FDA Extends PDUFA Date for SomatoKine to October 03, 2005

RICHMOND, Va., Jun 10, 2005 (BUSINESS WIRE) -- Insmed Incorporated (NASDAQ: INSM) today announced that it has received notification from the United States Food and Drug Administration (FDA) that the agency expects to complete the priority review of SomatoKine(R) on or before October 03, 2005, which is a three month extension from the original user fee goal date.

The extension is a result of the agency classifying responses to questions about the NDA as a major amendment to the NDA. The agency has reset the user fee goal date to give it additional time to review the information contained in the Company's response.

"We welcomed the opportunity to address questions the FDA had regarding our NDA," said Geoffrey Allen, President and CEO of Insmed. "The Company has not been notified of any specific deficiencies and we believe we have thoroughly and comprehensively addressed all of their questions. We remain confident that SomatoKine will become an important therapy for the treatment of growth hormone insensitivity syndrome (GHIS).

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.