Insmed Releases Positive Results from IPLEX Phase II HIV-Associated Adipose Redistribution Syndrome Clinical Study

RICHMOND, Va., Apr 30, 2007 (BUSINESS WIRE) -- Insmed Inc., (Nasdaq:INSM) today announced positive results from a Phase II investigator-sponsored clinical study of the company's drug IPLEX(TM) in HIV-infected patients affected with HIV-associated Adipose Redistribution Syndrome (HARS).

Preliminary results from the study, being conducted at the University of California, San Francisco, showed that three months of 0.5 mg/kg/day IPLEX treatment in seven patients increased IGF-I levels 3-fold and was associated with significant improvements in fasting glucose levels, the amount of insulin secreted during an oral glucose tolerance test, and overall insulin sensitivity. Moreover, there was a significant reduction in trunk fat and a positive downward trend in waist circumference when compared to baseline. Lipid profiles also tended to improve.

Notably, normal glucose tolerance was restored in half of the six patients diagnosed with impaired glucose tolerance (IGT) at the start of the study. These IGT patients also experienced a significant decrease in visceral adipose tissue (VAT). Impaired glucose tolerance is characterized by blood glucose between 140 and 200 mg/dl at the 120-minute measurement of an oral glucose tolerance test. The next phase of the study is underway to explore an IPLEX dose of 1.0 mg/kg/day given for six months.

"Our study has demonstrated that a low dose of IPLEX increased IGF-I levels 3-fold and positively impacted abnormal glucose metabolism, dyslipdemia and abnormal fat distribution, which are present in a significant number of HIV patients treated with highly active antiretroviral therapy (HAART)," said Morris Schambelan, M.D., the study's principal investigator and professor of medicine and director of the General Clinical Research Centers at University of California, San Francisco, and chief of endocrinology at San Francisco General Hospital.

"We are very encouraged by these preliminary results with low-dose IPLEX. We believe a product that improves fat distribution while also improving insulin sensitivity would be a valuable therapy for this patient population, and the positive effects on insulin sensitivity observed in this study are consistent with what we observed in our previous studies with IPLEX in patients with diabetes. These results support the most important differentiating property of our product in this patient population, which is IPLEX's ability to improve glucose homeostasis. Competitor products such as TH9507 and growth hormone reportedly either do not alter glucose homeostasis or exacerbate it, respectively. When considering that up to 40% of this population has impaired glucose homeostasis, then this property of IPLEX becomes even more valuable," said Dr. Geoffrey Allan, president and Chief Executive Officer of Insmed.

Study Description

The ongoing, open-label, investigator-sponsored Phase II clinical study is designed to evaluate the safety and efficacy of IPLEX in two cohorts of subjects, the first of which received a 0.5 mg/kg/day dose and the second of which will receive 1.0 mg/kg/day dose. The primary endpoints of the study are to determine the safety and tolerability of IPLEX and its effects on visceral fat and insulin sensitivity.

About HARS

An estimated 80,000 HIV patients in the U.S. have HARS, according to published reports. This disorder is marked by abnormal metabolism, including central fat accumulation (visceral adiposity and buffalo hump) with or without fat loss in the limbs. These features have increased markedly with the advent of highly active antiretroviral therapy (HAART) for HIV. Recent studies performed in subjects on HAART suggest nearly 40% of

individuals develop the morphologic features characteristic of this syndrome.

About IPLEX

IPLEX was approved in the United States in December 2005 for the treatment of children with growth failure due to severe primary IGF-I deficiency (Primary IGFD). IPLEX (rhIGF-I/rhIGFBP-3) is a complex of recombinant human insulin-like growth factor-I (rhIGF-I) and its predominant binding protein IGFBP-3 (rhIGFBP-3). The drug is also being investigated for various other indications with unmet medical needs, including myotonic muscular dystrophy, retinopathy of prematurity and amyotrophic lateral sclerosis (also known as ALS or Lou Gehrig's disease).

About the University of California, San Francisco

The University of California, San Francisco (UCSF), is a leading university that consistently defines health care worldwide by conducting advanced biomedical research and providing leading life science education and complex patient care. For more information, please visit www.ucsf.com.

About Insmed

Insmed is a biopharmaceutical company focused on the development and commercialization of drugs for the treatment of metabolic diseases and endocrine disorders with unmet medical needs. For more information, please visit www.insmed.com.

Forward-Looking Statements

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 study 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.