Burzynski Research Institute Gets SPA Clearance from the FDA to Initiate Pivotal Phase III Trial of Combination Antineoplaston Therapy and Radiation Therapy

Study to Evaluate Children with Newly-Diagnosed Diffuse Intrinsic Brainstem Glioma

HOUSTON, TX - January, 13, 2009 – The Burzynski Research Institute, Inc. (BRI) today announced that it has reached an agreement with the U.S. Food and Drug Administration (FDA) that enables the company to move forward immediately with a pivotal Phase III clinical trial of combination antineoplaston therapy plus radiation therapy in patients with newly-diagnosed, diffuse, intrinsic brainstem glioma. Antineoplaston therapy (ANP) uses a synthetic version of naturally occurring peptides and amino acid derivatives found in the human body to target and control cancer cells without destroying normal cells. The agreement was made under the FDA's Special Protocol Assessment (SPA) procedure and means that the design and planned analysis of the Phase III study is acceptable to support a regulatory submission seeking new drug approval.

"We are very pleased by our agreement with the FDA to move forward with a confirmatory study on a type of tumor that has shown itself to be highly treatment resistant and challenged further by severely limited treatment options and clinical trials that could expand and discover new, efficacious therapies," said Stanislaw R. Burzynski, M.D., Ph.D. "The SPA agreement puts antineoplaston therapy further down a straight path to regulatory approval, enabling the kind of study that should prove its merits as another option to cancer management."

"BRI has reached this important milestone independently without financial backing from the government, and without a major pharmaceutical partner—a unique accomplishment in the oncology field. From inception, we have been committed to developing a targeted gene therapy option that is less aggressive on the body than conventional therapies and have made considerable progress on the steps mandated by the FDA to bring a new drug to a patient community and cancer type that has unmet needs."

About the Phase III study

The primary objective of this randomized study is to compare overall survival of children with newly-diagnosed diffuse intrinsic brainstem glioma (DBSG) who receive combination antineoplaston therapy [Antineoplastons A10 (Atengenal) and AS2-1 (Astugenal)] plus radiation therapy (RT) versus RT alone.

DBSG are considered to be one of the most difficult types of cancer to treat. It combines highly malignant characteristics with the very difficult location of the brainstem. DBSG are inoperable because they involve most of the brainstem (diffuse and intrinsic). The number of children in the U.S. with brainstem gliomas is approximately 660. Absent treatment, the survival rate from time of diagnosis is six months or less.

At present, there are no standard curative treatments for the disease. RT is the only treatment that may slow its progress, but at two years 93% of children with this type of cancer die, and none of them survive for five years. Other conventional treatments such as chemotherapy have

generally been tried in clinical trials but are shown to be ineffective. There are no pharmacological treatments approved for DBSG at this time.

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 ANP research and 19 Phase II clinical trials.

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