# Insmed Initiates Phase II HIV-Associated Lipodystrophy Trial With Somatokine(R)

RICHMOND, Va., April 20, 2005 /PRNewswire-FirstCall via COMTEX/ -- Insmed Incorporated (Nasdaq: INSM) today announced that it has initiated a Phase II clinical trial examining the therapeutic benefit of treating HIV-Associated Lipodystrophy with SomatoKine(R), the Company's proprietary once daily IGF-I therapy.

The Phase II clinical trial, led by Principal Investigator Dr. Morris Schambelan, Professor of Medicine at UC San Francisco and Chief of Endocrinology and Director of the General Clinical Research Center San Francisco General Hospital, is an open-label study designed to evaluate the safety and efficacy of SomatoKine for 12 weeks in 12 subjects with HIV associated lipodystrophy. To qualify for inclusion in the study, patients must be between 18-65 years of age, have confirmed HIV-1 infection, fat accumulation (visceral adiposity), and evidence of insulin resistance. The primary goal of the study is to determine the effects of SomatoKine on visceral fat and insulin sensitivity.

"We have made tremendous strides in treating HIV infection with highly active antiretroviral therapy. However, with these advances, we have encountered a number of troublesome side effects, including insulin resistance and abnormalities in fat distribution. We are eager to identify effective therapies for these problems, so that affected patients may return to a more normal metabolic state. In previous studies, SomatoKine has demonstrated an ability to improve both insulin sensitivity and body composition in other patient populations, and we are optimistic that those benefits will be seen in our HIV positive patients as well," stated Dr. Schambelan.

More on HIV-Associated Lipodystrophy

Since the advent of highly active antiretroviral therapy (HAART), there has been a marked increase in adverse metabolic effects, such as insulin resistance, hyperglycemia, dyslipidemia and changes in body fat distribution that include syndromes of both central fat accumulation (visceral adiposity and buffalo hump) and fat loss in the limbs. Recent studies performed in subjects on HAART suggest nearly 50% of individuals develop the morphologic features of this syndrome. With the similarity to metabolic syndrome X, which has been associated with increased risk of cardiovascular disease, it is now feared that these side effects may impact on the long-term prognosis in patients whose life expectancies have been significantly extended due to effective viral suppression by HAART.

More on rhIGF-I/rhIGFBP-3, SomatoKine(R)

Insmed's SomatoKine is a proprietary drug product 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, capable of restoring IGF-I levels into the normal range in deficient individuals. On 10 March 2005, Insmed announced that the FDA had accepted Insmed's NDA submission for SomatoKine for the treatment of children with Growth Hormone Insensitivity Syndrome (GHIS), and on April 13, 2005 the Company announced that the FDA had granted the GHIS NDA submission Priority Review status.

In phase II studies in diabetic subjects, SomatoKine treatment resulted in improved blood glucose control and reduced daily insulin use. In studies in children and adults with severe burn injury, SomatoKine treatment resulted in increased muscle protein synthesis and reduced inflammatory response. In studies in elderly subjects recovering from hip fracture, SomatoKine treatment resulted in improved functional activity and preserved bone mineral density.

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 http://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.