Insmed Inc. Releases Investor Fact Sheet with Updates on Drug Development Progress

RICHMOND, Va., Apr 25, 2007 (BUSINESS WIRE) -- Insmed Inc. (NASDAQ:INSM), a biopharmaceutical company engaged in the development and commercialization of drugs to treat patients with unmet medical needs, today released an "Investor Fact Sheet" detailing the progress of its drug development programs. The full text of the Fact Sheet is as follows:

Focusing on Markets with Unmet Needs

Insmed Incorporated (NASDAQ:INSM) is a biopharmaceutical company engaged in the development and approval of drugs to treat patients with metabolic diseases that currently have limited or no treatment options.

Our lead drug, IPLEX(TM), is a complex composed of recombinant human insulin-like growth factor I and insulin-like growth factor binding protein-3.

Insmed is presently moving forward on two very specific pathways. We are continuing the development of IPLEX(TM) for additional clinical indications while concurrently studying the emerging generic biologic market, recognizing the potential opportunities that exist in this sector.

Headquartered in Richmond, Virginia, Insmed maintains a state-of the-art FDA-approved commercial biologic manufacturing facility, Insmed Therapeutic Proteins, in Boulder, Colorado.

Background

In 2005 IPLEX(TM) was approved for the treatment of growth failure in children with severe primary IGF-1 deficiency (Primary IGFD) and was granted orphan drug status by the United States Food and Drug Administration.

In March 2007, Insmed settled a patent litigation suit with Tercica, Inc. and Genentech, Inc. Pursuant to the settlement, Insmed agreed to take IPLEX(TM), which had been on the market for approximately six months, off the market for Primary IGFD and discontinue development in all short stature indications. In return, we retained the right to develop IPLEX(TM) for a wide range of non-short stature indications, with larger patient populations and greater market potential.

The IPLEX(TM) Pipeline - Targeted Research

IPLEX(TM) is currently being studied as a treatment for several serious medical conditions, Myotonic Muscular Dystrophy (MMD); Amyotrophic Lateral Sclerosis (ALS), also known as Lou Gehrig's Disease; HIV-Associated Adipose Redistribution Syndrome (HARS); and retinopathy of prematurity (ROP). Cumulatively, these disorders affect more than 100,000 patients in the United States, and an equal number in the European Union, representing potential markets that could be measured in the hundreds of millions of dollars.

Myotonic Muscular Dystrophy Research

MMD is the most common form of adult muscular dystrophy, affecting 1 in 8,000 individuals in the United States. Approximately 40,000 Americans are diagnosed with the disease, and close to 60,000 people in the European Union also suffer from this life-threatening disorder. Patients with MMD develop progressive muscle wasting and weakness, cardiovascular problems and digestive complications. In extreme cases patients eventually become totally disabled and typically die from respiratory or cardiac failure. At present there is no treatment to halt or reverse the progression of MMD.

IPLEX(TM) is being investigated in an ongoing open label Phase II clinical study at the University of Rochester

School of Medicine, with funding provided by the Muscular Dystrophy Association and the National Institutes of Health. The objective of the Phase II study is to examine the safety, tolerability and initial efficacy of a once-daily, subcutaneous injection of IPLEX(TM) in patients with MMD.

We expect initial data from the first of these trials to be available in the second quarter of 2007 and presented at a scientific meeting in the third quarter of 2007. We currently plan to initiate an expanded Phase II trial, with a larger number of participants, by the end of 2007 and enter Phase III clinical trials in early 2009.

Italy Requests IPLEX(TM) for ALS Patients

In January 2007, Insmed announced that the Italian Ministry of Health had requested IPLEX(TM) for Italian patients suffering from ALS. This life-threatening neuromuscular disease strikes adults in mid-life. In Italy approximately 1,000 new cases of ALS are diagnosed every year.

In cooperation with Cephalon, which holds the patent for IGF-1in the European Union, Insmed is currently supplying IPLEX(TM) on a cost recovery basis to these Italian patients under an Expanded Access Program. Data collected through the Expanded Access Program in Italy will be used to design future ALS clinical development studies with IPLEX(TM).

IPLEX(TM) for HARS

IPLEX(TM) is being explored as a possible therapy for HARS. An estimated 80,000 HIV patients in the United States have HARS, according to published reports. This disorder is marked by abnormal metabolism including both central fat accumulation (visceral adiposity and buffalo hump) with or without fat loss in the limbs. These features have increased markedly with the advent of highly active antiretroviral therapy (HAART) for HIV. Recent studies performed in subjects on HAART suggest nearly 50% of these individuals develop the morphologic features characteristic of this syndrome.

Preliminary data from a Phase II open-label clinical study is currently being analyzed. The study, directed by Morris Schambelan, M.D., a professor of medicine at University of California San Francisco and Chief of Endocrinology and Director of the General Clinical Research Center at San Francisco General Hospital, is designed to evaluate the safety and efficacy of 12 weeks of IPLEX(TM) treatment in subjects with HARS. The primary objective of the study is to determine the effects of IPLEX(TM) on visceral fat distribution, insulin sensitivity and glucose and lipid metabolism. We expect initial data from this trial to be available in 2007, with additional Phase II trials planned to begin in the first half of 2008 and Phase III trials planned to initiate in 2009.

IPLEX(TM) for Retinopathy of Prematurity

IPLEX(TM) is currently in the first phase of clinical development for the treatment of ROP. This disease, which affects an estimated 14,000 to 16,000 premature infants each year, impedes the development of the small blood vessels in the back of the eye leading to blindness in the majority of cases. A Phase I clinical study investigating IPLEX(TM) as a treatment for ROP has been initiated at the University of Gothenburg in Sweden, in collaboration with scientists at the Harvard Medical School in the United States.

Ten patients are being enrolled sequentially, with each subsequent patient receiving a higher dose of IPLEX(TM). The objective of the study is to determine the dose of IPLEX(TM) required to increase serum IGF-1 levels into the normal physiological range. Results of this study are currently expected by the end of 2007, at which point a timeline for future clinical development will be determined.

Beyond IPLEX(TM): Oncology Compounds

Insmed has two oncology compounds, rhIGFBP-3 and INSM-18, in development. Both hold promising potential treatments for a variety of cancers. Preclinical models show that one or both treatments interact with the IGF-1 system to reduce tumor growth in models of breast, prostate, lung, colorectal and head and neck cancers.

RhIGFBP-3 has demonstrated preclinical efficacy in numerous cancer indications, including breast, prostate, liver, ovarian and colon. Additionally, several lines of recent evidence, from various cell systems, have suggested that rhIGFBP-3 may play a more active, IGF-1-independent role in growth regulation of cancer cells, binding specifically with high affinity to the surface of various cell types and directly inhibiting monolayer growth of these cells in an IGF-1-independent manner. Also recent independent studies have demonstrated that when IGFBP-3 is used in combination with other cancer therapies it can accentuate and even synergize the efficacy of standard cancer therapies. We have an ongoing open label Phase I clinical study with rhIGFBP-3 which is a dose-escalation study designed to evaluate the safety, tolerability and pharmacokinetics of a single intravenous dose of rhIGFBP-3. The primary goal of this 30-patient study is to identify the appropriate dose of rhIGFBP-3 for a planned Phase II clinical trial in breast cancer patients.

INSM-18 is an orally available, small molecule, tyrosine kinase inhibitor. It has demonstrated dual inhibition of the IGF-1 and HER2 receptors. Two single-dose Phase I clinical studies in healthy volunteers have previously been completed with this drug candidate. In both studies, the drug was safe and well-tolerated. Additionally, a Phase I-II dose escalation clinical study designed to define the maximum tolerated dose of INSM-18 in patients with relapsed prostate cancer has been completed at the University of California, San Francisco. This study consisted of a 28-day treatment period at each dose level to investigate the effect of INSM-18 on levels of prostate specific antigen (PSA). An analysis of the data collected from the study is currently being conducted, and the results will be used to design further Phase II clinical studies.

Manufacturing Edge

Our state-of-the-art manufacturing facility, Insmed Therapeutic Proteins (ITP), is FDA-inspected and approved. Located in the biotechnology hub of Boulder, Colorado, we believe ITP is a significant technological asset for Insmed. Given its advanced protein manufacturing capability, combined with a skilled work force, we believe we are well placed to leverage our protein development and manufacturing expertise in a number of new ventures, either through acquisitions or partnering.

As pending legislation is paving the way for affordable and safe alternatives to existing biologics that will soon be coming off patent, we believe our ITP facility and the inherent expertise developed at the site positions Insmed for the potential development of generic biologics

Insmed Chairman and CEO Dr. Geoffrey Allan testified at the United States House of Representatives Oversight and Government Reform Committee with respect to generic biologics on March 16, 2007, stating, "Insmed has developed significant intellectual capital focused towards protein characterization and purification. We have invested in building the facilities required to manufacture quality recombinant proteins. The combination of our proprietary protein platform with a biogeneric protein platform meets our goal to sustain innovation along with the ability to provide safe and affordable drugs to address a growing economic issue."

Insmed has an ongoing development program in the biogeneric area. We are currently at an early stage in developing five protein products which collectively could potentially represent several billion dollars of sales in the United States market. We intend to seek a partner to undertake the commercialization of these protein products.

For more information about Insmed, or to review our SEC filings, please visit www.insmed.com

About Insmed Incorporated

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

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 trial 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.