



BIOVEX COMMENCES ONCOVEX^{GM-CSF} PIVOTAL TRIAL IN MELANOMA

Woburn, MA. -- April [14], 2009 -- BioVex Inc, a company developing new generation biologics for the treatment and prevention of cancer and infectious disease, announced today that its OPTiM (OncoVEX Pivotal Trial in Melanoma) Phase 3 study with OncoVEX^{GM-CSF} in previously treated patients with Stage III and Stage IV melanoma had initiated. The study has commenced recruiting patients in the US with sites in the United Kingdom, Germany and Australia due to open later in the year. Further details on this study can be found at www.oncovexgmcsf.com and at www.clinicaltrials.gov.

OPTiM Trial Design

The OPTiM protocol is the most recently added Phase III study for patients with previously treated advanced melanoma on the ClinicalTrials.gov web site. The trial is a multi national, open label, randomized Phase 3 study to assess the efficacy and safety of treatment with OncoVEX^{GM-CSF} as compared to sub cutaneously administered GM-CSF in patients with unresectable stage III (b-c) and Stage IV (M1a-c) disease. Patients will have received at least one prior therapy for active disease which includes any type of therapy including investigational drugs. A total of 360 patients will be enrolled (240 to the OncoVEX^{GM-CSF} arm and 120 to the control arm). The study design was agreed with the FDA under the Special Protocol Assessment process ("SPA"). The SPA process provides for a designation from the FDA that the trial's design, clinical endpoints and statistical analysis can be used for regulatory approval.

Dr Robert Coffin, Founder & CTO of BioVex Inc said:

"The treatment options for patients with recurrent or metastatic melanoma are currently very limited, with no therapy being approved or recognized to be effective in the second line setting and beyond. Currently, there are also very few late stage or pivotal clinical studies available for patients who have failed first line therapy. The initiation of this study, following the highly encouraging data generated in Phase 2, is therefore a highly significant milestone on the path towards meeting this major unmet need, and towards the approval of OncoVEX^{GM-CSF} in this first indication."

About OncoVEX^{GM-CSF} Phase II Clinical Trial

BioVex recently concluded a 50-patient Phase II trial for OncoVEX^{GM-CSF} as a stand-alone therapy in patients with Stage IIIc and Stage IV melanoma. The trial was designed to measure overall objective response, which is defined as a complete response (CR), where disease is completely eliminated, or partial response (PR), where there is a >50% reduction in disease burden. 74% of patients who entered the study were progressing after having failed prior

therapy. 13 objective systemic responses (26% objective response rate) were achieved including eight CRs, seven of which remain free of disease. 12 responses have so far continued for more than 6 months (range 6-29+ months). Responses were observed in patients with all stages of disease, including the complete resolution of un-injected visceral deposits.

About BioVex

BioVex is a privately held biotechnology company based in Woburn, MA where it also has an operational launch grade manufacturing facility. The Company is developing a new class of potent biologics for the treatment of cancer and prevention of infectious disease.

The Company's lead cancer technology platform, OncoVEX^{GM-CSF} is a first-in-class oncolytic, or cancer destroying virus technology. OncoVEX^{GM-CSF} works by: replicating and spreading within solid tumors, causing the death of cancer cells; while stimulating the immune system to destroy un-injected metastatic deposits. Both modes of action have been clearly validated in the clinic, where multiple patients with metastatic disease progressing at enrollment have been declared disease free. BioVex believes OncoVEX^{GM-CSF} has the potential to become a leading standard of care in the treatment of many solid tumors based on the strength of clinical data generated to date, coupled with a benign side effect profile. Previous clinical trials have enrolled patients with breast cancer, head and neck cancer, and pancreatic cancer in addition to melanoma, and clinical activity has been observed in each case. The Company plans to submit a second Phase 3 SPA to the FDA in head and neck cancer in the middle of the year.

The Company's second program is a vaccine for genital herpes, ImmunoVEX^{HSV2}, which provides complete protection in animal models of the disease. The vaccine has been authorized to commence clinical testing in the UK.

For further information, please go to www.biovex.com.

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