Insmed Reports Results from Nine Months of SomatoKine Therapy for a Patient with Extreme Insulin Resistance at the 43rd Meeting of the European Society of Pediatric Endocrinology

RICHMOND, Va., Sep 13, 2004 (BUSINESS WIRE) -- Insmed Incorporated (NASDAQ: INSM) today 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 has surpassed the average expected life-span for Leprechaunism, and continues to receive therapy to date. No adverse effects related to SomatoKine treatment were observed.

The results from the nine-month analysis were presented at the 43rd Annual Meeting of the European Society of Pediatric Endocrinology (ESPE) by Marc De Kerdanet, M.D. of the University Center Hospital, Rennes, France and Andreas Sommer, Ph.D., Insmed's Chief Scientific Officer.

The patient, referred to as Rennes-1, was a 4-month old female diagnosed with Leprechaunism. The diagnosis was confirmed by identification of two mutations in the insulin receptor gene. Prior to treatment, the patient had extremely high insulin levels (5490uU/mL), severe growth retardation (-3.3 SDS in height; -3.4 SDS in BMI), and poor blood sugar control.

After nine-months of treatment with SomatoKine(R), the following observations were made:

The abstract is available on Insmed's corporate website, www.insmed.com.

About Leprechaunism

Leprechaunism is characterized by extreme insulin resistance associated with a genetically defective insulin receptor resulting in hyperinsulinemia, uncontrolled glycemic variation, failure to thrive and short life expectancy. Leprechaunism is the most severe form of insulin resistance amongst a group of extreme insulin resistance syndromes that include Type A syndrome, Rabson-Mendenhall syndrome and type B syndrome.

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

Insmed's rhIGF-I/rhIGFBP-3 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. In diabetic subjects, administration of rhIGF-I/rhIGFBP-3 demonstrated a significant improvement in blood sugar control and a significant reduction in daily insulin use. Following severe burn injury, in both children and adults, administration of rhIGF-I/rhIGFBP-3 demonstrated a significant improvement in muscle protein synthesis and a significant reduction in the inflammatory response associated with the trauma. In recovery from hip fractures, administration of rhIGF-I/rhIGFBP-3 has demonstrated a significant improvement in functional recovery and bone mineral density. rhIGF-I/rhIGFBP-3 is currently in a pivotal Phase III clinical trial for the treatment of Growth Hormone Insensitivity Syndrome (GHIS).

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 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.