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WASHINGTON--(BUSINESS WIRE)--Oct. 29, 2009-- Results of two phase 1 studies demonstrate that the novel, investigational cancer vaccines MKC1106-MT and MKC1106-PP are well-tolerated and show encouraging immune response rates and objective tumor response in advanced melanoma, prostate cancer and other solid malignancies, setting the stage for phase 2 studies. The data are being presented at the International Society for Biological Therapy of Cancer 2009 Annual Meeting.

MKC1106-MT is an active immunotherapeutic product consisting of three components, a DNA plasmid and two synthetic peptides, each of which is administered separately by the unique route of intranodal injection and together are designed to target two tumor-specific antigens that are commonly expressed by melanoma tumor cells. MKC1106-PP is a similar agent that is designed to target two specific tumor antigens commonly expressed by various solid tumor cells.

“MKC1106-MT and MKC1106-PP met the primary end-points of both trials and, in addition, showed early evidence of clinical benefit, which marks an important step forward for MannKind’s oncology portfolio,” said Peter Richardson, MRCP, Corporate Vice President and Chief Scientific Officer, MannKind Corporation. “These encouraging results set the stage to move into phase 2 trials with these innovative, targeted therapies, which represent the cornerstone of our cancer immunotherapy program.”

MKC-1106 MT Study Design and Key Findings

In an ongoing, open-label, multicenter trial, 18 patients with advanced melanoma were treated with MKC1106-MT and were evaluated after each therapeutic cycle of six weeks. Patients demonstrating a clinical response or no evidence of disease progression remained in the clinical trial and received up to eight cycles of treatment over one year. In all patients, repeat administration of the treatment was well tolerated with limited adverse events.

Findings reveal an immune response rate of greater than 40 percent, defined as the percentage of patients who showed elevated numbers of antigen specific T cells in the blood upon immunization, and preliminary evidence of clinical benefit. Of the 18 patients treated, 14 had visceral metastases and the remaining four had metastases confined to the lymphatic system. All four patients with lymphatic metastatic disease achieved durable objective responses (partial response based on tumor imaging [RECIST criteria]), an unexpected outcome for a phase 1 study in this type of setting. A subset analysis identified the presence of melanoma-specific T cells at baseline in the patients with lymphatic metastatic disease. Overall, these results identified patients that could benefit most from this type of therapy and will be used to design the phase 2 trial of MKC1106-MT in advanced melanoma.

“Cancer vaccines have been explored in the past with very limited success to curb the disease progression of malignant melanoma,” said Antoni Ribas, MD, Associate Professor, Division of Hematology-Oncology, David Geffen School of Medicine at UCLA. “The promising preliminary results of this ongoing study warrant further evaluation of MKC1106-MT in advanced disease and as an adjuvant therapy.”

MKC1106-PP Study Design and Key Findings

In the second study, 26 patients with advanced cancer who had diverse tumor types, metastatic disease and/or progressive, refractory disease were treated with MKC1106-PP. Patients were evaluated after two therapeutic cycles (12 weeks) and again at 24 weeks, as applicable. Patients demonstrating a clinical response or no evidence of disease progression remained in the clinical trial and received up to six cycles of treatment over nine months. In all patients, repeat administration of the treatment was well tolerated with limited adverse events.

As with the MKC1106-MT trial, an immune response rate and encouraging preliminary evidence of clinical benefit were achieved. In this study, an immune response rate of 60 percent was observed. Of the 26 patients treated, seven patients achieved clinical responses defined as partial response (RECIST), change in PSA doubling time or stable disease for at least six months. Patients attaining an immune response against both antigens, persisting throughout the first two cycles of therapy, were more likely to show clinical benefit, setting the stage for further evaluation in phase 2 studies.

“These findings lay the foundation for additional trials evaluating the clinical benefit of MKC1106-PP in select indications,” said Nicholas J. Vogelzang MD, Chair and Medical Director, Developmental Therapeutics and Co-Chair, GU Committee, US Oncology Research, Comprehensive Cancer Centers of Nevada. “Further study of this investigational agent’s mechanism of action will also be important in assessing its promise in biomarker-defined patient populations.”

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 pipeline includes AFRESA®, MKC253, MKC1106-PP, and MKC1106-MT. MannKind has submitted an NDA to the FDA requesting approval of AFRESA for the treatment of adults with type 1 or type 2 diabetes for the control of hyperglycemia. Its other programs are currently in 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.

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