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Insmmed Announces Expansion of Patent Portfolio in the Treatment of Diabetes; New European Patent Granted for SomatoKine

RICHMOND, Va., Nov 9, 2004 (BUSINESS WIRE) -- Insmmed Incorporated (NASDAQ: INSM) today announced issuance by the European Patent Organization of patent EP1183042 entitled "Methods for Treating Diabetes", covering the use of SomatoKine(R) (rhIGF-I/rhIGFBP-3) for the treatment of diabetes mellitus, including type 1 diabetes, type 2 diabetes and insulin resistant diabetes such as Type A insulin resistance. This European patent corresponds to the Company's United States patent US 6,040,292 also entitled "Methods for Treating Diabetes". According to the World Health Organization (WHO), approximately 170 million people have diabetes worldwide, and that this number may double by the year 2025. WHO estimates that there are 33 million patients in Europe with these conditions and an additional 18 million patients in the United States.

"This patent is important to further strengthen our expansive intellectual property position surrounding our novel IGF-I replacement therapy, SomatoKine(R)," commented Philip J. Young, Chief Business Officer and Executive Vice President. "This new patent complements our United States patent covering the same patient types. Based on data we have generated to date, we believe SomatoKine(R) has the potential to enhance the treatment of diabetes as well as insulin resistant conditions."

Over the past several years Insmmed has conducted four Phase II clinical trials with SomatoKine in type 1 and type 2 diabetes patients demonstrating SomatoKine can significantly reduce daily insulin consumption, improve blood sugar and control improve insulin sensitivity. Insmmed is preparing to initiate an additional clinical trial in Europe in Type A insulin resistance, one of the most severe forms of insulin resistance.

David Clemmons, M.D., Chief of Endocrinology, University of North Carolina School of Medicine added, "SomatoKine may prove to be a very useful addition for the management of diabetic patient who cannot achieve adequate blood sugar control. Clearly physicians need new therapies to add to their diabetic patients' regimen to help control the growing epidemic of diabetes and the resulting complications."

There is an extensive unmet medical need for a therapy that can improve blood sugar control and improve insulin sensitivity. Diabetes is one of the most common diseases in the world and is the leading cause of blindness, end-stage kidney disease, and due to nerve damage caused by excessive blood sugar; diabetes is the leading cause of non-traumatic amputations. Good blood sugar control can delay the onset and progression of these complications.

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

Insmmed's SomatoKine(R) is a proprietary delivery composition of insulin-like growth factor-I (IGF-I). The novel compound is administered as a subcutaneous injection, which can restore IGF levels to physiological relevant levels. SomatoKine(R) is currently in a pivotal Phase III clinical trial for the treatment of Growth Hormone Insensitivity Syndrome (GHIS). On July 20, Insmmed provided the results from a six-month data analysis of the ongoing pivotal Phase III GHIS clinical trial showing a statistically significant increase (p

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 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.
