INSMED INCORPORATED

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## Press Release

# INSMED PROVIDES CORPORATE UPDATE

- ***Company Sets Current ARIKACE® Development Priorities*** -

- ***Insmed Projects Cash Sufficient to Generate Top-Line Data from Three Priority Studies*** -

**Monmouth Junction, N.J**. - May 30, 2012 - Insmed Incorporated (Nasdaq CM: INSM), a biopharmaceutical company, today provided a corporate update, including the Company's current strategic development priorities for ARIKACE® (liposomal amikacin for inhalation).

"Insmed has determined that its current resources will be applied towards the CLEAR-108 phase 3 European and Canadian registrational study of ARIKACE in patients with Cystic Fibrosis (CF)-related *Pseudomonas aeruginosa* lung infections, the TARGET-NTM phase 2 trial of ARIKACE in patients with non-tuberculous mycobacteria (NTM) lung disease and the 9-month dog toxicity study," said Timothy Whitten, President and CEO of Insmed.

"We believe this ARIKACE development program prioritizes the most compelling near-term opportunities for Insmed and its shareholders," continued Mr. Whitten. "The CLEAR-108 trial provides Insmed with the earliest opportunity to garner critical phase 3 ARIKACE data in a broad cystic fibrosis patient population while generating important information on the efficacy and safety of ARIKACE as compared to the current standard of care. In NTM, ARIKACE has the opportunity to become a part of standard therapy for a rapidly growing chronic disease that has a high unmet medical need with limited treatment options. We project our current cash position to be sufficient to generate top-line data from the three prioritized ARIKACE studies."

"Insmed believes that ARIKACE has the potential to address important unmet medical needs in CF and NTM, two key orphan indications with combined global market opportunity of up to $1 billion," concluded Mr. Whitten.

## Cystic Fibrosis

**CL**inical **E**valuation of **AR**IKACE **(CLEAR-108) Phase 3 CF Study**

- Randomized, phase 3 trial comparing ARIKACE 560 mg, delivered once daily via an optimized, investigational eFlow® Nebulizer System (PARI Pharma GmbH), to twice daily TOBI®[1] 300 mg (inhaled tobramycin solution), a commercially available inhaled antibiotic delivered via the PARI LC® Plus nebulizer

- Trial is underway in Europe and Canada and will include approximately 300 patients

- Primary endpoint is change in pulmonary function (FEV-1) measured after three 28 day on-treatment and three 28 day off-treatment cycles (approximately six months)

- Key secondary endpoint is time to pulmonary exacerbation

- Top-line data expected in mid-2013

The study design has been agreed upon by Insmed and the European Medicines Agency. The study's Principal Investigator is Diana Bilton, M.D., Director of Adult CF Centre at the Royal Brompton Hospital in London, England. Eligible patients will have the option to participate in a longer-term open-label multi-cycle safety study, called CLEAR-110.

**CF Market**

CF is a rare, life-threatening genetic disease affecting approximately 70,000 children and adults worldwide. Today, the median predicted age of survival for a person with CF is approximately 38 years, but the median age of death remains in the mid-20's. More than half of all CF patients have acquired *Pseudomonas* lung infections by age 18 and receive extensive and often chronic antibiotic treatments. Antibiotics delivered via inhalation have become part of standard treatment for CF patients with *Pseudomonas* lung infections. However, due to the thick sticky mucous these patients produce in their lungs, CF patients seldom clear the *Pseudomonas*, and they become chronically infected. This results in a continuous decline in lung function, despite all currently available antibiotic treatments.

**Non-TB Mycobacteria**

**T**reatment with **A**RIKACE to **R**ealize **G**reater **E**fficacy **T**rial **(TARGET-NTM) Phase 2 Clinical Trial**

- Randomized, placebo-controlled study of ARIKACE in approximately 100 adult patients that will include two of the most common species of NTM that cause lung disease - *Mycobacterium avium complex* (MAC) and *Mycobacterium abscessus*

- NTM culture positive patients will continue with their antibiotic regimen, and receive additionally either ARIKACE 560 mg, delivered once daily via an optimized, investigational eFlow Nebulizer System, or placebo, once daily

- Primary efficacy endpoint will be change in mycobacterial density from baseline to the end of 84 days of treatment, which is the end of the randomized portion of the trial

- At the conclusion of the randomized portion of the study, eligible patients may receive ARIKACE 560 mg once daily for an additional 84 days in an open-label design. Open-label means patients will know they are receiving ARIKACE.

- Patient enrollment currently expected to begin in mid-2012, with top-line results projected in the fourth quarter of 2013

The clinical trial design has been agreed upon by Insmed and the U.S. Food and Drug Administration, and several sites have recently begun screening patients. The Principal Investigator of the study is Kenneth N. Olivier, M.D., M.P.H., staff pulmonologist in the Laboratory of Clinical Infectious Diseases at the National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health.

**NTM Market**

According to a recent company sponsored patient chart study conducted by Clarity Pharma Research, approximately 50,000 patients suffering from NTM lung disease visited physician offices in the U.S. during 2011. More than half of these patients were treated with antibiotics for NTM.

MAC and *Mycobacterium abscessus* account for the vast majority of NTM lung disease, with combined prevalence rates reported from 75 percent to over 85 percent in the U.S.

**U.S. CF Status**

Insmed will defer plans to initiate a phase 3 study of ARIKACE in the U.S. for CF patients until the Company reviews top-line results from CLEAR-108, as the data generated from CLEAR-108 could provide additional clarity on the scope, design and conduct of a U.S. CF phase 3 clinical trial. In addition, the deferral of a U.S. CF phase 3 clinical trial allows Insmed to focus its current capital resources on the prioritized ARIKACE clinical studies, CLEAR-108 (together with the follow-on CLEAR-110) and TARGET-NTM, as well as the dog toxicity study, which recently started and is expected to generate top-line results in the second quarter 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. Insmed's primary focus is on the development of inhaled antibiotic therapy delivered via proprietary advanced liposomal pulmonary technology in areas of high unmet need. For more information, please visit http://www.insmed.com.

**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 device 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 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 position, results of operations, the status and the results of pre-clinical studies and clinical trials and preclinical and clinical data described herein, the timing of and costs associated with pre-clinical studies and clinical trials, the development of our products, our estimates of the size of the potential markets for our product candidates, 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 reviews and 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, we may experience unexpected regulatory actions, delays or requests, our future clinical trials may not be successful, 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, 2011 and our Quarterly Report on Form 10-Q for the quarter ended March 31, 2012. 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.

[1]TOBI® is a Registered Trademark of Novartis Pharmaceuticals Corporation