Insmed Incorporated Begins Screening Patients For TARGET-NTM U.S. Clinical Trial Of ARIKACE® In Patients With Non-tuberculous Mycobacterial Lung Disease

MONMOUTH JUNCTION, N.J., May 23, 2012 /PRNewswire/ -- Insmed Incorporated (Nasdaq CM: INSM), a biopharmaceutical company, today announced that it has begun screening patients for its U.S. phase 2 clinical trial, Treatment with ARIKACE to Realize Greater Efficacy Trial (TARGET-NTM), of ARIKACE® (liposomal amikacin for inhalation) in patients with non-tuberculous mycobacterial (NTM) lung disease.

There have been very few clinical trials to support current NTM treatment recommendations, and no new drugs have been assessed in randomized trials for NTM lung disease in many years. Additionally, NTM remains a significantly under-diagnosed disease. TARGET-NTM represents an opportunity to make significant advancement in the awareness and treatment of this debilitating chronic illness, according to Kenneth N. Olivier, M.D., M.P.H., Principal Investigator of the study and 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.

"Current treatment for NTM lung disease requires lengthy multi-drug regimens that can be poorly tolerated and have limited efficacy, especially in patients with severe disease or in those who have failed prior treatment attempts," said David E. Griffith, M.D., lead author of the American Thoracic Society's and the Infectious Disease Society of America's diagnosis and treatment guidelines for NTM, and Professor of Medicine at the University of Texas Health Science Center at Tyler. "If effective, ARIKACE has the potential to significantly impact the current NTM treatment paradigm." Dr. Griffith, along with Richard J Wallace, M.D., Professor of Medicine and Microbiology, also at the University of Texas Health Science Center at Tyler, are Co-Principal Investigators for the study.

NTM Increasingly Prevalent

According to a recent company sponsored patient chart study conducted byClarity 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. This reflects a much larger patient population than previous Insmed estimates.

Patients in the trial will have lung infections with Mycobacterium avium complex (MAC) or Mycobacterium abscessus, which account for approximately 75 percent to over 85 percent of all patients with NTM lung disease in the U.S.

Treatment with ARIKACE to Realize Greater Efficacy Trial (TARGET-NTM)

- Randomized, placebo-controlled study of ARIKACE in approximately 100 adult patients with recalcitrant NTM lung disease.
- Patients will continue with their antibiotic regimen, and receive additionally, either ARIKACE 560 mg or placebo, delivered once daily via an optimized, investigational eFlow® Nebulizer System (PARI Pharma GmbH).
- 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 the patient will know they are receiving ARIKACE.

Patient dosing is expected to begin in mid-2012, with top-line results for the randomized portion of the trial 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. For more information on the clinical trial, visit www.clinicaltrials.gov.

Also, as recently announced, Insmed has begun dosing patients in CLEAR-108, a European and Canadian registrational phase 3 clinical study of ARIKACE in CF patients with Pseudomonas aeruginosa lung infections, and is proceeding with CLEAR-110, a follow-on multi-cycle open-label study intended primarily to measure safety and tolerability for patients who complete CLEAR-108.

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 endedMarch 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.

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