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Insmed Announces FDA Issues Statement Regarding Position on Allowing Patients With ALS Access to IPLEX(TM) Under an IND

RICHMOND, Va., March 10, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Insmed Inc. (Nasdaq: INSM), a developer of follow-on biologics (FOB) and biopharmaceuticals, today announced that the U.S. Food and Drug Administration (FDA) has issued a statement on its website in regards to the agency's position on allowing patients with Amyotrophic Lateral Sclerosis (ALS or Lou Gehrig's disease) access to IPLEX(TM) under an Investigational New Drug (IND) application. The statement can be accessed at: http://www.fda.gov/cder/drug/infopage/mecasermin_rinfabate/FDA_statement.htm.

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 closing conditions under our agreement with Merck & Co., Inc. may not be met, 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 continuing efforts to grow the business and develop IPLEX(TM) may be unsuccessful, the actual market for MMD may not actually match up with our external assessment, 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.
