Insmed Receives European Orphan Drug Designation For rhIGF-I/rhIGFBP-3; Product Will Have 10 Years of Market Exclusivity in Treatment of Growth Disorder

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RICHMOND, Va.--(BUSINESS WIRE)--June 20, 2003--Insmed Incorporated (Nasdaq: INSM) today announced that the Committee for Orphan Medicinal Products of the European Agency for the Evaluation of Medicinal Products (EMEA) has approved the Company's application for orphan drug designation in Europe for rhIGF-I/rhIGFBP-3 for the treatment of growth hormone insensitivity syndrome (GHIS).

The European orphan medicinal product designation provides Insmed ten years of market exclusivity upon rhIGF-I/rhIGFBP-3 approval for GHIS. Orphan designation also provides protocol assistance from the EMEA, direct access to the EMEA centralized procedure for marketing authorization and reductions or exemptions of certain application fees.

Insmed's investigational drug rhIGF-I/rhIGFBP-3 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 growth disorders and diabetes.

More on GHIS

Growth hormone insensitivity syndrome is a rare genetic condition in which patients, when exposed to growth hormone (GH), do not generate insulin-like growth factor-I, the mediator of many of the effects ascribed to GH. IGF-I is essential for proper growth and metabolism. Children with GHIS do not recognize or respond to human growth hormone and as a result fail to produce physiologically relevant levels of IGF-I. The normalization of IGF-I levels has been shown to significantly increase growth in GHIS patients.

More on rhIGF-I/rhIGFBP-3

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.

About Insmed Incorporated

Insmed Incorporated is a biopharmaceutical company focused on the development of drug candidates for the treatment of metabolic diseases with unmet medical needs. For further information about Insmed and rhIGF-I/rhIGFBP-3, please visit the company's corporate website at 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.

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