FDA to Review Insmed's Complete Response to Approvable Letter for iPlex

RICHMOND, Va., Oct 25, 2005 (BUSINESS WIRE) -- Insmed Incorporated (NASDAQ-NMS: INSM) (NASDAQ: INSM) announced today that the United States Food and Drug Administration (FDA) considers Insmed's submission of October 12, 2005 as a complete, class 1 response to the Approvable Letter for iPlex(TM) (mecasermin rinfibate (rDNA origin) injection), for the treatment of children with growth failure who suffer from Severe Primary IGF-1 deficiency (Primary IGFD). The FDA has established December 12, 2005 as its target to complete its 60-day review of the iPlex New Drug Application (NDA).

In September 2005, the FDA issued an Approvable Letter indicating that the FDA has completed the review of the iPlex 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. The FDA has not yet determined whether the approval and granting of orphan exclusivity for mecasermin (rDNA origin) for Severe Primary IGF-1 deficiency will block the approval of iPlex.

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.