Insmed and Premacure Cite Study Results Demonstrating Potential Effectiveness of IPLEX(TM) in Preventing Blindness in Premature Infants

RICHMOND, Va. and UPPSALA, Sweden, Sept 23, 2008 /PRNewswire-FirstCall via COMTEX News Network/ -- - Premacure to Initiate Phase II Trial for IPLEX(TM) in Retinopathy of Prematurity -

Insmed Inc. (Nasdaq CM: INSM), a developer of follow-on biologics (FOBs) 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 noted the presentation of clinical study results demonstrating that Insmed's IPLEX(TM) product, a complex of recombinant human insulin-like growth factor (rhIGF-I) and its predominant binding protein IGFBP-3 (rhIGFBP-3), increased serum IGF-I levels into the normal range in significantly premature infants. Premacure is developing IPLEX(TM) as a potential treatment for Retinopathy of Prematurity (ROP) via a Material Transfer Agreement with Insmed.

These most recent study results were reported today at the European Society for Pediatric Endocrinology 47th annual meeting, Istanbul, Turkey, by Investigators from the Harvard Medical School, Boston MA, and the University of Gothenburg, The Karolinska Institute, Stockholm, Lund University, Sweden, in a poster entitled "Pharmacokinetic study of recombinant human (rh) insulin-like growth factor/rh IGFBP-3 complex administered to very low birth weight infants."

"The possibility of preventing ROP and other complications of prematurity by replicating the in utero environment after infants are born prematurely and lose the factors normally provided by the maternal environment is very exciting," said Lois Smith, Professor of Ophthalmology, Harvard Medical School, Children's Hospital Boston. "This work showing that it is now possible to raise the serum level of IGF-1 and IGFBP-3 to normal in utero levels in these fragile infants with IGF-1 / IGFBP-3 deficiency is a critical step in the development of interventions that prevent ROP. Since we have shown that low IGF-1 is associated with ROP, this offers the first possible intervention to prevent this blinding disease."

"Our research focuses on promoting neural, vascular and metabolic development in premature infants," said Ann Hellstrom, Professor in Pediatric Ophthalmology, Sahlgrenska Academy, Gothenburg, Sweden. "While in this study we are attempting to identify the benefits of IGF-I for ROP, our findings are also likely to be applicable to many aspects of complications of premature birth and could provide benefits for a lifespan."

"This is a crucial step in the clinical development of a preventative treatment against lifelong severe visual impairment or blindness in infants born preterm," said Jan Borg, CEO of Premacure. "Based in part on these results, we intend to initiate a phase II multicenter trial in the ROP indication during the fourth quarter."

"The ability of IPLEX(TM) to raise serum levels of two key proteins involved in the pathogenesis of ROP safely may offer a more effective preventive option in at-risk infants than the highly invasive and destructive treatment options of laser therapy or cryotherapy that are currently utilized to stem disease progression only," said Geoffrey Allan, President and CEO of Insmed. "We are pleased that researchers at such distinguished universities continue to see promise in IPLEX(TM) in ROP and intend to continue evaluating the drug in this indication. Moreover, these results serve as further evidence of the effectiveness of IPLEX(TM) in potentially treating some of the most under-served therapeutic populations, including Myotonic Muscular Dystrophy and Amyotrophic Lateral Sclerosis."

Clinical Study Results

Low levels of IGF-I are known to contribute to the pathogenesis of ROP. The objectives of this open label, investigator-sponsored clinical study were to determine whether intravenous administration of rhIGFI/rhIGFBP-3 (IPLEX(TM)) could increase serum levels of these proteins in at-risk infants to levels seen in normal infants, and to evaluate the drug's safety and tolerability. Due to consistency in response, the study was finalized after five infants. The gestational age in these infants ranged from 26 weeks + 0 days to 29 weeks + 1 day (birth weight 810-1,310 g). Treatment with IPLEX(TM) took place on the infant's chronological age day 3 and the investigators reported that the protein complex effectively raised serum IGF-I levels into the physiological range and that the drug's administration was well tolerated, with no acute adverse events.

About IPLEX(TM)

IPLEX(TM) is a complex of recombinant human insulin-like growth factor-I (rhIGF-I) and its predominant binding protein IGFBP-3 (rhIGFBP-3). The drug, approved in the United States in December 2005 for the treatment of children with growth failure due to severe primary IGF-I deficiency, is currently being investigated in MMD and ALS.

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, jan.borg@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, the FDA may not establish specific guidelines for a pathway for the approval of FOB products, FOB products may not be accepted by consumers, 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.