Press Release

Burzynski Research Institute Presents Positive Results From Phase II Trials of ANP for Inoperable Brainstem Glioma at the Congress

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HOUSTON--(BUSINESS WIRE)--The Burzynski Research Institute, Inc. (BRI) announced today that it made three presentations of the results of phase II trials and mechanism of action data on its antineoplaston A10 and antineoplaston AS2-1 therapy (ANP). These findings were discussed at the 3rd Quadrennial Meeting of the World Federation of Neuro-Oncology in Yokohama, Japan.

In phase II studies, a total of eighty evaluable patients with advanced non-operative brainstem glioma (BSG) have been treated with ANP administered intravenously through an ambulatory infusion pump. Most of the patients (79%) were children, and 63% of all patients failed prior radiation therapy and/or chemotherapy. Due to low performance status, 52 patients were treated under Special Exception. The median duration of treatment was 5 ½ months. ANP was well-tolerated with easy manageable side effects of fatigue, skin rash and electrolyte abnormalities and no chronic toxicities. In the study group, 32% of patients have complete and partial responses, 43% have stable disease and 25% developed progression. Overall survival is 36% at 2 years and 25% at 5 years. These results compared favorably to radiation therapy and chemotherapy (Mandell, et al. 1999, 7% overall survival at 2 years and 0% at 5 years), but should be confirmed in phase III trials scheduled to begin in 2009.

The remarkable response of one of the patients who was treated on the study protocol was the subject of the second presentation. The patient is currently a 10 ½ year-old female who, as a six-week-old infant was diagnosed with BSG on August 12, 1998. The tumor was inoperable and the pediatric oncology service felt that chemotherapy as well as radiation therapy would not be an option. On October 14, 1998, she began intravenous infusions of ANP, which were discontinued on June 8, 2000. She achieved complete response in February 1999 and continues to be tumor free and lives a normal life since then.

The third presentation described new data on the molecular mechanism of action of ANP and concentrated on the most important findings from the study of the effect of active ingredients of ANP on the entire genome of malignant glioma (glioblastoma). Gene expression study and pathway analysis revealed the effect of ANP on 94 genes vital for the growth of malignant brain tumors. The study indicated that major metabolic pathways such as glycolysis were down-regulated. Many pro-apoptotic genes such as CASP3, CASP4, several TNFRs, TRF3 were up-regulated. The cell cycle was disrupted, and major checkpoint proteins were suppressed leading to apoptosis of glioblastoma cells. The Minichromosome Maintenance Complex (MCM) proteins are highly expressed in malignant cells and are promising targets for anticancer drugs. All six genes of the MCM were markedly suppressed by ANP. In conclusion, ANP inhibited MCM complex in malignant glioma, which may play an important role in control of tumor growth.

“These preclinical and clinical results are very encouraging, since they describe a positive ANP effect on one of the worst malignancies in the entire oncology field; they strongly support phase III trials scheduled to start later this year,” said Stanislaw R. Burzynski, M.D., Ph.D., Chairman and CEO of BRI.
Burzynski Research Institute, Inc. (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.

Forward-looking statements in this release are made pursuant to the safe harbor provisions of the federal securities laws. Burzynski Research Institute, Inc. cautions investors not to place undue reliance on the forward-looking statements contained in this press release. Information contained in forward-looking statements is based on current expectations and is subject to change, and future events may differ materially from those discussed herein due to a number of factors, including, but not limited to, risks and uncertainties related to BRI's ability to obtain regulatory approval for Antineoplastons A10 and AS2-1, risks associated with BRI's ability to raise sufficient capital from the development of its technology towards commercialization, and other risks described in BRI's periodic reports filed with the Securities and Exchange Commission. BRI does not undertake to update any such forward-looking statements or to publicly announce developments or events relating to the matters described herein.

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