Insmed Announces European Medicines Agency Acceptance of Its Pediatric Investigation Plan for ARIKACEâ„¢ in the Cystic Fibrosis Pseudomonas Indication

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RICHMOND, Va., March 3, 2011 /PRNewswire/ -- Insmed Incorporated (Nasdaq: INSM [1]), a biopharmaceutical company, announced today that the Pediatric Committee of the European Medicines Agency (EMA) has issued a positive opinion on the Company's Pediatric Investigation Plan (PIP) for ARIKACE™ (liposomal amikacin for inhalation), Insmed's Phase 3-ready compound for cystic fibrosis (CF) *Pseudomonas* and non-TB mycobacteria (NTM) lung infections. The PIP covers children from birth to 18 years of age with cystic fibrosis that suffer from *Pseudomonas* lung infections.

An accepted PIP is a pre-requisite for European approval of new drugs, according to legislation passed in Europe in January 2007. The aim of the legislation is to facilitate the development of new medicines for children without subjecting them to unnecessary clinical trials or delaying the authorization of those medicines for use in adults.

"The acceptance of our PIP by the EMA is an important milestone in Insmed's regulatory submission plan for ARIKACE in Europe," said Renu Gupta, M.D., Executive Vice President Development & Chief Medical Officer of Insmed. "As previously disclosed, we intend to initiate our Phase 3 clinical trials for ARIKACE in the CF indication, as well as in NTM, in the second half of this year. Data in both indications are expected during the first half of 2013."

About Insmed Insmed Incorporated is a biopharmaceutical company focused on the development of innovative inhaled pharmaceuticals for the site-specific treatment of serious lung diseases, and has a proprietary protein platform aimed at niche markets with unmet medical need. Insmed's primary focus is on the development of inhaled antibiotic therapy delivered via proprietary advanced pulmonary liposome technology in areas of high unmet need in lung diseases. For more informat
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