

Press Release

Burzynski Research Institute Announces Positive Results of Phase II ANP Clinical Trial

HOUSTON, TX – Wednesday, May 6, 2009 – The Burzynski Research Institute (BRI) announced today positive safety and efficacy results in its Phase II clinical trial of Antineoplaston A10 and Antineoplaston AS2-1 therapy (ANP therapy) in children with optic pathway glioma (OPG). The results were presented to the FDA in the Request for End of Phase II Meeting Briefing Package (ANP in OPG), to be discussed at a meeting with the FDA on May 7, 2009. The FDA responded to the questions in the Briefing Package and issued additional comments before the meeting. The answers and comments were clear, and the meeting was cancelled since further discussion was not required. Based on preliminary responses and additional comments from the FDA, a protocol for a Phase III randomized trial with ANP in OPG will be prepared and submitted for FDA Special Protocol Assessment (SPA) to secure agreement on the design of a Phase III trial to serve as an efficacy claim in a New Drug Application (NDA).

OPG, with 150 new cases, per year is an uncommon brain tumor currently affecting approximately 2000 children in the U.S. The natural history of OPG is highly variable and indicates that more than 50% of patients diagnosed with OPG do not require treatment. Unfortunately, over 40% of OPG patients will have progressive or recurrent disease leading to disability and death. At present, curative treatment for this subpopulation of patients is not available. There is no successful surgery or radiation therapy, and chemotherapy provides only temporary relief. This type of brain tumor affects mostly children whose mean age at diagnosis is approximately eight years.

Results from the BRI Phase II study of ANP therapy (protocol BC-BT-23) suggests that this form of treatment is a very good alternative to chemotherapy. Based on the treatment of 16 patients, complete and partial responses were documented in five patients, stabilization of disease in six patients, and progressive disease in only one patient. ANP therapy was associated only with grade 1 and grade 2 toxicities in some patients. There were no grade 3 or 4 or chronic adverse events. A subpopulation of responding OPG patients maintain objective responses in excess of 10 years despite the fact that some of them had multicentric tumors.

“Children diagnosed with OPG are in need of therapies that can provide long-term responses and minimal toxicities. The results of the ANP trial in OPG demonstrate the potential role of ANP as a novel treatment option for this type of brain tumor. We are very encouraged by the outcome of our discussion with the FDA,” said Stanislaw R. Burzynski, M.D., Ph.D., Chairman and CEO of BRI.

Burzynski Research Institute, Inc. (OTCBB: BZYR) is a biopharmaceutical company committed to developing treatment for cancer based on genomic and epigenomic principles. Research and development efforts are focused on basic research and Phase III clinical trials.

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