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RICHMOND, Va., Dec 15, 2003 (BUSINESS WIRE) -- Insmed Incorporated (Nasdaq: INSM) today announced that the Office of Orphan Products Development of the Food and Drug Administration has approved the Company's application for orphan drug designation in the United States for SomatoKine®, for the treatment of extreme insulin resistance. With this orphan drug designation, Insmed will be granted seven years of market exclusivity upon SomatoKine® approval for this indication. There is currently no approved treatment available for patients with extreme insulin resistance in the United States.

Insmed's investigational drug rhIGF-I/rhIGFBP-3, SomatoKine®, is a proprietary delivery composition of insulin like growth factor-I (IGF-I). This drug is administered as a once-daily subcutaneous injection and is designed to restore IGF-I levels to more normal ranges in metabolic and anabolic disorders where IGF deficiency exists. Insmed is currently developing rhIGF-I/rhIGFBP-3 for the treatment of severe growth disorders and diabetes.

More on Extreme Insulin Resistance

Syndromes of Extreme Insulin Resistance appear to result from genetic defects in the insulin receptor or insulin action pathways. In addition to insulin resistance and glucose intolerance or overt diabetes, these syndromes share a number of common features including variable degrees of hyperandrogenism, hirsutism, and dysmorphic features.

More on rhIGF-I/rhIGFBP-3, SomatoKine®

Insmed's rhIGF-I/rhIGFBP-3 is a proprietary delivery composition of insulin-like growth factor-I (IGF-I). The novel compound is administered as a once-daily subcutaneous injection, which can restore IGF levels to physiological relevant levels. In diabetic subjects, administration of rhIGF-I/rhIGFBP-3 demonstrated a significant improvement in blood sugar control and a significant reduction in daily insulin use. Following severe burn injury, in both children and adults, administration of rhIGF-I/rhIGFBP-3 demonstrated a significant improvement in muscle protein synthesis and a significant reduction in the inflammatory response associated with the trauma. In recovery from hip fractures, administration of rhIGF-I/rhIGFBP-3 has demonstrated a significant improvement in functional recovery and bone mineral density. rhIGF-I/rhIGFBP-3 is currently in a pivotal Phase III clinical trial for the treatment of Growth Hormone Insensitivity Syndrome (GHIS), a severe growth disorder.

About Insmed Incorporated

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 include all statements regarding expected financial position, results of operations, cash flows, dividends, financing plans, business strategies, operating efficiencies or synergies, budgets, capital and other expenditures, competitive positions, growth opportunities for existing or proposed products or services, plans and objectives of management, demand for new pharmaceutical products, market trends in the pharmaceutical business, inflation and various economic and business trends. 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, the company may lack financial resources to complete development of product candidates, 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.
