Insmed Receives FDA Orphan Drug Designation for IPLEX(TM) in the Treatment of Myotonic Muscular Dystrophy

RICHMOND, Va., Dec 18, 2007 /PRNewswire-FirstCall via COMTEX News Network/ -- Insmed Inc. (Nasdaq: INSM), a developer of follow-on biologics and biopharmaceuticals, today announced that the Food and Drug Administration (FDA) has granted Orphan Drug Designation for IPLEX(TM) for the treatment of Myotonic Muscular Dystrophy (MMD). Insmed is currently conducting a 24-week Phase III enabling trial for IPLEX(TM) in MMD, and recently was awarded a grant of approximately $2.1 million from the Muscular Dystrophy Association (MDA), which is expected to cover a substantial portion of the external costs associated with the trial.

"This Orphan Drug Designation is another milestone for Insmed in our development and commercialization plan for IPLEX(TM) in MMD," said Geoffrey Allan Ph.D., Insmed's President and Chief Executive Officer. "Orphan status, combined with the recent $2.1 million MDA grant, positions us well to continue advancing this important product candidate through clinical development, and maximize the market opportunities for MMD available to us."

Orphan status is granted by the FDA to promote the development of products that demonstrate promise for the treatment of rare diseases affecting fewer than 200,000 Americans annually. This orphan drug designation for IPLEX(TM), grants Insmed seven years of market exclusivity upon approval for the MMD indication. In addition, Insmed is eligible for tax credits relative to its development costs, as well as assistance from the FDA in advancing the drug candidate through the regulatory process.

MMD affects approximately 37,000 Americans, and nearly 60,000 people in the European Union. MMD is a genetic disease characterized by endurance loss, muscle wasting, weakness, pain, cognitive impairment and gastro-intestinal dysfunction. There is currently no cure for the disease, and no specific treatment has been developed to satisfactorily reverse or ameliorate the common symptoms associated with the disease.

About IPLEX(TM)

IPLEX(TM) is a complex recombinant human insulin-like growth factor-I (rhIGF-I) and its predominant binding protein IGFBP-3 (rhIGFBP-3). The drug 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) is currently being studied as a treatment for several serious medical conditions, including two neuromuscular disorders, Myotonic Muscular Dystrophy (MMD) and ALS (Lou Gehrig's Disease); HIV-Associated Adipose Redistribution Syndrome (HARS); and retinopathy of prematurity (ROP).

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.

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.