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# Italian Ministry of Health Requests IPLEX(TM) for Treatment of ALS (Lou Gehrig's Disease)

RICHMOND, Va., Jan 10, 2007 (BUSINESS WIRE) -- Insmed Incorporated (NASDAQ: INSM) has been requested by the Italian Ministry of Health, to make its drug, IPLEX(TM) (rhIGF1/rhIGFBP-3), available to physicians in Italy to treat patients with Amyotrophic Lateral Sclerosis (ALS), also known as Lou Gehrig's Disease.

The request comes as a result of several Italian Court rulings ordering the Italian National Health System to provide the drug to specific ALS patients who have petitioned the Court. Through an agreement with Cephalon, which holds European patent rights to IGF-1 pertaining to the treatment of ALS, Insmed will be able to provide IPLEX to physicians in Italy. IPLEX will be distributed through an expanded access program, with Insmed receiving payment for drug from the Italian Health Authorities.

ALS is a neurodegenerative disorder that causes progressive muscle weakness and loss of motor neurons. IGF-1 is a neurotrophic factor essential for normal development of the nervous system. In animal models and cell culture systems IGF-1 protects motor neurons and promotes muscle and nerve regeneration.

"We are very pleased that the Italian ministry has approached us to help in treating this devastating disease," said Geoffrey Allan, President and CEO of Insmed. "We greatly appreciate the fact that Cephalon has collaborated with us in this effort. We hope that data collected from this expanded access program will be useful for the further clinical development of IPLEX for this indication," he added.

In Italy, there are an estimated 1000 new cases of ALS per year. The Ministry of Health has tried for several years to provide IGF-1 to these patients and in doing so has contacted several pharmaceutical companies worldwide.

"We are very pleased that Insmed responded to our request and are willing to provide IPLEX," said Carlo Tomino of the Italian Ministry of Health/AIFA.

## About ALS

Amyotrophic lateral sclerosis (ALS), often referred to as "Lou Gehrig's disease," is a progressive neurodegenerative disease that affects nerve cells in the brain and the spinal cord. Motor neurons reach from the brain to the spinal cord and from the spinal cord to the muscles throughout the body. The progressive degeneration of the motor neurons in ALS eventually leads to their death. When the motor neurons die, the ability of the brain to initiate and control muscle movement is lost. With voluntary muscle action progressively affected, patients in the later stages of the disease may become totally paralyzed. Yet, through it all, for the vast majority of people, their minds remain unaffected. While there is no cure or treatment today that halts or reverses ALS, there are several drugs in clinical trials that hold promise. The most recent study involving IGF-1 is being conducted by Dr. Eric Sorenson, of the Mayo Medical Center, in Rochester, Minnesota.

## About IPLEX(TM)

IPLEX is approved in the United States as the only once daily treatment for children with short stature associated with severe primary IGF-I deficiency (Primary IGFD). IPLEX (rhIGF-I/rhIGFBP-3), a complex of recombinant human insulin-like growth factor-I (rhIGF-I) and its predominant binding protein IGFBP-3 (rhIGFBP-3), is the only FDA-approved IGF-I replacement therapy that also replaces deficient IGFBP-3 in these patients. The drug, which was launched in the second quarter of 2006, is also being investigated for various other indications with unmet medical needs, including severe insulin resistance, myotonic muscular dystrophy and HIV-Associated Adipose Redistribution Syndrome (HARS). For more information about IPLEX please visit [www.go-IPLEX.com](http://www.go-IPLEX.com).

## About Insméd

Insméd is a biopharmaceutical company focused on the development and commercialization of drugs for the treatment of metabolic diseases and endocrine disorders with unmet medical needs. For more information, please visit [www.insmed.com](http://www.insmed.com).

## Forward Looking Statements

Statements included within this press release, which are not historical in nature, may constitute forward-looking statements for the 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 the Company's product plans. Such forward-looking statements are subject to numerous risks and uncertainties, including but not limited to the uncertainty of the ultimate outcome of any litigation with Tercica and Genentech, including litigation that resulted in a jury verdict finding that Insméd infringed three patents owned by Genentech and exclusively licensed by Tercica and awarding Genentech and Tercica past damages of \$7.5 million dollars as an upfront payment and a royalty of 15% for past sales under \$100 million and 20% for past sales over \$100 million, the risk 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 or the FDA or other regulatory agencies may interpret the results of our studies differently than we have. We can give no assurances that we will be successful in overturning the jury verdict either at the district court or on appeal or in avoiding an injunction that Genentech and Tercica have requested to stop the manufacture and sale of IPLEX or in avoiding the enhancement of damages and award of attorney fees and costs that Genentech and Tercica have also indicated they will seek or that such litigation would not have a material adverse effect on our business, financial condition and results of operation. Furthermore, we may not be able to afford the expense of defending against such a claim, or paying the damages awarded by the jury, as well as any enhanced damages or attorney's fees that may be awarded by the Court. We may also not be able to continue to operate should an injunction issue. 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.

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