Insmed Announces Promising Results From IPLEX Phase II Myotonic Muscular Dystrophy Clinical Study

RICHMOND, Va., May 03, 2007 (BUSINESS WIRE) -- Insmed Inc. (Nasdaq:INSM) today announced positive results from a Phase II investigator-sponsored study of the company's drug, IPLEX(TM), in patients with myotonic muscular dystrophy (DM1).

Preliminary results of the clinical study, being conducted at the University of Rochester School of Medicine and Dentistry, showed that six months of treatment with doses of IPLEX up to 1 mg/kg/day in six patients met the primary study endpoints of being safe and well tolerated. In addition, IPLEX treatment was associated with improvements in muscle mass, cholesterol and triglycerides. During the six months of treatment, 5 out of 6 patients experienced an improvement in lean muscle mass. Patients also reported improvement in gastrointestinal function, endurance and cognitive function during treatment with IPLEX.

"We are very encouraged by the results from this preliminary study of IPLEX in myotonic dystrophy. The results not only indicate IPLEX was safe, well tolerated and had a positive effect on muscle and lipid metabolism, they also suggest IPLEX may have a positive effect on aspects of the disease that affect patients' daily living," said Dr. Geoffrey Allan, president and CEO of Insmed.

Study Description

The primary objectives of this ongoing open-label, Phase II dose escalation study are to examine the safety and tolerability of once-daily, subcutaneous injection of IPLEX in up to 15 patients with DM1 and to identify the maximum tolerated dose. The next cohort of patients will be treated for six months with a dose of IPLEX which will be titrated up to 2 mg/kg/day.

The study is funded by the National Institutes of Health and the Muscular Dystrophy Association, with supply of IPLEX drug provided by Insmed. A Phase II, placebo-controlled study to further investigate the safety and efficacy of IPLEX in a larger number of patients with DM1 is being designed based on the preliminary results of this study.

About Myotonic Muscular Dystrophy

Myotonic muscular dystrophy, also known as myotonic dystrophy, dystrophia myotonica or Steinert's disease, is the most common type of adult muscular dystrophy, affecting 1 in 8000 individuals (approximately 40,000 people in the United States). Myotonic dystrophy patients develop progressive muscle wasting and weakness in the hands, forearms, legs, neck and face, as well as cataracts and cardiac arrhythmias, and eventually can become totally disabled, dying usually from respiratory or cardiac failure. At present, there is no treatment to reverse most of these symptoms. For more information about myotonic muscular dystrophy, please visit www.mda.org.

About IPLEX(TM)

IPLEX was approved in the United States in December 2005 for the treatment of children with growth failure due to severe primary IGF-I deficiency (Primary IGFD). IPLEX (rhIGF-I/rhIGFBP-3), a complex of recombinant human insulin-like growth factor-I (rhIGF-I) and its predominant binding protein IGFBP-3 (rhIGFBP-3). The drug is also being investigated for various other indications with unmet medical needs, including HIV-associated adipose redistribution syndrome, retinopathy of prematurity and amyotrophic lateral sclerosis (otherwise known as ALS or Lou Gehrig's disease).

About Insmed

Insmed is a biopharmaceutical company focused on the development and commercialization of drugs for the treatment of metabolic diseases with unmet medical needs. For more information, please visit www.insmed.com.

About the University of Rochester School of Medicine and Dentistry

The University of Rochester School of Medicine and Dentistry is a leading medical university that consistently defines health care worldwide by conducting advanced biomedical research and providing leading life science education and complex patient care. It has been designated by the National Institutes of Health (NIH) as one of several "centers of excellence" for muscular dystrophy research and is receiving up to $1 million per year for five years in federal NIH funding and up to $500,000 per year for three years from MDA, for a total of up to $6.5 million, to identify potential muscular dystrophy therapies. For more information, please visit www.urmc.rochester.edu.

About The Muscular Dystrophy Association

The Muscular Dystrophy Association (MDA) is a voluntary health agency -- a dedicated partnership between scientists and concerned citizens aimed at conquering neuromuscular diseases that affect more than a million Americans. MDA combats neuromuscular diseases through programs of worldwide research, comprehensive medical and community services, and far-reaching professional and public health education. MDA is the world's largest non-governmental sponsor of research seeking the causes of and effective treatments for neuromuscular diseases, sponsoring some 400 research projects annually. For more information, please visit www.mda.org.

Forward Looking Statements

Statements included within this press release, which are not historical in nature, may constitute forward-looking statements for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. Forward-looking statements in this press release include, but are not limited to, statements regarding planned clinical study design, our regulatory and business strategies, plans and objectives of management and growth opportunities for existing or proposed products. Such forward-looking statements are subject to numerous risks and uncertainties, including risks that product candidates may fail in the clinic or may not be successfully marketed or manufactured, the company may lack financial resources to complete development of product candidates, the FDA may interpret the results of our studies differently than we have, competing products may be more successful, demand for new pharmaceutical products may decrease, the biopharmaceutical industry may experience negative market trends and other risks detailed from time to time in the company's filings with the Securities and Exchange Commission. As a result of these and other risks and uncertainties, actual results may differ materially from those described in this press release. For further information with respect to factors that could cause actual results to differ from expectations, reference is made to reports filed by the Company with the Securities and Exchange Commission under the Securities Exchange Act of 1934, as amended. The forward-looking statements made in this release are made only as of the date hereof and Insmed disclaims any intention or responsibility for updating predictions or financial guidance contained in this release.