Insmed and Premacure Announce European Orphan Designation for IPLEX(TM) in Retinopathy of Prematurity in Infants

RICHMOND, Va., Jan 21, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Insmed Inc. (Nasdaq: INSM), a developer of follow-on biologics and biopharmaceuticals, and Premacure AB, a biopharmaceutical company dedicated to the development of, diagnosis and prevention of complications in neonates due to premature birth, today announced that the European Medicines Agency (EMEA) has granted Premacure orphan designation for Insmed's IPLEX(TM) product, also known as mecasermin rinfabate, for the prevention of retinopathy of prematurity (ROP) in neonates of less than 32 weeks of gestational age. Premacure AB intends to initiate a phase II multicenter trial for IPLEX(TM) in the ROP indication during the second quarter of 2009.

With an orphan designation in Europe, Premacure AB is eligible for protocol assistance (scientific advice), as well as fee reductions for pre-authorization activities, including the application for marketing authorization, and inspections. Post-authorization activities, such as variations and annual fees, are also subject to fee reductions. More details on EMEA orphan drug designation incentives can be found at http://www.emea.europa.eu/htms/human/orphans/incentives.htm. The EMEA Public Summary on the IPLEX(TM) in ROP positive opinion can be found at:

http://www.emea.europa.eu/pdfs/human/comp/opinion/6385108en.pdf.

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 ROP

ROP is a disease of the eye that affects prematurely born babies. It is thought to be caused by disorganised growth of retinal blood vessels which may result in scarring and retinal detachment. ROP can be mild and may resolve spontaneously, but may lead to blindness in serious cases. It is one of the most common causes of visual loss in childhood and can lead to lifelong vision impairment and blindness. As such, all preterm babies are at risk for ROP, and very low birth weight is an additional risk factor.

About Premacure AB

Premacure AB, based in Uppsala, Sweden is a biopharmaceutical company dedicated to the development of diagnosis and prevention of complications in neonates due to premature birth. The first of several indications to be developed is Retinopathy of Prematurity (ROP) a retinal disease being one of the major causes of blindness in infants throughout the world. Contact: Jan Borg, CEO, info@premacure.com.

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 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 Capital Market and other risks and challenges detailed in our filings with the U.S. Securities and Exchange Commission, including our Annual Report on Form 10-K for the year ended December 31, 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.