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INSMED Announces IPLEX(TM) Availability Nationwide for Children with Severe Short Stature; IPLEX Launch Marked By The First Product Shipments To Patients in States Across the Country

RICHMOND, Va., May 25, 2006 (BUSINESS WIRE) -- Insmmed Incorporated (NASDAQ:INSM) announced today the nationwide availability of IPLEX(TM) (mecasermin rinfabate (rDNA origin). IPLEX was approved as an orphan drug by the 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. IPLEX is the only once-daily IGF-I replacement therapy available for the treatment of severe primary IGFD.

"Insmmed is very pleased to provide this novel therapeutic protein complex for the treatment of children who suffer from severe primary IGFD," said Philip J. Young, CBO. "It has been a 20-year journey for the many researchers involved in the development of IPLEX, and we are very gratified to finally have the opportunity to provide the only once-daily IGF-I therapy to patients in the United States. It is with great pleasure that we announce that on May 24, 2006 the first US patients with Primary IGFD began receiving IPLEX."

Primary IGFD is a distinct diagnosis of short stature and is believed to affect as many as 30,000 children in the United States. A subset of these patients is classified as having Severe Primary IGFD, which is estimated to affect 6,000 children. Severe Primary IGFD is a genetic or acquired condition in which patients do not generate sufficient quantities of IGF-I due to defects in the GH receptor/IGF-I pathway. In addition to the growth failure, Severe Primary IGFD can be associated with psychosocial problems. The early recognition and proper treatment of Severe Primary IGFD is critical in helping patients normalize growth and metabolic function.

"Numerous areas of the growth process remained a mystery for many years," said Mary Andrews, Executive Director of the MAGIC Foundation. "Now, thanks to the hard work of the researchers at Insmmed, growth is better understood. It is so exciting to know that a new and convenient therapy is available for the many children with adequate levels of growth hormone who are not growing normally."

"As long time advocates for the diagnosis and treatment of children with growth issues, we recognize the importance of new and innovative approaches. We are pleased to welcome Insmmed's debut into the field of pediatric growth therapy," adds Patricia D. Costa, Executive Director of the Human Growth Foundation.

IPLEX became available starting May 24 through a nationwide distribution system called PlexPoint(TM). PlexPoint is a single point of contact system for patients, payers and healthcare providers. PlexPoint can be accessed by calling 866-GO-IPLEX (866-464-7539) or on the web at www.go-IPLEX.com. The PlexPoint system is designed to provide the highest level of customer service to all stakeholders in the therapeutic decision-making and treatment processes. This system has been designed to provide flexibility and support to the payers, physicians, distributors and patients by allowing them to customize the distribution process to meet their individual needs.

More About IPLEX

Much of the data to support the FDA's approval last December were recently presented at the Pediatric Academic Societies' (PAS) 2006 Annual Meeting in San Francisco, California. At 12 months the ongoing study demonstrated significant, dose-dependent increases in growth rate. 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 GH insensitivity or IGFD appeared to respond equally well to treatment.

The once-daily dosing regimen used in the study was associated with a high compliance rate of 95% of injections taken. The safety profile of IPLEX proved favorable as instances of low blood sugar (hypoglycemia) were mostly mild and asymptomatic. 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.

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 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) and short stature in children with Primary IGFD associated with Noonan Syndrome.

About Insmmed Incorporated

Insmmed is a biopharmaceutical company focused on the development and commercialization of drug candidates for the treatment of metabolic diseases and endocrine disorders with unmet medical needs. For more information, log onto www.insmed.com or call 866-GO-IPLEX (866-464-7539) toll free.

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 our regulatory and business strategies, plans and objectives of management and growth opportunities for IPLEX and other proposed products and our planned clinical trial design, . Such forward-looking statements are subject to numerous risks and uncertainties, including risks that IPLEX may not be successfully marketed or manufactured, competing products for IPLEX and our other proposed products may be more successful, our other product candidates may fail in the clinic or, we may lack financial resources to complete development of product candidates, the FDA may interpret the results of our studies differently than we have, and the biopharmaceutical industry may experience negative market trends and other risks detailed from time to time in our 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 our 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 Insmmed disclaims any intention or responsibility for updating predictions or financial guidance contained in this release.
