MannKind Announces Initiation of Phase 2 Trial of Cancer Vaccine for Advanced Melanoma

10/19/10
MannKind Announces Initiation of Phase 2 Trial of Cancer Vaccine for Advanced Melanoma

VALENCIA, Calif., Oct 19, 2010 (BUSINESS WIRE) -- **MannKind Corporation (NASDAQ:MNKD)** today announced the first patient has been dosed in a phase 2 clinical trial of the novel, investigational cancer vaccine MKC1106-MT. As a part of MannKind's cancer immunotherapy program, this phase 2 study will evaluate the safety, tolerability, immune response and clinical response of MKC1106-MT in patients with advanced melanoma. In a previous phase 1 study, repeat intranodal administration of the treatment regimen was well-tolerated and generated immune responses meeting the primary endpoints of the study. The phase 1 study also generated encouraging objective responses in a subset of patients with disease localized to the lymphatic system. Final results of the phase 1 study were presented as a poster at the annual meeting of the American Society of Clinical Oncology (ASCO) in June 2010.

"Following the promising results of our phase 1 trial, the initiation of this phase 2 study of MKC1106-MT marks an important step forward for MannKind's oncology portfolio," said Dr. Peter Richardson, MRCP, Corporate Vice President and Chief Scientific Officer, MannKind Corporation. "Given the lack of treatments available for individuals suffering from advanced melanoma, we are pleased to continue our evaluation of this innovative, targeted therapy, which has already shown early evidence of clinical response and tolerability."

MKC1106-MT is an active immunotherapeutic treatment consisting of three components: a DNA plasmid encoding select portions of Melan A and tyrosinase (two tumor-specific antigens that are highly expressed by melanoma tumor cells) and two synthetic peptides with sequences analogous to the targeted portion of Melan A and tyrosinase. The treatment is administered in a plasmid-prime/peptide-boost approach by intranodal injection to superficial lymph nodes in order to maximize antigen exposure to T-cells.

Study Design

The phase 2 study is an open-label, multicenter, nonrandomized, Simon Optimum 2-stage design with up to 19 subjects with metastatic melanoma primarily confined to the lymph nodes treated with MKC1106-MT in the first stage and a potential total of 44 subjects overall. The primary objective of the study is objective response per RECIST 1.1 where response is defined as complete response, partial response and stable disease for 12 weeks or longer. Secondary objectives include time to progression, progression-free survival and overall survival measured at six months and one year. Follow-up will be conducted one year from last dose administered with patients that demonstrate objective response. The study will continue to evaluate the safety and tolerability of the investigational treatment. Further information about the study is available at http://www.clinicaltrials.gov.

About MannKind Corporation

MannKind Corporation (NASDAQ:MNKD) focuses on the discovery, development and commercialization of therapeutic products for patients with diseases such as diabetes and cancer. Its diabetes pipeline includes AFREZZA® and MKC253. MKC253 is currently in phase 1 clinical trials. In March 2009, MannKind submitted a NDA to the FDA requesting approval of AFREZZA for the treatment of adults with type 1 or type 2 diabetes for the control of hyperglycemia. In March 2010, MannKind received a Complete Response letter to this NDA from the FDA, requesting additional information. In July 2010, the FDA accepted MannKind's reply to the Complete Response letter and set a PDUFA action date of December 29, 2010. Other products in MannKind's pipeline include the cancer immunotherapy products MKC1106-PP and MKC1106-MT, which have completed Phase 1 clinical trials. MannKind maintains a website at http://www.mannkindcorp.com to which MannKind regularly posts copies of its press releases as well as additional information about MannKind. Interested persons can subscribe on the MannKind website to e-mail alerts that are sent automatically when MannKind issues press releases, files its reports with the Securities and Exchange Commission or posts certain other information to the website.

SOURCE: MannKind Corporation

MannKind Corporation
Matthew Pfeffer
Chief Financial Officer
661-775-5300
mpfeffer@mannkindcorp.com