FDA Grants Priority Review for Insmed's NDA for SomatoKine for the Treatment of Growth Hormone Insensitivity Syndrome

RICHMOND, Va., Apr 13, 2005 (BUSINESS WIRE) -- Insmed Incorporated (NASDAQ: INSM) announced today that the Company has received Priority Review notification from the U.S. Food and Drug Administration (FDA) for the New Drug Application (NDA) for its drug candidate SomatoKine (mecasermin rinfabate). The FDA has notified the Company that the User Fee Goal Date is July 3, 2005.

The FDA previously granted SomatoKine, an IGF-I therapy, orphan drug designation, a designation conferred upon investigational products for diseases that affect fewer than 200,000 patients in the United States. Products with orphan drug designation that are the first to be approved for a specific indication have seven years market exclusivity within the United States.

More on SomatoKine(R)

Insmed's SomatoKine(R) is a proprietary delivery composition of insulin-like growth factor-I (IGF-I) and its principal binding protein, IGFBP-3. The novel compound is administered as a single daily subcutaneous injection, which can restore IGF levels into the normal range. On March 10 Insmed announced that the FDA had accepted Insmed's NDA submission for SomatoKine(R) for the treatment of Growth Hormone Insensitivity Syndrome (GHIS). Previously, Insmed provided the results from a six-month data analysis of the ongoing pivotal Phase III GHIS clinical trial showing a statistically significant increase (p

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.