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Tomorrow's Cancer Treatment Today



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Welcome to the Burzynski Clinic

"What makes us different is that we find and treat the cause and stimulation of your cancer..." SRB

- Innovative and cutting-edge [Personalized Gene Targeted Cancer Therapy](#)
- Customized treatment for over 50 types of malignancies
- Currently approved for Phase III Clinical Trial for Antineoplastons treatment (must meet criteria)
- Medical expertise based on over 40 years of clinical experience and research
- Concierge care centered around the patients and their families in a warm, supportive environment

Stanislaw R. Burzynski, M.D., Ph.D. - *Medical Pioneer*



Stanislaw R. Burzynski, MD, PhD, is an internationally recognized physician and scientist who has devoted his whole life to cancer research. Burzynski Clinic has been treating thousands of cancer patients from all over the world for over 40 years.

Dr. Burzynski is a pioneer in cancer research, known worldwide for discovering Antineoplastons, which act as molecular switches to turn off cancer cells without destroying normal cells.

Our Approach to Cancer

Burzynski Clinic does not believe in a "one size fits all treatment" for cancer patients. Our care encompasses a personalized and customized approach based on the individual genetic "fingerprint" of each cancer. Meaning what causes and stimulates that particular patient's cancer.

Our goal is to be as sophisticated as possible when treating our cancer patients. This method reduces the use of potentially ineffective medication and leads to remarkable health improvement, saving time and money.

News Headlines:

Burzynski Research Institute, Inc. Gets SPA Clearance from the FDA to Initiate Pivotal Phase III Trial of Combination Antineoplaston Therapy and Radiation Therapy. [Read more](#)

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In this video, 4-year-old Tori Moreno's father shares his story about his daughter's recovery from an inoperable brainstem tumor.

[More patient stories](#)



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About the Burzynski Clinic

Established in 1977, the Burzynski Clinic has grown to a world-renowned cancer center, that boasts over 100 employees. The Burzynski Clinic is an exceptional organization that provides cutting-edge, advanced cancer treatments, including [Antineoplaston treatment](#) and [personalized treatment plans](#). Burzynski Clinic is world-famous for its discovery of Antineoplastons which have been cleared for Phase III clinical FDA trials (patients must meet clinical criteria).

Our Mission

For over 35 years, Dr. Burzynski's cancer research and care has been inspired by the philosophy of the physician, Hippocrates, to "First, do no harm." True to this philosophy, our treatment regimens are based on the natural biochemical defense system of our body, capable of combating cancer without harming the healthy cells.

Every day, in everything we do, we are proudly committed to these values. Our goal is to continue cancer research. Our mission is to beat cancer.

Personalized Medicine

Instead of a one-size-fits-all approach to cancer treatments, the Burzynski Clinic believes that every patient requires a treatment plan as unique as they are. Burzynski Clinic offers a variety of [Personalized Treatment options](#) - designed around the patient's specific needs using custom selected gene targeted medications based on the identification of the oncogenes involved in their cancer. Therapy is highly personalized and designed to selectively kill cancer cells by targeting the abnormal genes in the cancer.

Patients' health and well-being are most important to us.

Our services include: gene-targeted cancer treatment, oncology consultations, genetic markers testing, oncogene testing, in-house pharmacy for formulary management, nutrition counseling, medication training and patient treatment monitoring.

Multilingual Assistance

Due to the international character of our clinic, we are able to assist our patients in various foreign languages, including French, German, Spanish, Portuguese, Russian, Danish, Norwegian, Swedish, Polish, Slovak, Czech, Hungarian, Chinese, Vietnamese, Arabic, Farsi and Hindi.

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About Dr. Stanislaw R. Burzynski

Stanislaw R. Burzynski, M.D., Ph.D., internationally recognized physician and biochemist-researcher who pioneered the development and use of biologically active peptides in diagnosing, preventing and treating cancer, since 1967.

In 1967, at the young age of 24, S.R. Burzynski graduated from the Medical Academy in Lublin, Poland, with a M.D. degree with distinction, finishing first in his class of 250. During the same year he identified naturally occurring peptides in the human body which he concluded control cancer growth. He found that there is a marked deficiency of these peptides in cancer patients.

The following year, 1968, he earned his Ph.D. in Biochemistry as one of the youngest candidates in Poland ever to hold both an M.D. and Ph.D.

From 1970 to 1977, while a researcher and Assistant Professor at Baylor College of Medicine in Houston, his research was sponsored and partially funded by the National Cancer Institute. At Baylor, he authored and co-authored 16 publications, including 5 concerning his research on peptides and their effect on human cancer. Four of these publications were also co-authored by other doctors associated with M.D. Anderson Hospital and Tumor Institute, and Baylor College of Medicine. It was at Baylor that Dr. Burzynski named these peptides "Antineoplastons" due to their activity in correcting and normalizing neoplastic, or cancerous, cells.

In May of 1977, Dr. Burzynski received a Certificate of Appreciation from Baylor College of Medicine, commending him for completing five years of dedicated service and acknowledging his contributions made to the "Advancement of Medical Education, Research, and Health Care."

That same year, Dr. Burzynski founded his clinic in Houston where he's since treated over 8,000 patients. He is also the president of the Burzynski Research Institute, where he continues to pursue scientific research on Antineoplastons.


Dr. Burzynski is a member in good standing of renowned medical associations, including the American and World Medical Associations, American Association for Cancer Research, Society for Neuroscience, Texas Medical Association, Royal Medical Association (U.K.), Academy of Medical Ethics, Society for Neuro-Oncology, and many others.

Dr. Burzynski is the author and co-author of over 300 scientific publications and presentations. In his career he has received numerous prestigious awards from various medical, educational and governmental institutions. Currently, he holds 242 patents registered in 35 countries, related to 17 proprietary scientific inventions (as of January 2011).

Other groups of scientists have expanded Dr. Burzynski's work, including researchers at the National Cancer Institute, the Medical College of Georgia, the Imperial College of Science and Technology of London, the University of Kurume Medical School in Japan, the University of Turin Medical School in Italy, and many others. There are several hundred publications on Antineoplastons and their active ingredients written by scientists working independently of the Burzynski Research Institute.

[Download full Curriculum Vitae of Dr. Burzynski](#)

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Burzynski Research Institute


Burzynski Research Institute (BRI), a biopharmaceutical company committed to developing treatment for cancer based on genomic and epigenomic principles. Research and developmental efforts are focused on cancer treatment with four pipeline drugs—antineoplastons (ANP) in 1 Phase III clinical trial and 14 Phase II clinical trials, some of which are ready to enter Phase III.

The ultimate goal of the BRI is to discover, develop, and obtain the FDA's marketing approval of ANP for the treatment of currently incurable types of cancer with emphasis on malignant brain tumors in adults and children.

BRI was incorporated under the laws of the State of Delaware in 1984 in order to engage in the research, production, marketing, promotion and sale of certain medical chemical compounds composed of growth-inhibiting peptides, amino acid derivatives and organic acids which are known under the trade name *antineoplastons*.

Please visit the [Burzynski Research Institute website](#) for more information.

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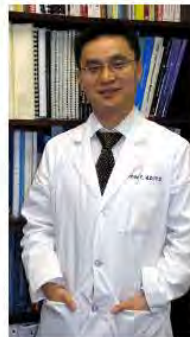
Jose L. Valladares, MD



Dr. Valladares is a Senior Oncologist at the Burzynski Clinic. He graduated Summa Cum Laude (First Place in his graduating class) from San Marcos University, Lima, Peru. He received an Award from the National Academy of Medicine. He was Medical and Specialist Professor at University Hospital eventually becoming Chief of Hematology, Oncology and the Blood Bank Service.

Dr. Valladares received training in United States of America at the State University of New York, University of Illinois and Johns Hopkins in Baltimore, Maryland; becoming a specialist in Internal Medicine, Hematology, Oncology and Bone Marrow Transplant. He is Specialist Board Certified. He was recently involved in private practice in the greater Corpus Christi Metropolitan Area. He is member of The Johns Hopkins Medical and Surgical Association, American Medical Association and Cameron Willacy County Medical Society and Texas Medical Association. Dr. Valladares provides standards of care in Internal Medicine, Hematology, Oncology and Bone Marrow Transplant consultations for all new and follow up patients seen at the Clinic. The treatment of most patients at this Clinic includes the NCCA Guidelines of the Cancer Society and FDA approved targeted agents based on the identification of serum and primarily tissue signal (tumor profiling) transduction pathway.

Zan Yi, MD



Dr. Zan Yi is a Senior Oncologist at the Burzynski Clinic. After receiving his medical training from China, he came to the US and obtained a Ph.D. degree in Molecular Genetics at the University of Arizona. Dr. Yi completed his Internal Medicine residency at Bridgeport Hospital Yale University Program, followed by Hematology-Oncology subspecialty training at New York University Medical Center. Dr. Yi provides Hematology and Oncology consultation services in compliance with published NCCN (National Comprehensive Cancer Network) guidelines. He has published numerous papers on basic research. He has particular interest in applying molecular genetics in the diagnosis and treatment of cancer patients.

Gregory S. Burzynski, MD



Dr. Gregory Burzynski joined the medical team at the Burzynski Clinic in the summer of 2010. He is now the Vice President of the Burzynski Clinic and oversees many operations. Dr. Gregory Burzynski graduated from the University of Texas at Austin with a Bachelor of Science in Neurobiology and later studied medicine at the Jagiellonian University Medical College in Krakow, Poland. He finished his internal medicine residency at the University of Texas at Austin and is Board Certified in Internal Medicine. Dr. Gregory Burzynski has been involved in co-authoring publications regarding Antineoplastons. Currently, he is a member of the American Medical Association, American College of Physicians and The Society of Neuro-Oncology. Dr. Gregory Burzynski's goal is to optimize personal medicine at the Burzynski Clinic and continue future advancements in Antineoplaston technology.

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In this video, 4-year-old Tori Moreno's father shares his story about his daughter's recovery from an inoperable brainstem tumor.

[More patient stories](#)

Alejandro A. Marquis, MD



Dr. Marquis has been a senior physician at the Burzynski Clinic since October 2006. He did his undergraduate work at The University of Texas at Austin where he graduated from the College of Pharmacy. He later graduated from medical school from The University of Texas Medical Branch at Galveston followed by his internship and residency program completed through Central Texas Medical Foundation, Family Practice Residency Program, Brackenridge Hospital, Austin, Texas.

Prior to working at the Burzynski Clinic, Dr. Marquis had a private practice in Austin, Texas, which included clinic work, daily hospital rounds and an extensive nursing home practice.



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Personalized Treatments

Burzynski Clinic offers variety of cancer treatments for patients diagnosed with over 50 different types of malignancies, including colon, pulmonary, breast, prostate, head and neck, ovarian, pancreatic, esophageal, hepatic, renal, bladder, brain, malignant melanoma, lymphoma, and many others.

Our approach to cancer: Personalized Medicine

For many years scientists have been trying to understand why some patients respond better to similar cancer treatments better than others. Recent studies have shown a strong link between patient's gene expression and the effectiveness of a cancer treatment. The understanding that all cancers are associated with changes in gene expression (activity) led to dramatic changes in the diagnosis and therapy of cancer and to creation of personalized medicine. Personalized medicine tries to identify these relations through detection of genes involved in cancer.

After determination of a sequence of the human genome it was found that only 10% of genes are active in adult life. This means that approximately 90% of our genes are silenced. The system of biochemical factors called epigenome consists of molecular switches that silence and activate the genes during our life.

At the age of 25, the body has the optimal combination of active genes, but soon thereafter, groups of genes are gradually turned off during the aging process. Silencing of tumor suppressor genes triggers increased activity of oncogenes leading to mutations and increasing the risk of cancer. Decreased activity of tumor suppressors and increased activity of oncogenes lead to cancer.

Based on the current knowledge of the epigenetic mechanisms the new approach in medical oncology is to reverse the relationship between the oncogenes and tumor suppressor genes.

Gene expression is a process, during which a gene's DNA sequence is converted into the structures and functions of proteins.

Personalized Treatment

Our approach to cancer is a result of Dr. Burzynski's extensive experience in cancer research in the field of genetics and genomics.

Personalized Treatments offered by the Burzynski Clinic are individual treatment plans, customized for each patient, based on:

- Identification of oncogenes responsible for the growth of cancerous cells in individual patients
- Selection of targeted pharmaceuticals that selectively kill cancer cells carrying the identified abnormal genes

The main goal of a Personalized Treatment is to match the right patient to the right treatment to achieve maximum effectiveness with minimum side effects.

How does the Personalized Treatment Work?

To establish a personalized treatment plan we first must identify the expression (activity) of patient's oncogenes. The gene expression is identified through the oncogene testing (genetic markers testing). The identification of oncogenes enables our medical team to assess patient's response chance and to determine the most optimal combination of medications.

[Read more about Treatment Options at the Burzynski Clinic](#)





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Ask a question

Patient (a person diagnosed with cancer or suspecting they might have cancer; all fields required)

First Name (*)

Last Name (*)

Address 1 (*)

Address 2

City (*)

State

Zip Code (*)

Country

E-mail (*)

Phone

Date of birth (*)

Cancer Type

Requestor (please, fill in only if different than Patient; all fields required)

First Name (*)

Last Name (*)

Address 1

Address 2

City

State

Zip

Country

Email

Phone

How does the cancer affect you

Select the type of informational materials (*)

The requested materials to be sent to (*)

Future info to be sent (*)

How did you hear about Burzynski Clinic (*)

Additional comments, inquiries or requests

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Events & Seminars

Informational Seminars at the Burzynski Clinic

Burzynski Clinic Patient Seminars



INFORMATION & EDUCATION SESSION

Directed by: Marlene Bestak, R.N., B.S.N.

Every Monday & Thursday at 5pm
Burzynski Clinic 2nd Floor Conference Room



EDUCATIONAL LECTURE:

GENE TARGETED THERAPIES & BURZYNSKI RESEARCH

Directed by: Azad Rastegar, B.A.

Every Wednesday at 3pm
Burzynski Clinic 3rd Floor Conference Room



BURZYNSKI THE MOVIE

Showings: Every Tuesday & Friday at 3pm

Burzynski Clinic 3rd Floor Conference



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Patient Reunion

Our last patient reunion was held in 2007 and was a huge success. The Burzynski Clinic celebrated '30 Years of Saving Lives' during an evening gala banquet held at the Omni Westside Hotel in Houston. The event was dedicated to cancer survivors who have overcome the odds and obstacles of facing cancer head on and won their lives back. Cancer survivors came to Houston from all over the country to celebrate their lives and to share their heartwarming stories.

[Photo Gallery from the Gala](#)



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Preparing for your appointment

What to bring:

Preparing for your Visit

In order for us to provide the best treatment plan for you, we need to clearly and completely understand your medical history and the treatment that you may have already had to date.

It is important to bring the following items to your first appointment:

- Medical Records and Written Reports
- Referring Physician Letter
- A List of Current Medications: This includes all prescription medications, over-the-counter medications, alternative medications, vitamins, herbs and supplements
- Radiology Tests: This includes X-rays, CT scans, MRI scans, PET scans, ultrasounds, and current mammogram. It is important that our physicians review the actual films, either in hard copy or digital format, in addition to the written reports.
- Pathology report(s): if you have been diagnosed with cancer, then a pathologist has already made a diagnosis by reviewing a biopsy or tumor specimen. A copy of 'All' pathology reports will be requested and reviewed by our clinic.
- Insurance ID & Prescription ID Card(s): As a courtesy to our patients, we will submit charges to your insurance and prescription companies. Please notify your insurance company prior to your visit, and you may want to confirm with them if you will need a referral letter. Since we are classified as "out of network" we are unable to accept Medicare, Medicaid and any HMO insurance. If you utilize an insurance broker, we will need that contact information as well.
- Contact information for your referring physician, PCP, oncologist, internist, and etc.
- Financial requirement: Deposits are required to initiate treatment, including genetic testing.
- Questions: It is always a good idea to bring a list of questions to ask your physician. In addition, we encourage patients to bring a family member or significant other to help you take notes and ask questions.

Our Patient Scheduling Coordinator will contact you by phone to obtain necessary information prior to your first visit and is available to answer any questions that you have regarding your appointment. Please call (800) 714-7181 if you have any questions or concerns.

Interpreter services are available at no charge, but need to be coordinated prior to your appointment. Please advise our Patient Scheduling e-Coordinator if you would benefit from this service. We prefer to have an interpreter available to you in addition to the support of your family members.

Travel & Accommodations

We believe that the comfort and safety of our patients during the course of treatment are important factors that might contribute to the treatment success and help in patient recovery.

To make your travel and stay in Houston easier and more convenient, please visit the [Travel Information](#) page to obtain information about our location, accommodation and transportation options as well as tips for affordable dining near our Clinic.

Multilingual Assistance

Due to the international character of our clinic, we are able to assist our patients in various foreign languages, including French, German, Spanish, Portuguese, Russian, Danish, Polish, Slovak, Czech, Hungarian, Chinese, Vietnamese, Arabic, Farsi and Hindi.

For additional information, please [contact one of our Cancer Information Specialists](#).

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Patient Advocacy Office

A diagnosis of cancer may be the most difficult challenge patients and family members ever face. Your health team at the Burzynski Clinic is always available to give you as much support as you need.

We always strive to do our best to help and assist every patient and family members, giving them the best experience possible.

If a patient or family member has any concerns or issues with their experience at the Burzynski Clinic, we encourage that you contact the Burzynski Clinic Advocacy office as soon as possible.

Advocacy Office:


Email: ptadvocacy@burzynskiclinic.com (click on the link to open up your mail program)

Phone: +1 (713) 335-5665

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We kindly ask that the patient's full name, date of birth, and a call back number is included in all emails in order to provide faster service.

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Treatment Options

To establish a personalized treatment plan we first must identify the expression (activity) of patient's oncogenes. The gene expression is identified through the oncogene testing (genetic markers testing). The identification of oncogenes enables our medical team to assess patient's response chance and to determine the most optimal combination of medications.

Conventional Therapies

In some cases conventional therapy is the most appropriate treatment for a patient. Our Clinic offers customized combination therapies consisting of conventional therapy and other approved targeted therapies to maximize effectiveness while minimizing the side effects that typically occur when using the traditional therapies alone.

- [Read more about chemotherapy \(National Cancer Institute\).](#)

Surgery, radiation therapy, and specialized imaging such as MRI, CT and PET scan, are provided at other local medical facilities.

- [Read more about radiation therapy \(National Cancer Institute\).](#)

Approved Targeted Therapies

Gene-targeted medications are drugs that selectively block the growth and spread of cancer without affecting the healthy cells. Targeted therapies interfere with cancer cell growth differently than cytotoxic chemotherapy and at various points during the development, growth, and spread of cancer. By switching off the signals that make cancer cells grow and divide uncontrollably, targeted cancer therapies can help stop the growth of cancer cells.

Targeted medications have shown to be tolerated easier than standard chemotherapy and radiation with no side effects or minimal adverse reactions noted.

There are currently close to 30 targeted therapeutics approved by the FDA (as of January 2011). This number grows rapidly with the advancement of the research in genomics. All of the FDA approved gene-targeted medications are available for treatment at the Burzynski Clinic. The combination of targeted medications is customized for each patient and determined by the type of oncogenes involved in patient's cancer (Personalized Treatment).

- [Read more about approved targeted therapies \(National Cancer Institute\).](#)

Experimental Therapy

Our Clinic provides an experimental therapy based on Antineoplastons which are peptide and amino acid derivatives discovered by Dr. Burzynski, M.D., Ph.D.

Antineoplastons are multi-targeted therapy that effects approximately 100 genes involved in cancer.

The Antineoplaston therapy is a subject of FDA supervised clinical trials. Currently, only patients eligible to enroll into a clinical trial may receive such treatment.

- [Read more about Antineoplastons in clinical trials](#)

Individual Patient Care and Continuous Follow-Up

We believe the quality of the treatment is determined not only by the effectiveness of the cancer therapy but also by the quality of the patient's life during and after the treatment.

Burzynski Clinic provides a wide range of services to assure the comfort, convenience and well being of our patients, including 24-hour monitoring, rehabilitation, dietary supplements and nutrition counseling.

We take pride in offering the highest quality of personalized patient care. Each patient receives personal attention of a medical team assigned to them, consisting of a monitoring nurse, research associate and senior physician caring for the patient during the entire treatment.

Our supervision continues after the patient returns home and resumes care under their local physician until the treatment is completed.

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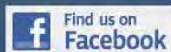
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In this video, 4-year-old Tori
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about his daughter's recovery
from an inoperable brainstem
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Cancer Type

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Last Name (*)

Address 1

Address 2

City

State

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How does the cancer affect you

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Introduction to Clinical Trials

Clinical trials (also clinical research, clinical studies) are research studies to determine whether experimental treatments, or new ways of using known therapies, are safe and effective. Carefully conducted clinical trials are necessary to find treatments that work in people and ways to improve health.

There are four phases of clinical trials in cancer treatment:

Phase I trials: to determine the safety of a new treatment

Phase II trials: to determine whether a certain kind of cancer responds to a new treatment

Phase III trials: to verify whether a new treatment is better than standard treatment

Phase IV trials: to find more specific information about a new treatment that has been already approved for use in patients

Antineoplastons - Subject of Clinical Trials

Antineoplaston treatment is an experimental therapy offered by the Burzynski Clinic, currently available only within clinical trials.

Currently, there is 1 open clinical trial on Antineoplastons (as of January 2012). The clinical trial is registered with the FDA and result of the trial is reported to the FDA on an annual basis.

▪ [Read more about Antineoplaston Therapy](#)

Quality Control

Clinical trials conducted in our Clinic are FDA approved protocols. A protocol determines what will be done in a clinical trial and why. It outlines how many patients will participate in a clinical trial, type and frequency of medical testing, treatment plan, monitoring requirements and the evaluation plan. Our staff physicians strictly follow the protocol and submit periodical reports on the progress of the study for FDA evaluation.

Enrollment in Clinical Trials

The clinical trials encompass a variety of brain tumors in both children and adults. Over the last ten years more than 2,000 patients have participated in the clinical trials on Antineoplastons. Only patients eligible to enroll in clinical trials may receive Antineoplaston treatment under the study. Ineligible patients may receive approval to enroll, from the FDA on an individual basis.

To find out if you qualify for enrollment in clinical trials, please [contact our Cancer Information Specialist](#).

The list of open clinical trials is available at [Clinicaltrials.gov](#) (the FDA official clinical trials data bank). For the most recent information please [contact the Burzynski Clinic directly](#).

Reports/Statistics

The official reports on the progress of the clinical trials on Antineoplastons are presented regularly by Dr. Burzynski and his associates at various medical symposia and conferences. Mid-term reports from the clinical research are regularly published in peer-reviewed journals and subject-related scientific books.

▪ [View the most recent scientific publications](#)

Latest Developments

Clinical Trials: Antineoplastons in Treatment of Brainstem Glioma

Orphan Drug designation

In September 2004, the FDA granted **Orphan Drug designation** for Antineoplastons A10 and AS2-1 for the treatment of Brainstem Glioma. The Orphan Drug designation has been extended to all Gliomas

The FDA's orphan drug program is intended to encourage research, development and approval of products for treatment of diseases that affect fewer than 200,000 patients in the United States per year and provide a significant therapeutic advantage over existing treatments.

Orphan drug designation enables the Burzynski Research Institute to apply for assistance from the Office of Orphan Product Development in guiding the drug through the regulatory approval process.

Phase III clinical trial - Brainstem Glioma

The protocol for the Phase III trials is ready. Phase III trials are expected to start in 2012.

Last Update: January 2012



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What are Antineoplastons?

Antineoplastons (ANP) are peptides and amino acid derivatives, discovered by Dr. S. Burzynski, M.D., Ph.D. in 1967.

Dr. Burzynski first identified naturally occurring peptides in the human body that control cancer growth. He observed that cancer patients typically had deficiency of certain peptides in their blood as compared to healthy individuals. According to Dr. Burzynski, Antineoplastons are components of a biochemical defense system that controls cancer without destroying normal cells.

Chemically, the Antineoplastons include peptides, amino acid derivatives and organic acids. They occur naturally in blood and urine and they are reproduced synthetically for medicinal use. The name of Antineoplastons comes from their functions in controlling neoplastic, or cancerous, cells (anti-neoplastic cells agents).

How do Antineoplastons work?

Antineoplastons act as molecular switches, which turn off life processes in abnormal cells and force them to die through apoptosis (programmed death of a cell). While they trigger the death of cancer cells, they do not inhibit normal cell growth. They specifically target cancer cells without harming healthy cells.

It is generally known that the cancerous process results from increased activity of oncogenes and decreased expression of tumor suppressor genes. Antineoplastons "turn on" tumor suppressor genes and "turn off" oncogenes restoring the proper balance in gene expression.

- [Genetic mechanisms of Antineoplastons \(pdf\)](#)
- [Chemical formulas of active ingredients of Antineoplastons \(pdf\)](#)

Antineoplaston Therapy

Antineoplaston Therapy is an experimental therapy offered at the Burzynski Clinic, currently available only within clinical trials. To find out more about the eligibility criteria for enrollment in clinical trials, please [contact our Cancer Information Specialist](#).

Research and Manufacturing

The continuous research on Antineoplastons is conducted and supervised by a team of experienced and committed scientists at our Clinic and the [Burzynski Research Institute](#).

The extensively trained staff and the advanced, specialized production line ensure the highest standards of Antineoplastons manufacturing.



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Introduction to Clinical Trials

Clinical trials (also clinical research, clinical studies) are research studies to determine whether experimental treatments, or new ways of using known therapies, are safe and effective. Carefully conducted clinical trials are necessary to find treatments that work in people and ways to improve health.

There are four phases of clinical trials in cancer treatment:

Phase I trials: to determine the safety of a new treatment

Phase II trials: to determine whether a certain kind of cancer responds to a new treatment

Phase III trials: to verify whether a new treatment is better than standard treatment

Phase IV trials: to find more specific information about a new treatment that has been already approved for use in patients

Antineoplastons - Subject of Clinical Trials

Antineoplaston treatment is an experimental therapy offered by the Burzynski Clinic, currently available only within clinical trials.

Currently, there is 1 open clinical trial on Antineoplastons (as of January 2012). The clinical trial is registered with the FDA and result of the trial is reported to the FDA on an annual basis.

▪ [Read more about Antineoplaston Therapy](#)

Quality Control

Clinical trials conducted in our Clinic are FDA approved protocols. A protocol determines what will be done in a clinical trial and why. It outlines how many patients will participate in a clinical trial, type and frequency of medical testing, treatment plan, monitoring requirements and the evaluation plan. Our staff physicians strictly follow the protocol and submit periodical reports on the progress of the study for FDA evaluation.

Enrollment in Clinical Trials

The clinical trials encompass a variety of brain tumors in both children and adults. Over the last ten years more than 2,000 patients have participated in the clinical trials on Antineoplastons. Only patients eligible to enroll in clinical trials may receive Antineoplaston treatment under the study. Ineligible patients may receive approval to enroll, from the FDA on an individual basis.

To find out if you qualify for enrollment in clinical trials, please [contact our Cancer Information Specialist](#).

The list of open clinical trials is available at [Clinicaltrials.gov](#) (the FDA official clinical trials data bank). For the most recent information please [contact the Burzynski Clinic directly](#).

Reports/Statistics

The official reports on the progress of the clinical trials on Antineoplastons are presented regularly by Dr. Burzynski and his associates at various medical symposia and conferences. Mid-term reports from the clinical research are regularly published in peer-reviewed journals and subject-related scientific books.

▪ [View the most recent scientific publications](#)

Latest Developments

Clinical Trials: Antineoplastons in Treatment of Brainstem Glioma

Orphan Drug designation

In September 2004, the FDA granted **Orphan Drug designation** for Antineoplastons A10 and AS2-1 for the treatment of Brainstem Glioma. The Orphan Drug designation has been extended to all Gliomas

The FDA's orphan drug program is intended to encourage research, development and approval of products for treatment of diseases that affect fewer than 200,000 patients in the United States per year and provide a significant therapeutic advantage over existing treatments.

Orphan drug designation enables the Burzynski Research Institute to apply for assistance from the Office of Orphan Product Development in guiding the drug through the regulatory approval process.

Phase III clinical trial - Brainstem Glioma

The protocol for the Phase III trials is ready. Phase III trials are expected to start in 2012.

Last Update: January 2012



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News & Events

Background Information for the Media

In 1997, three patients with incurable cancer types were interviewed by Harry Smith on the CBS 'This Morning' show, where they explained how Dr. Burzynski's treatment led them to a complete recovery. Today, 10 years later, all of them are still in good healthy and living normal lives - some of them celebrating as much as 15 years in complete remission. They also attended the Burzynski Gala and Patient Reunion in October 2007.

Patients of Dr. Burzynski on CBS This Morning [More info](#)



October 13, 2007

The Burzynski Clinic 30th Anniversary and Patient Reunion

The Burzynski Clinic celebrated '30 Years of Saving Lives' during an evening gala banquet held at the Omni Westside Hotel in Houston. The event was dedicated to cancer survivors who have overcome the odds and obstacles of facing cancer head on and won their lives back. Cancer survivors came to Houston from all over the country to 'Celebrate Life' and to share their heartwarming stories.

[Photo Gallery from the Gala](#)

Burzynski Clinic 30 Years Anniversary Gala [More info](#)





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Scientific Publications

Dr. Stanislaw R. Burzynski continuously publishes scientific articles, book chapters and delivers scientific presentations. Below is a list of published work. For more information about a specific publication or to obtain a copy, please email info@burzynskiclinic.com.

PUBLICATIONS BY S.R. BURZYNSKI AND ASSOCIATES

Burzynski, S.R., Weaver, R.A., Janicki, T.J., Burzynski, G.S., Szymkowski, B., Acelar, S.S. OT-15. Preliminary results of a phase II study of antineoplastons A10 and AS2-1 (ANP) in adult patients with recurrent mixed gliomas. *Neuro-Oncology* 2010;12(Suppl. 4):iv72.

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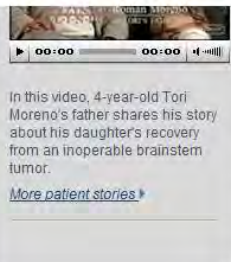
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SELECTED ABSTRACTS OF PRESENTATIONS BY S.R. BURZYNSKI AND ASSOCIATES

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Roy, Medulloblastoma, cancer-free since 2002
Jodi, Anaplastic Astrocytoma, cancer-free since 2004
Tori, Brainstem glioma, cancer-free for 2003
(left to right)

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Burzynski Clinic believes that each patient is a valuable person, not just a medical record number.

We have made it our goal to provide concierge care for every patient every day. The words of our patients say it best, they are our best advocates. Nothing illustrates who we are better than the inspiring stories of our remarkable patients.

Here are some stories of our patients journeys. As you read them, you will get an insight in to our facility, to our elite standard of care, and how the Burzynski Clinic approach to medicine can change people's lives.



Tracey Edry - Breast Cancer

Tracey was diagnosed with breast cancer in February 2005. As her life turned upside down into a series of tests, opinions, and doctors appointments, she came across the Burzynski Clinic and decided to undergo the treatment. Today, almost 3 years later, Tracey is cancer-free, a happy wife and a mom of two young boys.



Tori Moreno - Brainstem Glioma

Tori was diagnosed with brainstem glioma, a fast growing and aggressive tumor. After evaluating treatment options, her parents brought Tori to the Burzynski Clinic when she was less than six months old. After a year the tumor decreased 70% and today, at age of 9, Tori lives a normal life.



Dustin Kunnari - Medulloblastoma

Less than 2 and a half years old, Dustin was diagnosed with medulloblastoma of the brain. Shortly after initiating therapy at the Burzynski Clinic, Dustin's tumor began to shrink.

Dustin has been in remission for almost 12 years. He's now 16 years old, a happy teenager and an excellent student. He recently took a class in public speaking at school and was very proud to have his first public appearance in front of 500 guests at the Patient Reunion in October 2007 where he spoke about his victory over cancer.



James Treadwell - Glioblastom multiforme stage IV

In April 2004 James Treadwell was diagnosed with glioblastoma multiforme stage IV. The doctors advised him he had 3-6 months to live. It was the most unexpected and shocking news for an otherwise healthy and very active retired US Marine Corps Lieutenant Colonel. After two unsuccessful surgeries, failed radiation and chemo treatments, Jim started treatment at the Burzynski Clinic. Today, three years later, Jim is fully recovered, tumor-free and back in the water relearning how to surf. Himself, he says: "I walk the dog daily, we are traveling again and life is VERY good".



Paul Michaels - Optic-hypothalamic Glioma

Paul was diagnosed with an inoperable optic-hypothalamic glioma in November, 1985, when he was only 4 years old. Because of the treatment at the Burzynski Clinic, Paul has been cancer-free. He is now working as a personal trainer for a health/fitness club.



Sophia Gettino - Pineoblastoma Brain Tumor

Sophia was only 11 months old when, in December of 1996, she was diagnosed with pineoblastoma brain tumor. Today, Sophia is 11 years old and lives a normal life after therapy at the Burzynski Clinic. She also attended the Patient Reunion in October 2007 and personally spoke about her heart-warming story. [Click to see video](#)



Roy Hash - Medulloblastoma

Diagnosed with medulloblastoma, a deadly brain tumor, Roy Hash began the treatment

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In this video, 4-year-old Tori Moreno's father shares his story about his daughter's recovery from an inoperable brainstem tumor.

[More patient stories](#) ▶



at the Burzynski Clinic in March 2001. He was declared in "complete response" in December 2002. Roy is now 8 years old and in second grade - he's one of the best students in his class. He now has a wonderful little sister Jamie that makes his days full of adventure.

[Read Roy's full story](#) (with photo gallery)



Sara began treatment at the Burzynski Clinic on June 1, 1994. Six and a half weeks later her eye had opened up completely and most of her tumor was gone.

To connect with any of the these patients contact our [Cancer Information Specialists](#).

More patient stories are posted on the website of the [Burzynski Patient Group](#).

Visit our [YouTube channel](#) for patient videos and news stories.



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Burzynski Clinic YouTube Channel

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Burzynski Clinic News

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

December 3rd, 2010 by editor

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 5 Phase II clinical trials.

Media Contacts:

Burzynski Research Institute, Inc.
Darlene Hodge at (713) 335-5636, Darlene@burzynskiclinic.com
Carolyn Powers at (713) 335-5664, Carolyn@burzynskiclinic.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, 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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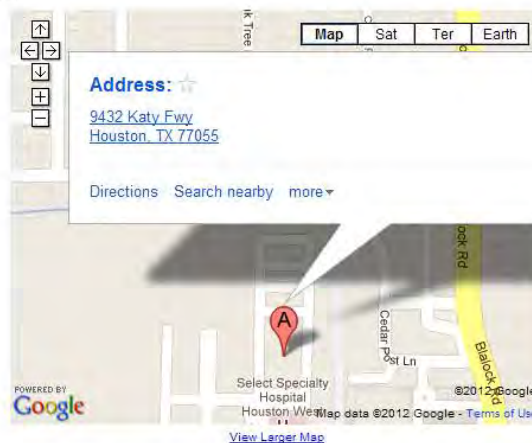
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Map & Directions

Burzynski Clinic
9432 Katy Freeway
Houston, TX 77055



[Download printable directions \(pdf\)](#)

There are two airports in Houston, both serviced by the major airlines.

DIRECTIONS FROM BUSH INTERCONTINENTAL AIRPORT

1. Take Sam Houston Tollway/Beltway 8 Westbound (stay for about 20 miles)
2. Exit to Highway I-10 East toward Downtown
3. Exit Blalock Road / Echo Lane (exit 758B)
4. At the first traffic light (Echo Lane) make a U-turn under the freeway onto Katy Freeway frontage road
5. After 100 yards turn right onto our drive (past 99 Ranch Market and then immediately after the red brick hospital building)
6. The Burzynski Clinic is in a 4 story, dark glass building at the end of the road at 9432 Katy Freeway

DIRECTIONS FROM HOBBY AIRPORT

1. Take highway I-45 South towards Galveston
2. Exit onto Beltway 8 West
3. Exit onto highway I-10 East toward Downtown
4. Exit Blalock Road / Echo Lane (exit 758B)
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Travel Information and Accommodations

Location

Burzynski Clinic is conveniently located in the Medical District of West Houston and is easily accessible from the airports and major highways.

General location: Highway I-10 West (exit Blalock). [Click for map and directions.](#)

Download our Patient Travel and Information Brochure (pdf)

- [Patient Travel and Information Brochure](#)

Multilingual Assistance

Due to the international character of our clinic, we are able to assist our patients in various foreign languages, including French, German, Spanish, Portugese, Philipino, Danish, Norwegian, Swedish, Polish, Russian, Slovak, Czech, Hungarian, Chinese, Vietnamese, Arabic, Farsi and Hindi.

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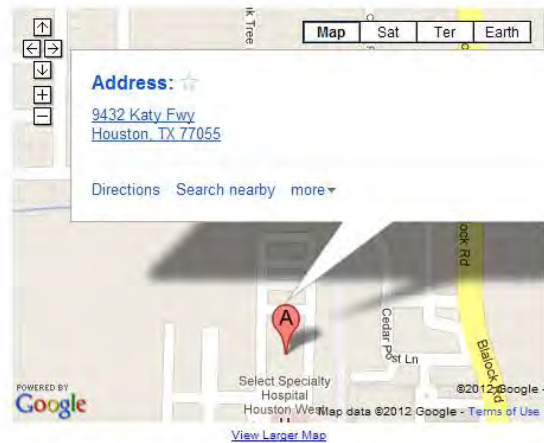
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9432 Katy Freeway
Houston, Texas 77055

Phone: (713) 335-5697
Toll-Free: 1 (800) 714-7181
Fax: (713) 935-0649

Departments:

Patient Scheduling & Patient Information (USA & International):
info@burzynskiclinic.com

Human Resources: jobs@burzynskiclinic.com

Interview & Speaker Requests, Media/Public Relations Info:
pr@burzynskiclinic.com

Business, Financial and Administrative Info:
corporate@burzynskiclinic.com

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In this video, 4-year-old Tori
Moreno's father shares his story
about his daughter's recovery
from an inoperable brainstem
tumor.

[More patient stories](#)

Patient (a person diagnosed with cancer or suspecting they might have cancer; all fields required)

First Name (*)
Last Name (*)
Address 1 (*)
Address 2
City (*)
State
Zip Code (*)
Country
E-mail (*)
Phone
Date of birth (*)
Cancer Type

Requestor (please, fill in only if different than Patient; all fields required)

First Name (*)
Last Name (*)
Address 1
Address 2
City
State
Zip
Country
Email
Phone
How does the cancer affect you

Select the type of informational materials (*)

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On October 13, 2007 the Burzynski Clinic celebrated '30 Years of Saving Lives' during an evening gala banquet at the Omni Westside hotel in Houston. The event was dedicated to all cancer survivors and to all those who lost the battle.



A very special heart, a gift to Drs. Burzynski from a 12 year old Sophie, brain tumor survivor, cancer-free for over 10 years.



The gala banquet was opened by a musical presentation performed by Andrzej Grabiec, professor of violin at the Moores School of Music, followed by appearances from distinguished guests such as Dr. Julian Whitaker, author of the Health & Healing newsletter and founder of the American Preventive Medicine Association, and Thomas Elias, Pulitzer Prize nominee, and author of the book The Burzynski Breakthrough. The event was hosted by Mr. Steven Siegel, founder of the Burzynski Patient Group and husband of a former patient Mary Jo Siegel.

Drs. Barbara and Stanislaw Burzynski introduced to the guests their son and successor, Dr. Greg Burzynski, who will continue Dr. Burzynski's scientific work.



The highlight of the evening was the Life Service Award Ceremony dedicated to the patients cured of cancer for the longest period of time. The first award went to a veteran, now cancer-free for 27 years, who was once diagnosed with malignant mesothelioma, a deadly cancer caused by exposure to asbestos. The remaining awards went to a large group of cancer survivors of 10 years and more. All those who lost the battle against cancer were honored with one minute of silence.



One of the most touching moments of the evening were the heart-warming testimonials of the patients and their relatives, filled with words of gratitude and appreciation to Dr. Burzynski as well as words of joy, encouragement and respect to life.



Several patients prepared their personal awards and trophies honoring Dr. Burzynski.



The Pink Ribbons Awards Ceremony was dedicated to all breast cancer survivors in recognition of National Breast Cancer Awareness Month. Breast cancer survivors received symbolic pink ribbon pins as a token of their victory over cancer, awarded by a cheerleader from the Houston Texans football team to show their support of the breast cancer awareness initiative.



More photos from the event:

<http://www.everytimephoto.com/foto/07/101330y/>



30 Years of Saving Lives

The Burzynski Clinic 30 Anniversary & Cancer Survivors' Reunion

October 13, 2007



Cocktail Hour



At the Tables



Performances



Survivors



Testimonials



Dancing



Late Evening

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Welcome To Burzynski Research Institute

Burzynski Research Institute (BRI), a biopharmaceutical company committed to developing treatment for cancer based on genomic and epigenomic principles. Research and developmental efforts are focused on cancer treatment with two pipeline drugs—antineoplastons (ANP) in one Phase III clinical trial and 5 Phase II clinical trials. Two additional Phase III trials are being discussed with the FDA. The ultimate goal of the BRI is to discover, develop, and obtain the FDA's marketing approval of ANP for the treatment of currently incurable types of cancer with emphasis on malignant brain tumors in adults and children.



Based on research sponsored by BRI, ANP affect approximately 100 human genes that are instrumental in the growth of highly-malignant tumors such as glioblastoma multiforme—the most common and uniformly deadly type of brain tumor. The results of our research with ANP are presented at a number of oncology and neuro-oncology meetings, and published in reputable medical journals.

> PRESS RELEASES

• [Burzynski Research Institute Signs Research Agreement with the University of Alabama at Birmingham \(UAB\), Division of Preventive Medicine, Biostatistics and Bioinformatics Shared Facility.](#)

September 28, 2009 (PDF)

• [Burzynski Research Institute Announces Presents Positive Results from Phase II Trials of ANP for Inoperable Brainstem Glioma at the Congress.](#)

May 11, 2009 (PDF)

• [Burzynski Research Institute Announces Positive Results of Phase II ANP Clinical Trial.](#)

May 6, 2009 (PDF)

• [Physicians from the Burzynski Clinic Present Initial Results of Combination Gene-Targeting Therapies on Advanced Pancreatic and Liver Cancers.](#)

February 5, 2009 (PDF)

• [Burzynski Research Institute Partners with Premier Research to Manage Phase III Clinical Study of Children with Newly-Diagnosed Diffuse Intrinsic Brainstem Glioma.](#)

January 26, 2009 (PDF)

• [Burzynski Research Institute Gets SPA Clearance from the FDA to Initiate Pivotal Phase III Trial of Combination Antineoplaston Therapy and Radiation Therapy.](#)

January 13, 2009 (PDF)

• [U.S. FDA Grants Orphan Drug Designation for Burzynski Research Institutes Antineoplaston Treatment for Gliomas](#)

December 2, 2008 (PDF)

• [Burzynski Research Institute, Inc. Presents Promising Phase II Data on Malignant Glioma](#)

November 21, 2008 (PDF)

• [Thought Leaders from Burzynski Research Institute Inc Present Encouraging Data on Antineoplastons for Treatment of Malignant Gliomas](#)

November 20, 2008 (PDF)



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About Institute

Current Operations

About Institute

Burzynski Research Institute (BRI) is based in Houston and Stafford, Texas, U.S.A., and is engaged in research and development of targeted gene therapies (antineoplastons or ANP) for the treatment of cancer. BRI was incorporated under the laws of the State of Delaware in 1984 in order to engage in the research, production, marketing, promotion and sale of certain

medical chemical compounds composed of growth-inhibiting peptides, amino acid derivatives and organic acids which are known under the trade name *antineoplastons*.

BRI believes ANP are useful in the treatment of human cancer, and is currently conducting Phase II clinical trials of ANP relating to the treatment of cancer and starting Phase III trials. ANP have not been approved for sale or use by the Food and Drug Administration of the United States Department of Health and Human Services ("FDA") or anywhere in the world.

In the event ANP receives such approval and are registered in the United States, Canada, or Mexico, of which there can be no assurance, BRI will commence commercial operations, which shall include the production, marketing, promotion and sale of ANP in the United States, Canada, or Mexico. In 2004, the FDA approved the designation of ANP as an "orphan drug" under the Orphan Drug Act of 1983, for the treatment of brainstem glioma. In 2008, ANP orphan drug designation by the FDA was extended to all gliomas. It is estimated that in 2010 more than 21,000 men and women in the U.S., will be diagnosed with glioma, with prevalence estimated at approximately 84,000 cases.

Orphan Drug Designation is granted by the FDA's Office of Orphan Drug Products Development, and is 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 credit.





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Current Operations

BRI's principal research and development efforts currently focus on ANP. The anticancer activity of these compounds has been documented in preclinical studies employing the methods of cell culture, pharmacology, cell biology, molecular biology, experimental therapeutics and animal models of cancer. At the level of Phase II clinical studies, BRI believes the anticancer activity of ANP is supported by results from ongoing, FDA-authorized, Phase II clinical trials.

The cellular mechanism underlying the anticancer effects of ANP continues to be investigated in both BRI's own basic preclinical research program and in independent laboratories around the world. A review of this work suggests several mechanisms that may underlie the antineoplastic activity of ANP. For example, it has been found, in cell culture experiments, that ANP induce pathologically undifferentiated cancer cells to assume a more normal state of differentiation. Cell culture experiments have also shown that ANP components can kill some cancer cells by activating the cell's intrinsic *suicide* program. It must be noted that data collected in cell culture experiments may or may not indicate the mechanism of action of ANP in humans.

At a more molecular or sub-cellular level, cell culture experiments have shown that ANP can block biochemical pathways involving oncogenes required to produce abnormal cell growth. In addition, cell culture experiments have shown that ANP can increase the expression of anticancer tumor suppressor genes. Although these experiments were conducted using human cancer cells, they may or may not indicate the mechanism of ANP action in humans.

In addition to the original family of ANP compounds (*parent generation*), BRI continues its development of a second generation of ANP. In cell culture experiments, the second generation ANPs, which were developed by BRI, have been proven to be significantly more potent than the parent generation.

BRI is also developing a third generation of structurally-altered ANP that BRI believes will exhibit markedly improved anticancer activity in human cancer cell lines that have been resistant to the parental generation. However, increased ANP activity in cell culture experiments may or may not translate into increased efficacy in humans.

BRI is also involved in ongoing studies examining the pharmacokinetics (absorption, distribution, metabolism, and excretion) and pharmacodynamics (dose-response) of ANP in patients with neoplastic disease.



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Research & Development



Dr. Stanislaw R. Burzynski commenced his cancer research in 1967 focusing on the isolation of various biochemicals produced by the human body as part of the body's possible defense against cancer. In the course of his research, Dr. Burzynski identified certain peptides, amino acid derivatives and organic acids in these biochemicals which appear to inhibit the growth of cancer cells. Dr. Burzynski named these derivatives *antineoplastons*.

Antineoplastons are found in the body fluids of humans and in foods, and initially were isolated by Dr. Burzynski from normal human blood and urine. Dr. Burzynski believes these substances counteract the development of cancerous growth through a biochemical process which does not inhibit the growth of normal tissues. All of the Phase II clinical trials currently sponsored by BRI involve the use of two formulations of synthetic ANP known as A10 and AS2-1 injections. BRI is also conducting laboratory research involving new generations of Antineoplastons A10 and AS2-1.



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Antineoplastons

> Antineoplastons A10 and AS2-1 for the Treatment of Brainstem Glioma

BRI currently intends to focus its efforts on the clinical development of its Antineoplastons A10 and AS2-1 for the treatment of brainstem glioma, which is the indication for which it received "orphan drug designation" from the FDA. BRI anticipates commencing Phase III trials during 2012, which will involve the treatment of newly diagnosed children with inoperable brainstem glioma.

> Phase 2 Clinical Trials

BRI began Phase II clinical trials in 1994 with four studies. Currently, BRI sponsors 5 ongoing Phase II clinical trials, which are conducted pursuant to investigational new drug applications (INDs) filed with the FDA and approved by an Institutional Review Board (IRB) designed according to federal regulations. All of the trials involve the use of intravenous formulations of ANP. Dr. Burzynski acts as principal investigator for all clinical trials. Prior to approving a New Drug Application (NDA), the FDA requires that drug safety and efficacy be demonstrated in well-controlled clinical trials. The ultimate goal of all treatment for cancer is patient survival. However, the FDA has determined that requiring exhaustive data showing improved patient survival may unnecessarily delay the approval of new cancer drugs. For that reason, the FDA may grant marketing approval for a new drug product on the basis of adequate and well-controlled clinical trials establishing that the drug has an effect on a surrogate endpoint (milestone) that is reasonably likely to predict clinical benefit. Each of BRI's Phase II trials describes such milestones which are used to determine success or failure of the treatment employed.

In most of the trials, the milestones are radiographic evidence of tumor shrinkage by x-ray, computer aided tomography (CT) or magnetic resonance imaging (MRI). Where tumor size is used as the milestone, each clinical trial protocol describes a complete response (CR) as the complete disappearance of all tumors with no recurrence of tumor for at least four weeks. A partial response (PR) is described as at least a 50% reduction in total tumor size, with such reduction lasting at least four weeks. Stable disease (SD) is described as less than 50% reduction in tumor size, but no more than 50% increase in size of the tumor mass, lasting for at least 12 weeks. In 2008, twelve of the prospective clinical trials reached a milestone. Unfortunately, there can be no assurance that the results of any of these trials can be repeated, or that the other clinical trials will result in the same or similar responses.

Notwithstanding the response results of the trials that have reached a milestone, BRI management believes it is likely that the FDA may require additional clinical trials based upon such protocols to be conducted by an institution not affiliated with BRI.



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Phase III Clinical Trials (updated 1/6/2012)

| Description | Protocol | IND # |
|--|-----------|--------|
| A Randomized Phase III Study of Combination Antineoplaston Therapy [Antineoplaston A10 (Atengenal) and AS2-1 (Astugenal)] Plus Radiation Therapy vs. Radiation Therapy Alone in Subjects with Newly Diagnosed, Diffuse, Intrinsic Brain Stem Glioma. | BRI-BT-50 | 43,742 |

Phase II Clinical Trials (updated 1/6/2012)

| Description | Protocol | IND # |
|--|-----------|--------|
| PHASE II STUDY OF ANTINEOPLASTONS A10 AND AS2-1 IN CHILDREN WITH BRAIN TUMORS. | BRI-BT-10 | 43,742 |



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Investors

Please find below, quick facts for investors. For additional information please contact investors@burzynskiresearch.com. For stock quotes and latest SEC filings, please visit Yahoo! finance and look up ticker [BZYR.OB](#)

> State of Incorporation:

The Burzynski Research Institute, Inc. (BRI) was incorporated under the laws of the State of Delaware in 1984 in order to engage in the research, production, marketing, promotion and sale of certain medical chemical compounds composed of growth-inhibiting peptides, amino acid derivatives and organic acids which are known under the trade name *antineoplastons*.

> Shares and Shareholders:

Shares of Burzynski Research Institute are publicly traded with ticker symbol BZYR.OB. As of As of May 20, 2008, there were approximately 2,027 holders of record of BRI's Common Stock, as shown on the records of the Transfer Agent and Registrar of the Common Stock. Since many shares may be held by investors in nominee names, such as the name of their broker or their broker's nominee, the number of record holders often bears little relationship to the number of beneficial owners of the Common Stock.

> Orphan Drug Designation

Orphan Drug Designation has been granted to the Burzynski Research Institute, Inc., by the FDA's Office of Orphan Drug Products Development, and is 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 credit.

> Dividends

Burzynski Research Institute, Inc. has never paid cash dividends on its Common Stock and the Board of Directors intends to retain all of its earnings, if any, to finance the development and expansion of its business. However, there can be no assurance that Burzynski Research Institute, Inc. can successfully expand its operations, or that such expansion will prove profitable. Future dividend policy will depend upon BRI's earnings, capital requirements, financial condition and other factors considered relevant by BRI's Board of Directors.

> Board of Directors

Set forth below are the names, ages and positions of BRI's directors and executive officers:

| Name | |
|-------------------------------------|---|
| | 67 |
| Stanislaw R. Burzynski, M.D., Ph.D. | Director, President, Secretary, and Treasurer |
| | 69 |
| Barbara Burzynski, M.D. | Director |
| | 63 |
| Michael H. Driscoll, J.D. | Director |
| | 74 |
| Robert H. Burzynski, Ph.D. | Director |

STANISLAW R. BURZYNSKI, M.D., PH.D., has been the President and Chairman of the Board of Directors of BRI since its inception in 1984. He also serves as BRI's Secretary and Treasurer. Dr. Burzynski is a physician in private practice in Houston, Texas specializing in the treatment of cancer. Dr. Burzynski is the husband of Barbara Burzynski, M.D., who is a director of BRI.

Currently listed in Who's Who In The World and a member in good standing with both the American and World Medical Associations, Dr. Burzynski is an internationally recognized physician and scientist who has pioneered the development and use of biologically active peptides in diagnosing, preventing, and treating cancer since 1967. In 1967, Dr. Burzynski graduated with distinction with an M.D. degree from the Medical Academy in Lublin, Poland, finishing first in his class of 250, and he subsequently earned his Ph.D. in Biochemistry.

From 1970 to 1977, he was a researcher and Assistant Professor at Baylor College of Medicine in Houston. At Baylor, Dr. Burzynski's research was sponsored and partially funded by the National Cancer Institute. Also at Baylor, he authored and co-authored sixteen publications, including five concerning his research on peptides and their effect on human cancer. Four of these publications were also co-authored by other doctors associated with M.D. Anderson Hospital and Tumor Institute and Baylor College of Medicine. In May 1977, Dr. Burzynski received a Certificate of Appreciation from Baylor College of Medicine and in that same year founded BRI.

Dr. Burzynski is a member of the American Medical Association, American Association for Cancer Research, Harris County Medical Society, New York Academy of Sciences, Society for Neuroscience, Texas Medical Association, the Society of Sigma Xi, and the Society of Neuro-oncology. He is the author of over 300 scientific publications, presenter of scientific papers at major international conventions, and has been awarded 242 patents covering 44 countries for his Antineoplaston treatment and other inventions. Other groups are working in conjunction with him, including researchers at the University of Kurume Medical School in Japan.

BARBARA BURZYNSKI, M.D., a Director since 1984 and the wife of Dr. Burzynski, has been the Chairman of the Department of Pharmacy of the Burzynski Clinic since 1977. From January 1976 to July 1977, she was a Research Assistant in the Department of Pediatrics at Baylor College of Medicine. She was a physician at the Medical Academy, Lublin, Poland, from 1970 to 1975. Dr. Barbara Burzynski graduated with an M.D. in 1966 from the Medical Academy, Lublin, Poland, and has published nine publications on studies with ANP.

MICHAEL H. DRISCOLL, J.D., has been a Director of BRI since 1984. Mr. Driscoll was formerly a judge and served as the County Attorney of Harris County, Texas from 1981 until he retired in 1997.

CARLTON HAZLEWOOD, PH.D., has been a Director of BRI since 1997. He also serves as Chairman of the IRB, an independent review board for BRI's clinical trials designated according to federal regulations. Dr. Hazlewood currently operates his own consulting company, Research Consultant's International, and is president of Petroclean, L.L.C. In addition, Dr. Hazlewood was employed in various capacities by the Baylor College of Medicine from 1965 until December 31, 1997, where he was a professor of Molecular Biology and Biophysics. Dr. Hazlewood received his Ph.D. in Medical Physiology from the University of Tennessee. Dr. Hazlewood is a prolific writer on medical topics and has been recognized for his research with numerous awards, honors and research grants.



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Burzynski Research Institute, Inc. filed this Form 10-K on 05/29/2012

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[XBRL Taxonomy Extension Definition Linkbase Document](#)

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

On Monday May 11, 2009, 1:19 pm EDT

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-operable 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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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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Thought Leaders from Burzynski Research Institute Inc Present Encouraging Data on Antineoplastons for Treatment of Malignant Gliomas

Convene at Society of NeuroOncology Meeting to Share Early Results of Phase II Study
of ANP on Patients with Newly-Diagnosed Anaplastic Astrocytoma and ANP Affect on
Cell Cycle Checkpoints in Human Glioblastoma Cells

HOUSTON, TX and LAS VEGAS, NV– November 20, 2008 - Several thought leaders from the Burzynski Research Institute, Inc. (BRI) and the Burzynski Clinic (BC) in Houston, Texas are presenting at the 13th Annual Scientific Meeting of the Society for Neuro-Oncology. Held in Las Vegas, the international meeting convenes physicians and academia to share knowledge, discuss and advance the treatment of brain tumors. The content presented by BRI is significant as it adds to an expanding body of evidence that suggests certain malignant gliomas to be responsive to antineoplaston therapy.

"The early clinical data associated with antineoplastons are promising for patients affected by certain malignant gliomas whose options historically have been limited to conventional chemotherapy and radiation therapy for management of their disease," said Stanislaw R. Burzynski, M.D., Ph.D. "We are encouraged by the growing body of evidence and excitement around ANP as we continue our commitment to introducing less aggressive, efficacious cancer treatment options."

Leading the discussions from BRI and the clinic are Robert Weaver, M.D., Barbara Burzynski, M.D., Gregory S. Burzynski, M.D., Barbara Szymkowski, M.D., Sonali Patil, Ph.D., and Stanislaw R. Burzynski, M.D., Ph.D.

On Friday, November 21st, the group will present ***"Phase II study of Antineoplastons A10 and AS2-1 (ANP) in Patients with Newly-Diagnosed Anaplastic Astrocytoma: A preliminary Report."***

In this Phase II clinical trial, ANP is administered daily on an outpatient basis, via an ambulatory infusion pump, to adult patients with newly-diagnosed anaplastic astrocytoma (AA), a common type of malignant glioma. The prognosis for patients with AA is usually poor with five-year's survival in less than 30% of patients, even after surgery, chemotherapy and radiation therapy.

The report being presented summarizes the treatment of a group of 20 evaluable patients, none of whom received radiation or chemotherapy prior to starting ANP. Six patients underwent surgery and had residual tumor; and 14 patients had biopsy only. ANP was well tolerated, with just two cases of serious reversible toxicities. Complete disappearance of tumors was achieved in 25% of patients, 40% of patients had stabilization of disease, and 35% of patients failed ANP treatment. Preliminary results indicate that satisfactory percentage of objective response to ANP was achieved.

On Saturday, November 22nd BRI will reveal findings on ***"Antineoplaston AS2-1 Affects Cell Cycle Checkpoints, Leading to Apoptosis in Human Glioblastoma Cells."***

Antineoplastons are naturally occurring peptides and amino acid derivatives currently being used with positive results in Phase II clinical trials for treatment of several brain tumor types. Phenylacetate (PN) and phenylacetylglutamate (PG) are two major components of antineoplaston AS2-1 (AS) and are metabolites of phenylbutyrate (PB). Though PN has been well

studied, the mechanism of action for PG is not well understood. PN has been reported to cause G1 arrest in several tumor cell lines. This study reports that PG also exerts its effect as an anti-proliferative agent by similar mechanism and provides evidence that PG causes G1 blockade and apoptosis. The effect is enhanced when PG and PN are used in combination, as in AS. Based on pathway analysis, it was observed that antineoplastons affected the expression of more than 40 genes instrumental in the cell cycle in glioblastoma cells. Antineoplastons may target multiple levels in the cell cycle and enhance the anti-cancer effect of tumor suppressor genes.

Abstracts were published in the October 2008 issue of *Neuro-Oncology*, the official journal of the Society of Neuro-Oncology.

Burzynski Research Institute, Inc. (BZYR.OB) 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 19 Phase II clinical trials, some of which are coming now to a successful conclusion. Since antineoplastons effect approximately 100 genes instrumental in the growth of glioblastoma multiforme, the results of research will be presented in a number of neuro-oncology meetings and published as abstracts in *Neuro-Oncology*. Earlier this year BRI and the BC team presented at the 13th International Symposium of Pediatric Neuro-Oncology in Chicago, Illinois (June 29-July 2, 2008), a successful preliminary report on the Phase II study of antineoplastons A10 and AS2-1 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 glycolysis pathways in glioblastoma cells. The second report described preliminary successful results of Phase II study of ANP in patients with recurrent anaplastic astrocytoma.

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