Insmed Initiates Phase II Trial With SomatoKine(R) in Type A Extreme Insulin Resistance

RICHMOND, Va., April 26, 2005 /PRNewswire-FirstCall via COMTEX/ -- Insmed Incorporated (Nasdaq: INSM) today announced that it has initiated a Phase II clinical trial examining the therapeutic benefit of treating Type A Extreme Insulin Resistance with SomatoKine(R), the Company's proprietary once daily IGF-I therapy.

The clinical trial, led by Principal Investigator Professor David Dunger, University of Cambridge, Cambridge, U.K., is a Phase II, open-label, dose-ranging study designed to evaluate the safety and efficacy of SomatoKine for 16 weeks in 10 patients with Type A Extreme Insulin Resistance. To qualify for inclusion in the study, patients must be between 10-65 years of age and have a diagnosis of Type A insulin resistance. The primary efficacy endpoints of the trial are improvement in glycemic control, improvement in insulin sensitivity, reduction in hemoglobin A1c and improvement in body composition.

"As there are no effective therapies for these patients and the long term prognosis of declining health is well documented, I am pleased to have the opportunity to be evaluating SomatoKine as a potential treatment to reverse the significant insulin resistance and abnormalities in these patients," commented Professor Dunger. "Our past studies have demonstrated that with SomatoKine administration, these abnormalities can be overcome leading to an improved insulin sensitivity with ultimately better blood sugar control."

More on Insulin Resistance

Syndromes of Insulin Resistance result from genetic defects in the insulin receptor or insulin signaling 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. Individuals with Type A insulin resistance who develop frank diabetes require large doses (>200 units/day) of subcutaneous insulin, oral hypoglycemic agents and insulin sensitizers. Despite this intense regimen, glycemic control remains poor and these patients are at high risk of the complications of diabetes, such as cardiovascular disease, nephropathy, retinopathy and neuropathy. Previous Phase II clinical trials completed with SomatoKine in diabetic patients have shown improved glycemic control, improved insulin sensitivity as well as a reduction in daily insulin consumption. SomatoKine has Orphan Drug Designation in both the United States and Europe for Extreme Insulin Resistance.

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

Insmed's SomatoKine is a proprietary drug product of insulin-like growth factor-I (IGF-I) and its principal binding protein, IGFBP-3. The novel compound is administered as a single daily subcutaneous injection, capable of restoring IGF-I levels into the normal range in deficient individuals. On March 10, 2005, Insmed announced that the FDA had accepted Insmed's NDA submission for SomatoKine for the treatment of children with Growth Hormone Insensitivity Syndrome (GHIS), and on April 13, 2005 the Company announced that the FDA had granted the GHIS NDA submission Priority Review status.

In phase II studies in diabetic subjects, SomatoKine treatment resulted in improved blood glucose control and reduced daily insulin use. In studies in children and adults with severe burn injury, SomatoKine treatment resulted in increased muscle protein synthesis and reduced inflammatory response. In studies in elderly subjects recovering from hip fracture, SomatoKine treatment resulted in improved functional activity and preserved bone mineral density.

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 that are not historical in nature may constitute forward-looking statements for purposes of the safe harbour 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.