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Insmed Receives Approvable Letter for iPlex(TM); Conference Call Tomorrow at 8:00am EST

RICHMOND, Va., Sep 27, 2005 (BUSINESS WIRE) -- Insmed Incorporated (NASDAQ-NMS: INSM) (NASDAQ: INSM) announced today the receipt of an Approvable Letter from United States Food and Drug Administration (FDA) for iPlex(TM) (rhIGF-I/rhIGFBP-3) (Mecasermin rinfibate), for the treatment of children with growth failure who suffer from Severe Primary IGF-1 deficiency (Primary IGFD). Previously Insmed referred to its primary indication as Growth Hormone Insensitivity Syndrome (GHIS). Based on FDA input GHIS is now referred to as Severe Primary IGFD. iPlex is the new worldwide trade name for Insmed's proprietary combination of rhIGF-I/rhIGFBP-3 which was previously called SomatoKine.

The Approvable Letter Insmed received is an official notification that the FDA has completed the review of the iPlex New Drug Application (NDA) and has found the application to be sufficiently complete for full approval pending the submission of additional information primarily regarding the Chemistry, Manufacturing and Controls (CMC) section of the application. FDA is not requiring the Company to conduct additional preclinical or clinical trials. FDA has informed Insmed that they are still considering iPlex's orphan exclusivity status.

"The Company plans to rapidly respond to these questions and work with the Agency to resolve all outstanding issues. I look forward to the completion of our work with the FDA so that we may bring this product to the clinic, and provide caregivers with this important therapeutic option for their patients", added Geoffrey Allan, Ph.D., President and Chief Executive Officer of Insmed.

"Based on my experience with therapies for a variety of growth disorders, it is clear that the pediatric endocrine community will welcome this alternative therapy. Throughout the clinical development program, iPlex therapy has demonstrated a very favorable safety profile, in addition to the robust growth response," commented Kenneth Attie, M.D. Chief Medical Officer for Insmed.

Conference Call at 8:00am

Insmed management will host a conference call at 8:00am ET, September 28, 2005. To participate in the conference call, dial 800-811-8824 (domestic) or 913-981-4903 (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: 2242133 A web replay of the call will be available through the corporate website beginning at 10:00 a.m.

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.
