

Home / Investors/ News Releases

IPLEX(TM) Demonstrates Significant, Dose-Dependent Increases in Growth Rate

SAN FRANCISCO, May 1, 2006 /PRNewswire-FirstCall via COMTEX News Network/ -- Insmed Incorporated (Nasdaq: INSM) today announced results from a prospective, multicenter clinical trial of rhIGF-I/rhIGFBP-3, or IPLEX(TM) (mecasermin rinfabate [rDNA origin] injection) administered once daily to children with severe primary insulin-like growth factor-I (IGF-I) deficiency. The study showed that treatment resulted in statistically significant, dose-dependent increases in height velocity (growth rate) with a favorable safety profile. The first-year results from the 24-month study were presented in an oral presentation at the Pediatric Academic Societies' (PAS) 2006 Annual Meeting at the Moscone Center in San Francisco, CA.

In the scientific abstract presenting the safety and efficacy data for IPLEX in children with severe primary IGF-I deficiency (primary growth hormone insensitivity), the investigators reported that the mean height velocity for the dose group titrated with up to 2 mg/kg/day increased from 2.0 cm/year pre- treatment to 8.3 cm/year during treatment. Children with genetic and acquired forms of growth hormone (GH) insensitivity appeared to respond equally well to treatment. IPLEX is the only once daily IGF-I replacement therapy available for the treatment of severe primary IGFD. The once-daily dosing regimen used in the study was associated with a high compliance rate of 95% of injections taken.

"We are very pleased with the growth rates and safety profile achieved with IPLEX in this patient population," remarked Dr. Kenneth Attie, Vice President, Medical Affairs at Insmed. "Once-daily administration of the complex provided physiologic replacement of IGF-I and was well-accepted by patients and their families in the study," he added.

The safety profile of IPLEX proved favorable as instances of low blood sugar (hypoglycemia) were mostly mild and asymptomatic, with no hypoglycemic seizures reported. Patients with severe GH insensitivity have a predisposition to hypoglycemia without treatment. Of the subjects enrolled in the study, 28% reported a history of hypoglycemia prior to treatment. This was similar to the proportion of subjects (31%) who experienced at least one incidence of hypoglycemia during the first year of treatment with IPLEX, usually described as mild and asymptomatic.

In the study, no patients discontinued IPLEX due to a related adverse event. Two patients had papilledema (one with a blocked pre-existing ventriculo-peritoneal shunt and one asymptomatic). No instances of facial nerve paralysis were reported. As is common with protein therapeutics, antibodies to the protein complex were detected in most patients, but were not associated with growth attenuation or adverse effects.

IPLEX was approved as an orphan drug by the United States Food and Drug Administration in December 2005 for the treatment of growth failure in children with severe primary IGF-I deficiency (Primary IGFD) or with growth hormone (GH) gene deletion who have developed neutralizing antibodies to GH.

About IPLEX

IPLEX, a complex of recombinant human IGF-I and its binding protein IGFBP- 3 (rhIGF-I/rhIGFBP-3), is the only once-daily IGF-I replacement therapy. It is also the only FDA-approved therapy that provides both IGF-I and IGFBP-3 to treat children with severe primary IGFD. The drug, to be launched during the second quarter of 2006, is also being investigated for various other indications with unmet medical needs, including extreme insulin resistance, myotonic muscular dystrophy and HIV Associated Adipose Redistribution Syndrome (HARS). For more information about IPLEX please go to http://www.go-IPLEX.com.

About the Condition

Severe primary IGFD is a genetic or acquired condition in which patients do not generate sufficient quantities of

insulin-like growth factor-I (IGF-I) due to defect in the growth hormone (GH) receptor/IGF-I pathway. Gene mutations leading to growth failure due to IGF-I deficiency have been identified in the growth hormone receptor, in the GH receptor signalling pathway, and in the IGF-I gene itself. Patients with severe primary IGFD present with marked short stature and a poor prognosis for adult stature.

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 http://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 planned clinical trial design, our regulatory and business strategies, plans and objectives of management 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.