FDA Approves Insmed's Orphan Drug, IPLEX, for the Treatment of Severe Primary IGF-1 Deficiency; The First Once-Daily Therapy for the Treatment of Severe Primary IFG-1 Deficiency

RICHMOND, Va., Dec 12, 2005 (BUSINESS WIRE) -- Insmed Incorporated (NASDAQ: INSM) announced today the United States Food and Drug Administration (FDA) approved IPLEX(TM) (mecasermin rinfabate (rDNA origin) injection) for the treatment of growth failure in children with severe primary IGF-1 deficiency (Primary IGFD) or with growth hormone (GH) gene deletion who have developed neutralizing antibodies to GH. As an orphan drug, IPLEX is entitled to seven years of marketing exclusivity for the treatment of Primary IGFD.

"We are very pleased IPLEX was approved, making IPLEX the only approved once-daily IGF-1 replacement therapy available to treat children with severe short stature," stated Geoffrey Allan, Ph.D., President and Chief Executive Officer of Insmed. "Today marks the beginning of a new treatment paradigm for treating children with Primary IGFD. I am grateful to all who have made this drug approval possible. This is also an exciting transition for Insmed as we now begin to focus on the commercialization of IPLEX, which we expect to launch during the second quarter of calendar year 2006."

Andreas Sommer, Ph.D., Chief Scientific Officer of Insmed added, "This event marks the end of a long road and two decades of hard work by hundreds of dedicated people. I'm thrilled that our visionary efforts have now culminated in making available a novel therapeutic composition for the treatment of children who suffer from Primary IGFD."

"It is gratifying to see that a Company who cares for the needs of patients has developed a needed therapy that allows physicians to treat children with Primary IGFD. From my experience in treating these types of patients, IPLEX therapy has produced improvements in growth rates while providing an excellent safety profile" said Louis Underwood, M.D., Professor of Pediatrics, University of North Carolina, Chapel Hill, and a Principal Investigator and a member of Insmed's Pivotal Trial Steering Committee. Dr. Underwood is a world renowned Pediatric Endocrinologist who pioneered the early use of GH and IGF-1.

Conference Call at 8:00am

Insmed management will host a conference call to discuss FDA approval of IPLEX and provide a corporate update at 8:00am ET December 13, 2005. To participate in the conference call, dial 800-289-0529 (domestic) or 913-981-5523 (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: 9626439. A web replay of the call will be available through the corporate website beginning at 10:00 a.m.

More on IPLEX(TM)

IPLEX, mecasermin rinfabate, is the human recombinant of the naturally occurring protein complex of insulin-like growth factor-I (IGF-1) and insulin-like growth factor binding protein-3 (IGFBP-3). The targeted treatment indication for IPLEX is Primary IGFD which encompasses a variety of genetic and acquired conditions in which the action of growth hormone (GH) is absent or attenuated resulting in low serum levels of IGF-I.

Patients with Primary IGFD present with extreme short stature (height standard deviation score, SDS

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 Insmed disclaims any intention or responsibility for updating predictions or financial guidance contained in this release.