Insmed Receives European Orphan Drug Designation for SomatoKine for the Treatment of Extreme Insulin Resistance; Company to Initiate Clinial Trial in Type A Insulin Resistance

RICHMOND, Va., Oct 25, 2004 /PRNewswire-FirstCall via COMTEX/ -- Insmed Incorporated (Nasdaq: INSM) today announced that the Committee for Orphan Medicinal Products of the European Agency for the Evaluation of Medicinal Products (EMEA) has approved the Company's application for orphan drug designation in Europe for SomatoKine(R), for the treatment of extreme insulin resistance. In December 2003, Insmed reported that the Office of Orphan Products Development of the Food and Drug Administration has approved the Company's application for orphan drug designation in the United States for SomatoKine(R), for the treatment of extreme insulin resistance. The European orphan drug designation may provide Insmed ten years of market exclusivity in Europe upon SomatoKine(R) approval for this indication. The United States orphan drug designation may provide Insmed seven years of market exclusivity upon SomatoKine(R) approval for this indication. There is currently no approved treatment available for patients with extreme insulin resistance in Europe or the United States. Insmed plans to initiate a Phase II clinical trial in patients with Type A insulin resistance later this year.

Efficacy of SomatoKine in an Extreme Insulin Resistant Patient:

In September Insmed reported on results from a nine-month analysis of therapy with SomatoKine(R) (rhIGF-I/rhIGFBP-3) (mecasermin rinfibate) for a patient with Leprechaunism, the most extreme form of insulin resistance. The nine-month analysis demonstrated substantial improvements in growth, metabolic control, and neurological development. Of significant importance, the patient surpassed the average expected life-span for Leprechaunism, and continues to receive therapy to date.

More on Extreme Insulin Resistance

Syndromes of Extreme Insulin Resistance appear to result from genetic defects in the insulin receptor or insulin action pathways. In addition to insulin resistance and glucose intolerance or overt diabetes, these syndromes share a number of common features including variable degrees of hyperandrogenism, hirsutism, and dysmorphic features.

More on rhIGF-I/rhIGFBP-3, SomatoKine(R)

Insmed's SomatoKine(R) is a proprietary delivery composition of insulin- like growth factor-I (IGF-I). The novel compound is administered as a subcutaneous injection, which can restore IGF levels to physiological relevant levels. SomatoKine(R) is currently in a pivotal Phase III clinical trial for the treatment of Growth Hormone Insensitivity Syndrome (GHIS). On July 20, Insmed provided the results from a six-month data analysis of the ongoing pivotal Phase III GHIS clinical trial showing a statistically significant increase (p

About Insmed

Insmed is a biopharmaceutical company focused on the discovery and development of drug candidates for the treatment of metabolic diseases and endocrine disorders with unmet medical needs. For more information, please visit http://www.insmed.com.

Statements included within this press release, which are not historical in nature, may constitute forward-looking statements for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. Forward-looking statements in this press release include, but are not limited to, statements regarding clinical trials and goals, our regulatory and business strategies and growth opportunities for existing or proposed products. Such forward-looking statements are subject to numerous risks and uncertainties, including risks that product candidates may fail in the clinic or may not be successfully marketed or manufactured, the company may lack financial resources to complete development of product candidates, the FDA may interpret the results of our studies differently than we have, competing products may be more successful, demand for new pharmaceutical products may decrease, the biopharmaceutical industry may experience negative market trends and other risks detailed from time to time in the company's filings with the Securities and Exchange Commission. As a result of these and other risks and uncertainties, actual results may differ materially from those described in this press release. For further information with respect to factors that could cause actual results to differ from expectations, reference is made to reports filed by the Company with the Securities and Exchange Commission under the Securities Exchange Act of 1934, as amended. The forward-looking statements made in this release are made only as of the date hereof and Insmed disclaims any intention or responsibility for updating predictions or financial guidance contained in this release.

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