Insmed's ARIKACE® Demonstrates Sustained Benefit Through Six Cycles of Treatment for Cystic Fibrosis Patients With Pseudomonas Lung Infections

- Data Presented at 34th European Cystic Fibrosis Conference -

MONMOUTH JUNCTION, N.J., June 10, 2011 /PRNewswire/ -- Insmed Incorporated (Nasdaq CM: INSM), a biopharmaceutical company, today announced positive data through six treatment cycles (72 weeks total duration) of its Phase 2 clinical trial program for ARIKACE® (liposomal amikacin for inhalation) in cystic fibrosis (CF) patients with *Pseudomonas* lung infections. The data were presented at the 34th European Cystic Fibrosis Conference in Hamburg, Germany, by Predrag Minic, M.D., Professor of Pediatrics and Head of Pediatrics Pulmonology Department, Mother and Child Health Institute, Belgrade, Serbia, and co-lead investigator of the study.

The open label Phase 2 study was designed to evaluate ARIKACE over multiple treatment cycles in CF patients with *Pseudomonas* lung infections. The study enrolled 49 patients to receive ARIKACE 560 mg once daily for 28 days of therapy, followed by a 56-day off-treatment observation period. ARIKACE was administered using an optimized, investigational eFlow® Nebulizer System (PARI Pharma GmbH).

The data demonstrated that ARIKACE, delivered once-daily for 28 consecutive days, followed by 56 days off-treatment, for a total of six cycles, resulted in statistically significant improvement in lung function that was sustained over a 72 week period. Specifically, inhalation of 560 mg of ARIKACE produced a mean increase in pulmonary function (FEV1) of 11.7% at the end of the 28 day treatment period of the sixth cycle ($p<0.0001$).

During the course of the study, FEV1 improvement was also sustained at the end of 56 days off-treatment in each of cycles one through six, with an estimated relative increase in FEV1 of 5.7% (95% CI +3.0%, +8.5%; $p=0.0001$). Overall, ARIKACE was well-tolerated during all six cycles, with adverse events reported as consistent with those expected in a population of CF patients receiving inhaled medicines.

"ARIKACE demonstrated consistent results of improved lung function throughout all six cycles of this study," said Professor Minic. "In addition, there were no unexpected adverse events associated with the longer term use of the drug. Taken as a whole, these data indicate that ARIKACE has the potential, if approved, to be an important product for CF patients with *Pseudomonas* lung infections."

ARIKACE also demonstrated statistically significant reduction from baseline in *Pseudomonas aeruginosa* density, including mucoid strains, which was sustained during the treatment and off-treatment periods of the six cycles. The estimated change from baseline in Log10 CFU over time was -0.6 log (95% CI, -0.2 to -0.9 log; $p=0.0030$). Mucoid strains of *Pseudomonas* are often difficult to suppress with antibiotics and play a significant role in progression of CF lung disease. In addition, there was no significant shift in the minimum inhibitory concentration (MIC90) of ARIKACE against *Pseudomonas* over the course of the six cycles, which suggests a lack of resistance development during the study period.

"These results further strengthen the clinical data package Insmed is developing for ARIKACE in the treatment of CF patients," said Renu Gupta, M.D., Executive Vice President Development & Chief Medical Officer of Insmed. "The data are also indicative of why we are so excited to begin our Phase 3 clinical program in the CF indication, which we expect to initiate in the second half of this year. For potential registration of ARIKACE in the U.S., we intend to conduct a placebo-controlled clinical trial, and for European registration, we intend to conduct a trial that compares ARIKACE to Novartis Corporation's TOBI®. Results from these studies are anticipated in the first half of 2013."

"We are pleased that the development of ARIKACE continues to proceed expeditiously," said Robert J. Beall, Ph.D., President and CEO of the Cystic Fibrosis Foundation. "Based on the currently

available data, we believe ARIKACE has the potential to address a significant medical need for CF patients suffering from *Pseudomonas* lung infections."

Cystic Fibrosis Foundation Therapeutics, Inc., a nonprofit affiliate of the Cystic Fibrosis Foundation, previously provided Insmed with $3.9 million to support the development of ARIKACE in CF. The Foundation is the leading organization devoted to curing and controlling CF.

The data presented today at the 34th European Cystic Fibrosis Conference will be available on Insmed's website at: http://www.insmed.com/newsroom/category/publications-presentations/.

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. 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 information, please visit http://www.insmed.com.

About ARIKACE®

ARIKACE is a registered trademark of Transave, a subsidiary of Insmed Incorporated. ARIKACE is a form of the antibiotic amikacin, which is enclosed in nanocapsules of lipid called liposomes. This advanced pulmonary liposome technology prolongs the release of amikacin in the lungs while minimizing systemic exposure. The technology uses biocompatible lipids endogenous to the lung that are formulated into small (0.3 micron), charge-neutral liposomes that enable penetration of the biofilm. ARIKACE is administered once daily using an optimized, investigational eFlow® Nebulizer System (PARI Pharma GmbH), a novel, highly efficient and portable aerosol delivery system enabling more effective distribution in the lungs.

ARIKACE has been granted orphan drug status in the United States by the FDA, and has received an orphan drug designation in Europe by the European Medicines Agency for the treatment of *Pseudomonas* infections in patients with CF. In addition, the Company recently filed for orphan drug designation for NTM lung infections in the United States and plans to do so in the European Union once the process is completed in the United States.

About The Cystic Fibrosis Foundation

The Cystic Fibrosis Foundation is the world's leader in the search for a cure for cystic fibrosis. The Foundation funds more CF research than any other organization, and nearly every CF drug available today was made possible because of Foundation support. Based in Bethesda, Md., the Foundation also supports and accredits a national care center network that has been recognized by the National Institutes of Health as a model of care for a chronic disease. The CF Foundation is a donor-supported nonprofit organization. For more information, go to www.cff.org.

About eFlow® Technology and PARI Pharma

ARIKACE is delivered by an investigational eFlow® Nebulizer System developed by PARI Pharma and optimized specifically for ARIKACE. The optimized, investigational eFlow Nebulizer System uses eFlow Technology to enable highly efficient aerosolization of medication including liposomal formulations via a vibrating, perforated membrane that includes thousands of laser drilled holes. Compared to other nebulization technologies, eFlow Technology produces aerosols with a very high density of active drug, a precisely defined droplet size, and a high proportion of respirable droplets delivered in the shortest possible period of time. eFlow® Technology is not an ultrasonic nebulizer technology, and it is not a general purpose electronic aerosol generator nebulizer technology. Combined with its quiet mode of operation, small size, light weight, and battery use, eFlow Technology reduces the burden of taking daily, inhaled treatments. PARI Pharma focuses on the development of aerosol delivery devices and comprehensive inhalation drug development to

advance aerosol therapies where drug and device can be optimized together. Online at www.paripharma.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 our financial positions, results of operations, the results of clinical trials and clinical data described herein, the development of our products, and the business strategies, plans and objectives of management, 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. Our results may be affected by such factors as the receipt and timing of FDA and other regulatory approvals, if at all, competitive developments affecting our product development, delays in product development or clinical trials, and patent disputes involving currently developing products. The risks and uncertainties include, without limitation, our future clinical trials may not support the data described in this release, we may be unsuccessful in developing our product candidates or receiving necessary regulatory approvals, we may experience delays in our product development or clinical trials, our product candidates may not prove to be commercially successful, our expenses may be higher than anticipated 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, 2010. Investors 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.

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