



[Home](#) / [Investors](#) / [News Releases](#)

# **Insmed Provides Update on IPLEX(TM) Expanded Access Program in Italy for the Treatment of Amyotrophic Lateral Sclerosis**

RICHMOND, Va., Jan 24, 2008 /PRNewswire-FirstCall via COMTEX News Network/ -- Insmed Inc. (Nasdaq: INSM), a developer of follow-on biologics and biopharmaceuticals, today provided an update on the IPLEX(TM) Expanded Access Program (EAP) in Italy for the treatment of Amyotrophic Lateral Sclerosis (ALS). Since early 2007, the EAP has grown to include 15 physicians and approximately 70 subjects have been enrolled into the program. Additional subjects continue to be enrolled into the program. IPLEX(TM) appears to have been safe and well tolerated in the subject population to date and no individuals have dropped out of the study for reasons related to IPLEX(TM). The Company received cost recovery of \$5.2 million for drug supplies for the full-year 2007.

The study utilizes a Revised ALS Functional Rating Scale (ALSFRS) to monitor the progress of the subjects. The ALSFRS is used to determine a patient's capacity and independence in several functional activities including speech, salivation, swallowing, handwriting, cutting foods and handling utensils, dressing and hygiene, turning in bed, walking, climbing stairs, and respiratory function. The purpose of collecting this information is to help ensure safety and to gain an understanding as to whether IPLEX(TM) provides any benefit to these subjects.

ALS, often referred to as Lou Gehrig's disease, is a progressive neurodegenerative disorder that affects nerve cells in the brain and 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 movement action progressively negatively affected, those patients in the later stage of the disease may become totally paralyzed. The ALS Association believes that 5,600 people in the U.S. are diagnosed with ALS annually, and an estimated 30,000 Americans suffer from the disease. Most ALS patients die within three to five years after onset of symptoms, according to the National Institute of Neurological Disorders and Stroke.

"We are pleased with the progress of the EAP for IPLEX(TM) in Italy," said Geoffrey Allan Ph.D., Insmed's President and Chief Executive Officer. "Because this disease has few treatment options, the patients participating in this study are in desperate need of effective medicines. We look forward to continuing to work with Italian health authorities and clinicians to advance this important study and, in conjunction with them, will proceed with a thorough analysis of the data from this study at an appropriate point in the future."

## **About IPLEX(TM)**

IPLEX(TM) was approved in the United States in December 2005 for the treatment of children with growth failure due to severe primary IGF-I deficiency (Primary IGFD). IPLEX(TM) rhIGF-I/rhIGFBP-3, is a complex of recombinant human insulin-like growth factor-I (rhIGF-I) and its predominant binding protein IGFBP-3 (rhIGFBP-3). The drug is also being investigated for various other indications with unmet medical needs.

## **About Insmed**

Insmed Inc. is a biopharmaceutical company with unique protein process development and manufacturing experience and a proprietary protein platform aimed at niche markets with unmet medical needs. For more information, please visit [www.insmed.com](http://www.insmed.com).

## **Forward-Looking Statements**

This release contains forward-looking statements which are made pursuant to provisions of Section 21E of the

Securities Exchange Act of 1934. Investors are cautioned that such statements in this release, including statements relating to planned clinical study design, regulatory and business strategies, plans and objectives of management and growth opportunities for existing or proposed products, constitute forward-looking statements which involve risks and uncertainties that could cause actual results to differ materially from those anticipated by the forward-looking statements. The risks and uncertainties include, without limitation, risks that product candidates may fail in the clinic or may not be successfully marketed or manufactured, we may lack financial resources to complete development of product candidates, the FDA may interpret the results of studies differently than us, competing products may be more successful, demand for new pharmaceutical products may decrease, the biopharmaceutical industry may experience negative market trends, our entrance into the follow on biologics market may be unsuccessful, our common stock could be delisted from the Nasdaq Global Market and other risks and challenges detailed in our filings with the U.S. Securities and Exchange Commission, including our Quarterly Report on Form 10-Q for the quarter ended September 30, 2007. Readers are cautioned not to place undue reliance on any forward-looking statements which speak only as of the date of this release. We undertake no obligation to publicly release the results of any revisions to these forward-looking statements that may be made to reflect events or circumstances that occur after the date of this release or to reflect the occurrence of unanticipated events.

---