). G-CSF concentration profiles for the two products were identical. The Cmaxs following INS-19 and Neupogen(R) administration were 44.7 +/- 2.1 and 45.5 +/- 1.9 ng/mL, respectively (mean +/- standard error). The AUCs for INS-19 and Neupogen(R) were 341 +/- 16 and 343 +/- 14 ng/mL*hr, respectively. In comparing INS-19 to Neupogen(R), the CI for the ratio of Cmaxs was 92-103% and the CI for the ratio of AUCs was 94-103%. These data demonstrate that the pharmacokinetic behaviour of the products was statistically indistinguishable. Absolute neutrophil count, the primary pharmacodynamic marker for G-CSF products, exhibited the same response profile to dosing with INS-19 as with Neupogen(R).

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.

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. Follow-on biologics 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. G-CSF mimics the biological effects of naturally occurring G-CSF 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. 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.

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, strategic alternatives, 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 strategic alternatives may never be consummated, 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 the Company's filings with the U.S. Securities and Exchange Commission, including the Company's 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. The Company undertakes 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.

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