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Insmmed Initiates Phase I Clinical Study for Novel Anti-Tumor Protein

RICHMOND, Va., Sep 8, 2004 (BUSINESS WIRE) -- Insmmed, Inc. (NASDAQ: INSM) announced today the initiation of a Phase I clinical study for the company's novel anti-tumor agent, recombinant human Insulin-Like Growth Factor Binding Protein-3 (rhIGFBP-3). The Phase I clinical study is an open-label, dose-escalation study designed to evaluate for the first time in humans, the safety, tolerability and pharmacokinetics of a single intravenous dose of rhIGFBP-3. The primary goal of this 30 patient study is to identify the appropriate dose of rhIGFBP-3 for a planned Phase II clinical trial in 2005.

"The FDA's approval of growth factor inhibitors to treat cancer not only validates this approach but also encourages the development of other growth factor inhibiting agents, such as rhIGFBP-3" noted Laura Shiry, Ph.D., Insmmed's head oncology scientist. "Our research shows that rhIGFBP-3 is an essential regulator of the IGF signaling pathway, which is known to be permissive to tumor growth while facilitating other tumor-promoting pathways, including EGF and VEGF. We have what we believe to be solid preclinical evidence demonstrating that rhIGFBP-3 could provide substantial benefit in treating a number of human cancers, including those of the breast, prostate, colon and lung."

The Role of rhIGFBP-3 in the Tumor Growth

Insulin-Like Growth Factor Binding Protein-3 (IGFBP-3) is a naturally occurring protein in the body whose normal role is to regulate the activity of Insulin-Like Growth Factor-I (IGF-I). Although the IGF-I is critical for normal growth and metabolism, aberrant signalling through this pathway is closely linked to the abnormal and unregulated growth of a variety of tumors. Blocking tumor-associated IGF signaling has been proven to prevent tumor growth in a variety of preclinical models. In preclinical models, rhIGFBP-3 has demonstrated efficacy in preventing tumor formation and progression. Based on these findings, Insmmed is developing rhIGFBP-3 as a novel anti-IGF-I treatment for cancer.

About Insmmed

Insmmed 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 and goals, 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 Insmmed disclaims any intention or responsibility for updating predictions or financial guidance contained in this release.
