



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

## European Medicines Agency Validates Insmed's Regulatory Application For Marketing IPLEX(TM) in Europe

RICHMOND, Va., July 5, 2006 /PRNewswire-FirstCall via COMTEX News Network/ -- Insmed Incorporated (Nasdaq: INSM): Insmed today announced the European Medicines Agency (EMA) has validated its application to market IPLEX(TM) (mecasermin rinfabate (rDNA origin) injection), in the European Union (EU). The validation was granted within the scope of the EU Commission designations of IPLEX as an orphan medicinal product for the Treatment of primary insulin-like growth factor-1 deficiency due to molecular or genetic defects (EU/3/06/378); and Treatment of patients with growth hormone (GH) gene deletion who have developed neutralizing antibodies to GH (EU/3/06/377).

"We are pleased to have reached this important milestone in the European drug approval process and particularly at this time as it positions us ahead of schedule in our pursuit of EU approval," said Geoffrey Allan, President and Chief Executive Officer of Insmed. "This is just one more example of Insmed's ability and commitment to execute our development and commercialization plans."

The validation signifies that the EMA can now begin review of Insmed's marketing authorization application. The review process is being coordinated by the EMA under the centralized licensing procedure, which, if resulting in approval, provides one marketing authorization for all 25 member states of the EU, as well as Norway and Iceland. With the validation step complete, the application will be assessed on a timetable that could lead to an approval and marketing authorization in 2007. The orphan medicinal product status would assure Insmed Inc. a ten year period to market IPLEX in the EU.

### About IPLEX

IPLEX is approved in the United States as the only once daily treatment for children with short stature associated with severe primary IGF-I deficiency (Primary IGFD). IPLEX, a complex of recombinant human IGF-I and its binding protein IGFBP-3 (rhIGF-I/rhIGFBP-3), is the only FDA-approved IGF- I replacement therapy that also replaces deficient IGFBP-3 in these patients. The drug, which was launched in the second quarter of 2006, is also being investigated for various other indications with unmet medical needs, including severe insulin resistance, myotonic muscular dystrophy and HIV Associated Adipose Redistribution Syndrome (HARS). For more information about IPLEX please go to [www.go-IPLEX.com](http://www.go-IPLEX.com).

### About Insmed

Insmed is a biopharmaceutical company focused on the development and commercialization of drugs for the treatment of metabolic diseases and endocrine disorders with unmet medical needs. For more information, please visit [www.insmed.com](http://www.insmed.com).

### Forward Looking Statements

Statements included within this press release, which are not historical in nature, may constitute forward-looking statements for the purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. Forward-looking statements in this press release include, but are not limited to, statements regarding the pending litigation and or future ability to conduct our business as now conducted and as it is currently proposed to be conducted. Such forward-looking statements are subject to numerous risks and uncertainties, including but not limited to the uncertainty of the outcome of any litigation with Tercica, the risk that product candidates may fail in the clinic or may not be successfully marketed or manufactured, the company may lack financial resources to complete development of product candidates or the FDA or other regulatory agencies may interpret the results of our studies differently than we have. We can give no assurances that we would be successful in any litigation or that such litigation would not have a material adverse effect on our business, financial condition and results of operation. Furthermore, we may not be able to afford the expense of defending against such a claim. As a result of these and other risks and uncertainties, actual results may differ materially from those described in this press release. For further information with respect to factors that could cause actual results to differ from expectations, reference is made to reports filed by the Company with the Securities and Exchange Commission under the Securities Exchange Act of 1934, as amended.

---