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Insmmed Incorporated Receives Orphan Drug Designation for SomatoKine for the Treatment of Growth Hormone Insensitivity Syndrome -Laron Syndrome- and Initiates Clinical Study

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RICHMOND, Va., Jul 17, 2002 (BW HealthWire) -- Insmmed Incorporated (Nasdaq: INSM) today announced that the Office of Orphan Products Development of the Food and Drug Administration has approved the Company's application for orphan drug designation in the United States for SomatoKine®, for the treatment of growth hormone insensitivity syndrome (GHIS/LARON SYNDROME).

With this orphan drug designation, Insmmed will be granted seven years of market exclusivity upon SomatoKine approval for this indication. There is currently no approved treatment available for growth deficiency due to Laron syndrome.

In addition, Insmmed has announced that a Phase II dose-range finding study with SomatoKine in children with GHIS has been initiated at Saint Bartholomew's and the Royal London School of Medicine in London, England. Professor Martin O. Savage, M.D. and Cecelia Camacho-Hubner, M.D., Ph.D. both recognized experts in growth hormone disorders, are serving as Principal Investigators for the study.

"This is a major milestone in the development of a treatment for children afflicted with Laron syndrome. We are delighted to have the opportunity to work with Professor Savage and his colleagues to treat these patients with what we believe to be a safe and powerful growth-promoting therapy," commented Geoffrey Allan, Ph.D., President and CEO of Insmmed Incorporated.

Growth Hormone Insensitivity Syndrome (GHIS) is a condition in which patients fail to produce adequate quantities of insulin-like growth factor-I (IGF-I) due to failure to recognize or respond to the growth hormone signal. In GHIS subjects, IGF-I deficiency results in a diminished growth rate and a short stature. Treatment with IGF-I restores growth in this patient population. Since the bioactive component of SomatoKine is IGF-I, treatment of this growth deficiency with SomatoKine serves as hormone replacement therapy.

About SomatoKine®

The company's product candidate, SomatoKine®, is being developed as an insulin sensitizer and growth promoting/anabolic agent. The drug is the recombinant form of human insulin-like growth factor-I (IGF-I) and its regulatory binding protein, IGFBP-3. SomatoKine is currently in clinical development for type 1 and type 2 diabetes, and growth hormone insensitivity syndrome (GHIS).

About Insmmed Incorporated

Insmmed Incorporated is a biopharmaceutical company focused on the discovery and development of pharmaceutical products for the treatment of metabolic diseases and endocrine disorders. Further information is available at <http://www.businesswire.com> Today's News On The Net - Business Wire's full file on the Internet with Hyperlinks to your home page.

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