Insmed Submits New Drug Application -NDA- to Seek Regulatory Approval of SomatoKine for the Treatment of Growth Hormone Insensitivity Syndrome

RICHMOND, Va., Jan 3, 2005 (BUSINESS WIRE) -- Insmed Incorporated (Nasdaq: INSM) announced that it has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for regulatory approval of SomatoKine(R) (mecasermin rinfabate) for the treatment of growth hormone insensitivity syndrome (GHIS). The application includes safety and efficacy results from Insmed's prospective, multicenter, Phase III clinical trial with SomatoKine conducted in patients with growth hormone insensitivity syndrome. SomatoKine is Insmed's proprietary insulin-like growth factor I (IGF-I) therapy, composed of recombinant human IGF-I and IGF binding protein 3 (rhIGF-I/rhIGFBP-3 complex).

"The submission of the NDA for SomatoKine represents a great achievement for the Company, highlighting our efforts to bring the first specific treatment for children with this disease. We believe that SomatoKine is a breakthrough therapeutic agent and that it will become the standard of care for treating GHIS," said Geoffrey Allan, Ph.D., President and CEO of Insmed Incorporated.

SomatoKine has already received orphan drug designation for the GHIS indication. Orphan drug designation is conferred upon investigational products by the FDA for indications that affect fewer than 200,000 people in the United States. The GHIS indication encompasses a variety of genetic and acquired conditions in which the action of growth hormone (GH) is absent or severely attenuated, resulting in low serum levels of IGF-I. Because IGF-I is the primary mediator of the growth-promoting actions of GH, replacement therapy in children with GHIS using SomatoKine is intended to bypass the blockade of GH action and improve longitudinal growth.

Conference Call

Insmed will host a conference call on Wednesday, January 5, at 11:00 a.m. Eastern Time (10:00 a.m. Central Time) to provide an update on recent corporate events and planned activities for 2005. To participate in the conference call, dial 800-479-9001(domestic) or 719-457-2618 (international). The call will be webcast live through Insmed's corporate website: www.insmed.com. A telephonic replay of the call will be available for one week at 888-203-1112 (domestic) or 719-457-0820 (international), passcode: 238426. A web replay of the call will be available through the corporate website beginning at 1:00 p.m. Wednesday.

More on 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-I levels to physiologically relevant levels. On July 20, Insmed provided the top-line results from a six-month data analysis of the pivotal Phase III GHIS clinical trial showing a statistically significant increase (p

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. In recovery from hip fractures, administration of SomatoKine(R) demonstrated a significant improvement in functional recovery and 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 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.