



[Home](#) / [Investors](#) / [News Releases](#)

Insmed Reports Update on Pivotal Clinical Trial with SomatoKine: Statistically Significant Increase in Growth Rate Observed at Six Months

RICHMOND, Va., Jul 20, 2004 (BUSINESS WIRE) -- Insmed Incorporated (Nasdaq: INSM) today provided an update on the Company's ongoing pivotal Phase III clinical trial evaluating SomatoKine(R) (rhIGF-I/rhIGFBP-3) in children with severe short stature due to growth hormone insensitivity syndrome (GHIS). The six-month data analysis showed a statistically significant increase (p

This prospectively designed Phase III trial is intended to evaluate the safety and efficacy of SomatoKine(R) in prepubescent children with GHIS. The multi-center, open label study is led by a formal Steering Committee of GHIS thought leaders consisting of Louis Underwood, M.D., Professor of Endocrinology, University of North Carolina, Chapel Hill, Martin Savage, M.D., Professor of Pediatric Endocrinology, St. Bartholomew's Hospital, London and Cecilia Camacho-Hubner, M.D., Reader of Pediatric Endocrinology, St. Bartholomew's Hospital, London. The Steering Committee was established to prospectively identify GHIS patients for this clinical trial and to evaluate the safety and efficacy of SomatoKine(R) in this patient population on an ongoing basis.

GHIS is a genetic condition in which patients produce insufficient IGF-I to stimulate normal linear growth. IGF-I is essential for proper growth and metabolism. Children with GHIS do not recognize or respond to endogenous or exogenous human growth hormone, and as a result, fail to produce physiologically relevant levels of IGF-I.

More on SomatoKine(R)

Insmed's SomatoKine(R) (Mecasermin rinfabate) is a proprietary delivery composition of insulin-like growth factor-I (IGF-I) bound to its primary binding protein, IGFBP-3. The novel compound is administered as a once-daily subcutaneous injection, which can restore IGF-I levels to physiological relevant levels. In diabetic subjects, administration of SomatoKine(R) 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 SomatoKine(R) demonstrated a significant improvement in muscle protein synthesis and a significant reduction in the inflammatory response associated with the trauma. Following recovery from hip fracture, administration of SomatoKine(R) has demonstrated a significant improvement in functional recovery and bone mineral density. SomatoKine(R) is currently in a pivotal Phase III clinical trial for the treatment of Growth Hormone Insensitivity Syndrome (GHIS), a severe growth disorder.

About Insmed Incorporated

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 planned clinical trial design, our regulatory and business strategies, plans and objectives of management 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 Insmid disclaims any intention or responsibility for updating predictions or financial guidance contained in this release.
