

## **U.S. FDA Grants Orphan Drug Designation for Burzynski Research Institute's Antineoplaston Treatment for Gliomas**

**HOUSTON, TX - December 2, 2008** – The Burzynski Research Institute, Inc. (BRI) today announced that its antineoplaston A10 and antineoplaston AS2-1 therapy (ANP) has been granted orphan drug designation by the U.S. Food and Drug Administration (“FDA”) for the treatment of gliomas. It is estimated that in 2008 more than 21,000 men and women in the U.S. will be diagnosed with this type of cancer, with prevalence estimated at approximately 84,000 cases.

“We are encouraged by the FDA’s action. Initially, BRI sought orphan drug designation for ANP in optic pathway glioma in children, a much narrower indication involving a smaller segment of tumors,” said Dr. Stanislaw R. Burzynski, M.D., Ph.D. “However, the FDA extended orphan drug designation to all gliomas, a recognition we believe underlies the broad potential of antineoplaston therapy for the treatment of patients with cancer of the brain and nervous system. There is now even more motivation for us to evaluate our therapy as an innovative and efficacious choice in a treatment spectrum where disease management options are still quite limited.”

Orphan drug designation, as granted by the FDA’s Office of Orphan Products Development, was designed to encourage clinical development of products for use in rare diseases or conditions, usually defined as affecting fewer than 200,000 people in the United States. Orphan drug designation provides an economic incentive that stimulates the development of new products in the oncology field and allows for seven years of market exclusivity upon final FDA approval, as well as clinical study and R&D support, reduction in regulatory fees and potential tax credits.

**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, some of which are coming now to a successful conclusion. Since ANP effects approximately 100 genes instrumental in the growth of glioblastoma multiforme, the results of research have been and will be presented in a number of neuro-oncology meetings and published as abstracts in *Neuro-Oncology*. Earlier this year the BRI team presented at the 13<sup>th</sup> International Symposium of Pediatric Neuro-Oncology in Chicago, Illinois (June 29-July 2, 2008), a successful preliminary report on the phase II study of ANP in children with optic pathway glioma. At the September 2008 annual meeting of the European Association for Neuro-Oncology in Barcelona, Spain, BRI presented two reports. In one of them, it was described how the ingredients of ANP down-regulate energy producing pathways in glioblastoma cells. The second report described preliminary successful results of Phase II study of ANP in patients with recurrent anaplastic astrocytoma. Most recently, BRI presented two additional reports on preliminary results of phase II study of ANP in patients with newly-diagnosed anaplastic astrocytoma and on the effects of ANP’s ingredients on cell cycle checkpoint which lead to apoptosis in human glioblastoma cells at the Society of Neuro-Oncology’s annual meeting in November 2008.

**Media Contacts:**

Burzynski Research Institute, Inc.

Darlene Hodge at 713.335.5636; [Darlene@burzynskiclinic.com](mailto:Darlene@burzynskiclinic.com)

Carolyn Powers at 713.335.5664; [Carolyn@burzynskiclinic.com](mailto:Carolyn@burzynskiclinic.com)

Amanda Cheslock at 212.446.1884; [acheslock@sloanepr.com](mailto:acheslock@sloanepr.com)

+++

*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. BRI does not undertake to update any such forward-looking statements or to publicly announce developments or events relating to the matters described herein.*