



[Home](#) / [Investors](#) / [News Releases](#)

Insmmed Announces Results of IPLEX(TM) Phase II Trial in Myotonic Muscular Dystrophy

RICHMOND, Va., June 25, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Insmmed Inc. (Nasdaq: INSM), a biopharmaceutical company, today announced results from its exploratory U.S. Phase II clinical trial evaluating IPLEX(TM) (mecasermin rinfabate) in patients with myotonic muscular dystrophy ("MMD"). The randomized, double-blind, placebo-controlled Phase II trial conducted in 13 centers across the U.S. enrolled 69 patients with MMD, for a six-month period. As this was an exploratory trial, a primary endpoint was not pre-defined. The trial explored measures of endurance, using the six-minute walk test, muscle function and strength, cognitive function, gastrointestinal function, pain, quality of life, insulin sensitivity, lipid metabolism, and safety and tolerability of IPLEX(TM).

The results of the trial indicated that IPLEX(TM) did not exhibit a statistically significant improvement in the functional measure of endurance by the six-minute walk test, muscle function, muscle strength, or quality of life in any of the tests utilized in this study. Based on the limited number of subjects enrolled with significant impairments in cognitive function, gastrointestinal function or pain, Insmmed was unable to reach any conclusions regarding the effects of IPLEX(TM) on these endpoints.

IPLEX(TM) did, however, demonstrate improvements in standard measures of insulin sensitivity and reductions in fasting glucose, fasting insulin, cholesterol and triglycerides, which is consistent with the expected metabolic profile of insulin-like growth factor. Administration of IPLEX(TM) also resulted in anabolic effects of increased body mass index and higher levels of testosterone. The drug was well tolerated in MMD subjects and demonstrated a safety profile consistent with previous studies of IPLEX(TM).

Based on the metabolic improvements observed in patients treated with IPLEX(TM) in this trial, and discussions with key opinion leaders, the Company intends to apply for a grant from the Muscular Dystrophy Association ("MDA") to facilitate an additional Phase II trial focused solely on a subset of MMD patients with severe insulin resistance who, based on the results of this trial, may be more likely to benefit from IPLEX(TM) treatment. Alternative methods of assessing muscle function will be considered for the proposed trial.

Dr. Melvin Sharoky, Insmmed's Chairman, commented, "We are disappointed that this trial did not meet the majority of its functional endpoints. However, the statistically significant improvement in insulin sensitivity seen in this study suggests that an additional phase II study in MMD patients with severe insulin resistance may be warranted. We appreciate the MDA's financial support for the completed trial and look forward to the possibility of continuing to work with them."

Sharon Hesterlee, Senior Vice President and Executive Director of MDA Venture Philanthropy, said, "While the phase II clinical trial of IPLEX(TM) did not show efficacy in the overall MMD population in this trial, based on the data generated, we look forward to evaluating Insmmed's grant application for a possible Phase II trial aimed at MMD patients with severe insulin resistance."

Dr. Sharoky continued, "IPLEX(TM) continues to demonstrate a strong safety profile and we believe it offers a potential treatment in multiple therapeutic areas, including Amyotrophic Lateral Sclerosis. Beyond IPLEX(TM), our current cash reserves of approximately \$120 million provides us with a significant opportunity to continue growing our business through a variety of potential business development initiatives. We look forward to continuing to explore these possibilities with our strategic financial advisor, RBC Capital Markets."

About Myotonic Muscular Dystrophy

Myotonic muscular dystrophy is a genetic disorder resulting in a highly variable presentation of symptoms across multiple body systems. The most prevalent symptoms include progressive muscular weakness and myotonia, cardiac arrhythmias, cognitive defects, cataracts, as well as endocrine, sexual,

gastrointestinal and reproductive disturbances. There is currently no cure for the disease, which affects approximately 37,000 individuals in the U.S., and no specific treatment has been discovered to satisfactorily reverse or ameliorate the common symptoms associated with the disease. For more information on MMD, please visit www.mda.org.

About Insmmed

Insmmed Inc. is a biopharmaceutical company with unique protein development experience and a proprietary protein platform aimed at niche markets with unmet medical needs. For more information, please visit <http://www.insmed.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 an additional phase II trial, 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. The risks and uncertainties include, without limitation, Insmmed may not apply for or receive a grant for an additional phase II trial, the FDA may interpret the results of studies differently than us, product candidates may fail in the clinic or may not be successfully marketed or manufactured, competing products may be more successful, our continuing efforts to grow the business and develop IPLEX(TM) may be unsuccessful, we may lack financial resources to complete development of product candidates, we may be unsuccessful in finding or pursuing business development initiatives, 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, 2008. Readers 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.
