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Insmed Announces Initiation of Clinical Study of Small Molecule IGF-IR Tyrosine Kinase Inhibitor

RICHMOND, Va. & SAN FRANCISCO, Oct 19, 2004 (BUSINESS WIRE) -- Insmed Incorporated (NASDAQ: INSM) today reported that the Company will begin clinical development of a small molecule tyrosine kinase inhibitor in collaboration with the University of California, San Francisco School of Medicine, an NCI designated Comprehensive Cancer Center.

Insmed and UCSF will initiate a dose-escalating clinical study primarily designed to define the maximum tolerated dose of INSM-18 in patients with relapsed prostate cancer. The study will consist of a 28-day extension at each dose level to investigate the effect of INSM-18 on prostate specific antigen (PSA) levels. PSA is a standard serum marker for prostate cancer progression.

INSM-18, a small molecule tyrosine kinase inhibitor, has demonstrated selective inhibition of the insulin-like growth factor-I receptor (IGF-I) and human epidermal growth factor receptor (Her2/neu). It has demonstrated anti-tumor activity in preclinical studies of breast, lung, pancreatic and prostate tumors. Two single dose Phase I clinical studies have been previously completed with INSM-18. In both studies, INSM-18 was safe and well tolerated.

Ira D. Goldfine, M.D. Professor of Medicine at UCSF, a lead investigator of the study stated, "INSM-18 is a very interesting molecule that inhibits the IGF-IR tyrosine kinase, activation of which can trigger tumorigenesis. In addition, the clinical safety of this molecule has already been established. Thus this study should allow us to very quickly determine signs of efficacy of this drug in the treatment of prostate cancer." Working with Dr Goldfine at UCSF are: Drs Jack Youngren, Betty Maddux, Eric Small, and Charles Ryan, Department of Medicine; Dr John Kerner Department of Obstetrics and Gynecology; and Dr Michael Campbell, Department of Surgery.

Insmed's CEO Geoffrey Allan, Ph.D. commented, "INSM-18 is a small molecule originally licensed to the company for metabolic indications. The findings by Dr. Goldfine and his colleagues identifying the IGF-IR tyrosine kinase as a molecular target for this compound have prompted us to initiate studies in collaboration with UCSF to explore the clinical potential for this compound. We are very excited to expand our pipeline with this novel tyrosine kinase inhibitor, utilizing our extensive knowledge in IGF biology and growth factor signalling. A small molecule approach could be very complimentary to our cancer program with rhIGFBP-3, our lead compound in this area, which has just entered Phase I clinical studies."

About Prostate Cancer

Prostate cancer is a malignant tumor that usually begins in the outer part of the prostate. Symptoms of prostate cancer can include difficulty urinating, blood in the urine or semen, pain or burning during urination and even the inability to urinate. Prostate cancer can be detected by a digital rectal exam (DRE) or a prostate specific antigen test (PSA test). PSA is a substance produced by the prostate gland and is easily measured in the blood. Elevated PSA levels may indicate prostate cancer. Experts recommend an annual DRE exam beginning at the age of 45 and an annual PSA test beginning at the age of 50. Examinations should begin earlier depending on certain risk factors such as race and family history. In 2004, the American Cancer Society estimates that 230,000 new cases of prostate cancer will occur in the United States. An estimated 30,000 deaths in 2004 will occur as a result of prostate cancer, making it the second leading cause of cancer death in men.

About UCSF School of Medicine

University of California, San Francisco, an NCI designated Comprehensive Cancer Center, is one of the leading biomedical research and health science education facilities in the world. Ranked among the top 10 medical schools in the nation, the UCSF School of Medicine earns its greatest distinction from the outstanding faculty - including 3 Nobel laureates, 32 National Academy of Sciences members, 34 American Academy of Arts and

Sciences members, 62 Institute of Medicine members, and 16 Howard Hughes Medical Institute investigators. The school is comprised of 26 academic departments, 9 organized research units, and 8 interdisciplinary centers at sites throughout San Francisco. For more information, please visit www.ucsf.edu.

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, 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 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.
