



BIOVEX REPORTS POSITIVE PHASE II CLINICAL TRIAL RESULTS OF ONCOVEX^{GM-CSF} IN METASTATIC MELANOMA AT THE 2008 AMERICAN SOCIETY OF CLINICAL ONCOLOGY MEETING

Chicago, IL – June 1, 2008 – BioVex Inc, a biotechnology company developing clinical stage treatments for cancer and the prevention of infectious disease, today announced positive results from its Phase II clinical trial of OncoVEX^{GM-CSF}, an oncolytic for the treatment of advanced metastatic melanoma, at the 2008 Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago, IL.

Clinical Trial Details

Phase II Trial Design: The Phase II trial was conducted at seven U.S. clinical centers, including the Mary Crowley Cancer Research Center, Dallas, TX; Columbia University, New York, NY; The Hubert H. Humphrey Cancer Center, Minneapolis, MN; and the University of California San Diego, San Diego, CA. Fifty patients with inoperable Stage IIIc/IV melanoma were enrolled. Patients were given OncoVEX^{GM-CSF} injections every two weeks for up to a year. The trial was designed to measure overall objective response, which is defined as a complete response, where disease is completely eliminated, or partial response, where there is a >30% reduction in disease burden. The target efficacy endpoint detailed in the Phase II protocol and agreed with the FDA was to achieve two objective responses or stable disease >2 months.

Phase II results: Among 43 patients currently evaluable of the 50 patients enrolled, tumors injected with OncoVEX^{GM-CSF} routinely responded, often with local complete responses or palliative benefit. With regard to systemic overall responses required for treatment success (including tumor responses at sites distant from injected tumors), six patients showed complete clinical responses; five of which are ongoing at between four and 27 months post first injection. The sixth complete response patient presented with a new lesion 15 months after initiating therapy. A further six patients achieved a partial response, five of which are ongoing 7-13 months post first injection and two of which have no disease after surgical resection of residual tumors.

The current rate of objective response stands at 28%. Other patients have shown clinical benefit including prolonged periods of stable disease as well as post treatment responses after being withdrawn from the study for initial progression. Seven patients remain on study with stable disease 3 to 10 months post initiation of therapy. Side effects were mild and mainly limited to transient flu-like symptoms.

Commenting on these results, Dr. Neil N. Senzer of The Mary Crowley Cancer Research Center in Dallas, TX said:

“Patients with advanced melanoma have few current treatment options that produce a lasting clinical response. OncoVEX^{GM-CSF} has shown it can engender durable objective responses in a substantial proportion of patients. This efficacy profile combined with a lack of any serious side effects makes this product candidate one of the most promising later stage experimental cancer therapies currently in clinical development.”

FDA approved pivotal Phase III study design

BioVex recently announced that the U.S. Food and Drug Administration (FDA) has approved the design of a single, pivotal, Phase III clinical trial evaluating OncoVEX^{GM-CSF} in previously treated patients with metastatic melanoma. The agreement was made under the Special Protocol Assessment (SPA) procedure. The Phase III study design agreed upon with the FDA follows directly from the study design successfully employed in Phase II, incorporating a response rate based primary endpoint – the rate of objective responses maintained for six months or more. The study is expected to commence in the first quarter of 2009, with a potential projected biologics licensing application (BLA) filing in late 2010.

BioVex President and CEO Philip Astley-Sparke commented:

“OncoVEX^{GM-CSF} is poised to become the first product in its class to enter into a pivotal, Phase III study. I am extremely proud of the commitment that all our management, employees and investigators have made to ensure that this pioneering approach is now just one successful study away from providing a new treatment modality for patients who currently have few, if any, attractive options.”

About Metastatic Melanoma

According to the American Cancer Society, more than 8,000 people died in the U.S. of melanoma in 2007. Prevalence of Stage III and Stage IV disease is 120,000 and median survival for Stage IV disease is six months.

Treatment of melanoma depends on the stage of the disease with surgical resection being effective in less severe non metastatic forms of the disease. However, survival rates for later Stage III and IV patients are poor reflecting the lack of any efficacious drugs for metastatic disease. Current systemic therapies are not generally effective in terms of generating durable responses or in impacting survival and therefore many patients presenting with metastatic disease are directly enrolled into a clinical trial. The vast majority of experimental therapies have failed to show more than a single digit durable response rate.

EMBARGOED UNTIL JUNE 1, 2008 AT 11AM EDT, 10AM CDT, 8AM PDT

About BioVex

BioVex is a privately held biotechnology Company based in Woburn, MA. 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 an unpartnered, 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 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.

BioVex is currently completing a Phase II clinical trial of OncoVEX^{GM-CSF} for melanoma and Phase I/II clinical trials for head & neck cancer and pancreatic cancer. The Company recently announced that the FDA has approved the design of a single, pivotal Phase III clinical trial evaluating OncoVEX^{GM-CSF} in previously treated patients with metastatic melanoma under the Special Protocol Assessment (SPA) procedure and plans to make a second SPA submission for head & neck cancer later in 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. A Phase I study with ImmunoVEX^{HSV2} is scheduled to commence in the third quarter of 2008.

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

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