Insmed Launches Pivotal Phase III Clinical Trial in GHIS; Data Analysis Planned for Early 2004

Insmed Launches Pivotal Phase III Clinical Trial in GHIS; Data Analysis Planned for Early 2004

RICHMOND, Va., Jun 23, 2003 (BUSINESS WIRE) -- Insmed Incorporated (Nasdaq: INSM) announced today the initiation of a pivotal Phase III clinical trial with rhIGF-I/rhIGFBP-3 in children with growth hormone insensitivity syndrome (GHIS).

The pivotal Phase III study with rhIGF-I/rhIGFBP-3 in children with GHIS is designed to measure an increase in linear growth velocity, with a 6-month primary endpoint analysis planned for early 2004. Data generated from this trial combined with data from Pharmacia's extensive GHIS European regulatory filings acquired in the fall of 2002 will be used to support marketing applications in 2004.

Geoffrey Allan, Ph.D., president and chief executive officer of Insmed, commented, "This marks a critical milestone in the transformation of Insmed to a commercially-focused organization. An approval in GHIS will set the stage for other markets where IGF-I therapy may be indicated. Given the serious nature of low IGF-I levels for the developing body, we will continue to work diligently to make this therapy available to meet this important unmet medical need."

Insmed recently announced that the EMEA has granted the company orphan drug designation for rhIGF-I/rhIGFBP-3 in GHIS, which provides the company with 10 years of market exclusivity in Europe upon approval. Last year, the FDA granted orphan drug designation to the company for rhIGF-I/rhIGFBP-3 in GHIS, which provides the company seven years of market exclusivity in the United States upon approval.

GHIS 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.

Corporate Presentation to be Webcast Live Today at 11:15 a.m. Eastern Time

Insmed Incorporated has been selected to present to the Biotechnology Industry Organization Annual Convention, BIO 2003, to take place June 22-25 at the Washington Convention Center, Washington, D.C. The presentation will take place today at 11:15 a.m. Eastern Time.

The presentation will be webcast live, and a recording will be made available following the presentation. The webcast and recording will be available on Insmed's corporate website, www.insmed.com. To access the webcast, please log on to Insmed's website approximately ten minutes prior to the presentation to register and download any necessary audio or visual software.

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.

Insmed Incorporated
Investor Relations: Baxter Phillips, III, 804/565-3041
bphillips@insmed.com