

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

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MONMOUTH JUNCTION, N.J., June 10, 2011 /PRNewswire/ -- Insmmed 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.

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Insmed's ARIKACEĀ,® Demonstrates Sustained Benefit Through Six Cycles

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