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RICHMOND, Va., Apr 8, 2003 (BUSINESS WIRE) -- Insmed Incorporated (Nasdaq: INSM) has initiated a named patient programme in Europe, that will make available the investigational drug rhIGF-I/rhIGFBP-3, a novel, first in class compound currently in clinical studies for the treatment of a severe genetic growth disorder known as growth hormone insensitivity syndrome/Laron syndrome (GHIS).

Interest in Insmed's program recently resulted in the initiation of treatment for patients in Scandinavia, with authorisation pending in several other European countries.

Insmed's investigational drug rhIGF-I/rhIGFBP-3 is a proprietary delivery composition of insulin like growth factor-I (IGF-I). The 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.

"Insmed is proud to provide this pioneering IGF-I replacement therapy to GHIS patients in desperate need of treatment. It is our hope that they will benefit greatly from this special licence program," stated Tage Ramakrishna, M.D., Medical Director of Insmed Incorporated.

The investigational drug will be made available to those GHIS patients who, in the opinion of their doctor, may benefit from IGF-I therapy. At pre-commercial scale quantities, the drug will be available on a limited basis. Patients may be treated at an initial dose of 0.5mg/kg/day at a cost of $177.00/0.60ml vial and $230.00/0.75ml vial. Doctors should contact Insmed Incorporated; patient inquiries cannot be accepted.

A pivotal Phase III trial to support product approval is currently scheduled to begin in the first half of this year. This twelve month study is designed to measure an increase in linear growth velocity, with a 6-month interim analysis planned for early 2004. Safety data generated from the named patient program will be used to support marketing applications in 2004.

"Insmed is excited to be at the forefront of efforts to treat growth and metabolic disorders where IGF-I replacement therapy can potentially restore normal biological function," stated Dr. Geoffrey Allan, president and chief executive officer of Insmed Incorporated.

About GHIS

Growth hormone insensitivity syndrome/Laron 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.

About IGF-I Therapy

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. Because of these and other risks and uncertainties, actual results may differ materially from those described in this press release.

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