BURZYNSKI
RESEARCH INSTITUTE, INC.

December 23, 2013

Constance Cullity, M.D., M.P.H.
Branch Chief
Good Clinical Practice Enforcement Branch
Division of Good Clinical Practice Compliance
Office of Scientific Investigations
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration
Building 51, Room 5354
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: Burzynski Research Institute, Inc. Response to Warning Letter / Ref: 13-HFD-45-11-05

Dear Dr. Cullity:

We acknowledge receipt of the Warning Letter, Ref: 13-HFD-45-11-05, pertaining to observations of the inspection conducted between January 17th and March 15th, 2013 and our subsequent written response letter of April 5, 2013. Attached is our response to the FDA Warning Letter issued to me by the Thomas N. Moreno, M.S. Acting Office Director dated December 3, 2013.

We recognize and take seriously the comments in the FDA Warning Letter and are committed to taking all actions necessary to address them as part of our effort to continually strengthen our processes.

In your letter you inform us of objectionable conditions observed. We would like to address observations described in your warning letter and provide you with actions we had taken prior to the receipt of your latest letter, as well as to provide corrective actions we have or are in the process of instituting. We would also like to address some issues relating to information we feel the Agency misinterpreted or erred in the review of patient data, particularly as it relates to clinical response.

We wish to comment on the following:

1. ***Failure to ensure proper monitoring of the investigations and failure to ensure that the investigations are conducted in accordance with the general investigational plan and protocols contained in the IND [21 CFR312.50 and 21 CFR 312.56(a)].***

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a. i. Classification of Complete Response which requires complete disappearance of all contrast-enhancing tumor on neuroimaging studies and ancillary radiographic studies if appropriate, for a minimum duration of four weeks and that the subjects be off corticosteroids.

BRI Response:

As both head of Burzynski Research Institute (BRI) and as principal investigator, I assumed there is implied understanding that there is simultaneous awareness of the conduct of the studies and the decisions made pertaining to categorizing patient response to treatment. Below I will give an explanation of events and the corrective actions we have imposed.

We wish to confirm that BRI was provided with and reviewed patient information on an ongoing basis, as evidenced by documentation provided to the Agency in BRI Annual reports dated from January 22, 2002 through January 23, 2012, inclusive. Copies of relevant sections of the Annual report are attached in support of our study oversight (see appendix 1).

In our response of April 5, 2013, we indicated that we would amend protocols to reflect steroid use and determining clinical response. Several protocol amendments were provided to the BRI IRB and approved on July 26, 2013. These protocol amendments reflect the current standard of practice for corticosteroid use and for maintaining patient neurologic stability of brain tumor patients. The amendments referring to the protocols cited in your letter are attached (appendix 2).

- Protocol BT-09, "Phase II Study of Antineoplastons A1 0 and AS2-1 in Patients with Brain Tumors";
- Protocol BT-10, "Phase II Study of Antineoplastons A1 0 and AS2-1 in Children with Brain Tumors";
- Protocol BT-21, "Phase II Study of Antineoplastons A10 and AS2-1 in Adults with Primary Malignant Brain Tumors";
- Protocol BT-22, "Phase II Study of Antineoplastons A10 and AS2-1 in Children with Primary Malignant Brain Tumors"; and
- Protocol AD-02, "Phase II Study of Antineoplastons A10 and AS2-1 in Patients with Carcinoma of the Adrenal Gland."

We now acknowledge that our monitoring activities should have reflected a clear separation between BRI and the investigator. We believe that this lack of separation led to the implication of a failure to ensure proper monitoring of the investigations and the failure to ensure that the investigations were conducted in accordance with the general investigational plan and protocols contained in the IND. As part of our corrective actions, we have separated administrative investigational study oversight to BRI as the IND sponsor by reestablishing the use of dedicated BRI monitor(s) to review data and GCP documentation on an ongoing basis that is produced by the investigative site. We have engaged/assigned individuals to specifically carry out the task of monitoring studies in a timely manner to ensure adherence to the regulations and GCP practices on behalf of BRI. Training and monitoring activities of these individuals have been ongoing. In addition to prospective monitoring, these individuals have been retrospectively ensuring corrections and are ensuring that GCP deficiencies are being appropriately addressed, including those identified during the inspection conducted between

January 17th and March 15th, 2013. Where indicated, we are committed to ensuring correction of all study records pertaining to incorrect response classifications. Copies of the monitors' resumes (appendix 3) and several of their monitoring reports related to ongoing efforts are included, as referenced below.

We acknowledge the approved protocols, at the time of the inspection, were deemed to be out-of-date, in that they did not represent currently viewed standard-of-care response definitions, which are more apropos. As corrective action, we committed to technical/medical changes in protocols through protocol amendments, which we have made. These amendments reflect a more current standard for definition of response. Specifically, we amended the classification of responses, the basis of which relates to use of corticosteroids to maintain neurologic stability. The standard previously used for assigning a Complete Response (CR) did not allow any corticosteroids for a 4-week treatment window.

Current standard therapy for high-grade tumors, such as GBM, consists of maximal surgical resection, followed by combined temozolomide and radiation therapy. Despite these measures, prognosis remains inadequate, with a median survival time of around 15 months. Owing to tumor angiogenesis with permeable neo-vessels, brain tumor patients develop peritumoral edema, leading to increased neurologic deficits and intracranial pressure. Steroids alleviate peritumoral edema and are needed in most patients for neurologic stability, with dosages ranging from 1.5 to 15 mg dexamethasone [1-3]. The standard notion of physiologic doses in brain tumor patients does not apply.

[1] Behin A, Hoang-Xuan K, Carpentier AF, Delattre JY. Primary brain tumors in adults. Lancet; 361: 323 - 331, (2003).
[2] Stupp R., Mason W.P., van den Bent M.J., et al. Radiotherapy plus concomitant and adjuvant temozolomide for glioblastoma. N Engl J Med; 352:987-996 (2005).
[3] Marantidou A, Levy C, Duquesne A, Ursu R, Bailon O, Coman I, Belin C, Carpentier AF. Steroid requirements during radiotherapy for malignant gliomas. J Neuro-Oncology; 100 (1): 89-94 (2010).

(References appear in appendix 4)

Regarding 1 a. Subject 006389 / Protocol BT-10: *The Agency had stated that the subject was incorrectly classified by the clinical investigator as having a complete response, based on the pre-amended protocol and that the CRFs show none of the imaging studies indicating disappearance of contrast enhancing tumor for at least 4 weeks. Thus, the subject did not fulfill the criteria of complete response.*

BRI response:

Based on our initial response to the 483 observation of April 2013, we indicated that we modified the tumor assessment from CR to PR. These changes have been reviewed by our monitors according to the amendment and their review is documented in their monitoring report (appendix 5). As a point of explanation, according to the documentation and our interpretation, PR was duly noted on 4/27/00 and the subsequent MRI of 6/26/2000 fulfilling the criteria **of at least 4 weeks** time for the response. A prior MRI dated January 16, 2002 had indicated PR (i.e. minus 68% from baseline). This response has also been confirmed by an outside radiologist, J. Pleasure, M.D., in his report dated 12/31/00 (see appendix 2). The preliminary report from the outside radiologist dated 9/24/00 indicated the impression of PR, and is confirmed by the subsequent MRI. Patient was then classified as CR based on PET 9/5/2001, but

due to lack of confirmation by a PET scan, we concurred with the Agency and are assigning the patient response as PR. Please note that the patient is currently alive and in very good condition, surviving over 12 years from start of antineoplaston treatment. Note that during the interval for PR between 4/27/00 and 6/26/00, the patient was on Decadron PO 1mg daily, as documented in the medical records (appendix 6). Note that the patient did not have radiation therapy or chemotherapy for three brain lesions and leptomeningeal metastases. We were informed that the patient is in good condition and his recent scans were forwarded for our review. In case his CR is now confirmed, his response will be changed from PR to CR.

Regarding 1 b. Subject 013660 / Protocol BT-10 : *The Agency had stated that the subject was incorrectly classified by the clinical investigator as having a complete response, based on the pre-amended protocol and that the CRFs show none of the imaging studies indicating disappearance of contrast enhancing tumor for at least 4 weeks. Thus the patient did not fulfill the criteria of complete response.*

BRI response:

Based on enhanced portion of tumor, CR started on 5/19/2010, which was confirmed by the MRI of 7/14/10. During this time the patient was off corticosteroids. The subject received their last dose of Decadron PO on 4/1/2010. During the treatment the patient received Decadron PO stat from 8/27/2010. Our initial response to the 483 letter of April 5, 2013 indicated that tumor assessment of CR was being maintained. Please refer to the amended protocol definition of CR in Appendix 1, the patient notes (appendix 7) and the attached monitoring report confirming our review of data to substantiate the assessment response of CR is being maintained (appendix 8).

Regarding Item 2: Subject 007197 / Protocol BT-09: *The Agency states that the Tumor Measurements CRF indicates (from the pre-amended protocol), based on the Magnetic Resonance Imaging (MRI) taken on July 25, 2001; September 11, 2001; and November 8, 2001, complete disappearance of all contrast-enhancing tumor for a minimum duration of four weeks. However, the Steroids Report CRF and the Oncology-Hematology Flow Sheets show that the subject was on corticosteroids preceding the July 25, 2001 and September 11, 2001 MRIs; during the period between these MRIs; and up to one week prior to the November 8, 2001 MRI. Therefore, the subject did not meet the criteria for Complete Response.*

BRI Response:

The CR indicated by MRI of 7/25/2001, established as CR by 9/11/2001 and 11/8/2001, was confirmed by outside radiologist reviewer (see attached report 12/1/2001). During this time, the patient was on dexamethasone PO tapering dose of 6 mg PO daily with dose reduced to 5 mg, 3 mg, 2mg and 1 mg in early September, 9/12, 9/21, and 9/27/2001, respectively and discontinued on 10/30/2001. Patient maintained CR, which was confirmed on 11/8/2001 until 12/11/2001. Thus, the subject met the criteria for CR. Patient started treatment on 32 mg dexamethasone daily and gradually decreased to 24 mg, 16 mg and 6 mg daily and thereafter, further reduced as described above. Our initial response to the 483 letter of April 5, 2013 indicated that tumor assessment of CR was being maintained.

Please refer to the amended protocol definition of CR in Appendix 2, the patient notes (appendix 9) and the attached monitoring report confirming our review of data to substantiate the assessment response of CR is being maintained (appendix 10).

Regarding *(i)* Item 3 Subject 009990 / Protocol BT-21: *The Agency has indicated that the subject was not off corticosteroids and, therefore, was incorrectly classified by the investigator, as having a Complete Response. The Tumor Measurements CRF shows that the subject was classified as having a Complete Response based on Positron Emission Tomography (PET) scan results. However, the Steroids Report CRF shows that the subject was on corticosteroids preceding all of the relevant PET scan dates (i.e. January 4, February 4, June 14, and August 16, 2005), as well as during the period between these PET scans. Therefore, the subject did not meet the criteria for Complete Response.*

BRI Response:
The tumor measurement CRF shows CR based on PET, but steroid report CRF shows subject on steroids preceding all relevant pet scans of 1/4/2005, 2/4/2005, and 6/14/2005.

CR was noted between 1/4/2005 per PET scan and on 2/4/2005, and 6/14/2005 confirmed by independent radiologist on a report form 3/22/2013 (see attached).

The median dose of Decadron was 7.5 mg PO daily. As indicated in our 483 response letter of April 2013, we maintain that the patient meets the definition of CR as determined by our assessment criteria according to the protocol amendment. These changes have been reviewed by our monitors according to the amendment and their review is documented in their monitoring report (attached). Our initial response to the 483 letter of April 5, 2013 indicated that the tumor assessment of CR was being maintained.

Please refer to the amended protocol definition of CR in Appendix 1, the patient notes (appendix 11) and the attached monitoring report confirming our review of data to substantiate the assessment response of CR is being maintained (appendix 12).

ii. For a classification of Partial Response prior to any protocol amendment, Protocol BT-09 required: (1) that subjects have more than 50% reduction in the sum of the products of the greatest perpendicular diameters of contrast-enhancing tumors, compared to the corresponding baseline evaluation, for at least four weeks; (2) that no simultaneous increase in size of any lesion or the appearance of new lesions may occur; and (3) that subjects be on a stable or decreasing dose of corticosteroids.

Regarding Subject 008765 / Protocol BT-09: *The Agency indicated that the investigator incorrectly classified Subject 008765 as having a Partial Response. The Tumor Measurements CRF showed that the subject was classified as having a Partial Response based on a radiology report dated May 1, 2003. Although the May 1, 2003 radiology report shows a tumor reduction of greater than 50%, there are no MRIs between November 1, 2002 (baseline MRI) and the May 1, 2003 radiology report that show that*

the tumor reduction of greater than 50% was maintained for at least four weeks during that time period. Further, the April 29, 2003 radiology report (for the April 21, 2003 MRI) actually shows an increase in tumor size. Therefore, the subject did not meet the criteria for Partial Response.

The Agency asserts that tumor measurement CRF shows PR based on radiology report 5/1/2003 and that there are no MRIs between 11/1/2002 and 5/1/2003 showing the reduction greater than 50%. Furthermore, it is stated that the radiology report of 4/29/2003 shows an increase in tumor size.

BRI Response:
As noted by FDA, there are two outside radiology reports, 5/1/2003 and 4/29/2003. The 5/1/2003 report shows 72 % decrease in the product of the maximal orthogonal measurements on the axial images. This has been indicated when comparing the MRI dated 4/23/2003 to baseline 11/1/2002. Our evaluation didn't indicate this because we used FLAIR images. However, based on the advice of the outside radiologist, FLAIR images were not used as shown in the outside radiology report 4/29/2003. We used outside radiology measurements because they evaluated both axial and coronal sequences on T1 projections, rather than FLAIR images. The outside radiology report of 5/1/2003 also confirmed the beginning of PR based on PET scan of 4/21/2003. The duration of PR was confirmed by follow up PET scan of 6/25/2003. Based on the radiologist's opinion, PET scan was utilized rather than MRI, since PET could produce more reliable information.

Furthermore, the 4/29/2003 radiology report from the outside radiologist, Dr. Pleasure, was misinterpreted by the agency, since this report indicates an even earlier PR was noted as per PET scan of 3/3/2003. In summary, the PR for this subject is maintained between 3/3/2003, confirmed by 4/25/2003 and 6/25/2003 reports. We maintain the tumor assessment of PR using ancillary radiologic evidence. Please refer to the amended protocol definition of PR in Appendix 1, the patient notes (appendix 13) and the attached monitoring report confirming our review of data to substantiate the assessment response of PR is being maintained (appendix 14).

iii. For a classification of Stable Disease, Protocol BT-10 required: (1) that subjects have less than 50% change (either greater or smaller) in the sum of the products of the perpendicular diameters of the enhancing tumor compared to the baseline evaluation; (2) that this state be maintained for a minimum of 12 weeks; and (3) that the corticosteroid dose is stable or decreasing.

The Agency indicated that BRI failed to identify and correct the clinical investigator's incorrect classification of subjects having stable disease, namely, Subjects 012184, 012206, and 012252.

***Regarding Subject 012184 / Protocol BT-10** : The Agency asserts that the subject did not meet the criteria for stable disease based upon that the steroid report CRF showing that subject was not on stable or decreasing dose on SD as indicated by tumor measurements CRF.*

BRI Response:
This subject initiated treatment 11/17/2008. As per our response to the 483 observation of April 2013, we indicated that this patient would remain categorized as SD. The initial period of time of 12 weeks

elapsed on 2/9/2009. The subsequent MRI of 3/13/2009 indicates SD. Between 11/17/2008 and 3/13/2009 the patient was on a median Decadron dose of 2 mg PO daily. Based on the data, the patient meets the criteria of stable disease as per amended protocol.

Please refer to the amended protocol definition of SD in Appendix 1, the patient notes (appendix 15) and the attached monitoring report confirming the review of data to substantiate the assessment response of SD is being maintained (appendix 16).

***Regarding Subject 012206 / Protocol BT-10**: The Agency asserts that the subject was not on stable or decreasing dose of corticosteroids based upon the steroid report CRF and as indicated by tumor measurements CRF based on MRIs taken on 1/15/2009 and 5/6/2009 and thus does not fulfill the criteria for Stable Disease.*

BRI Response: The subject initiated ANP on 12/11/2008, with 84 days elapsing on 3/2/2009. The subsequent MRI on 4/2/2009 confirms SD, since the subject was on stable dose of Decadron of 4 mg PO daily, between 1/15/2009 and 4/2/2009. The tumor was stable between the above dates. Therefore, the patient did meet the criteria of stable disease using the current definition of stable disease. As per our previous response to the 483 letter dated April 2013, this patient was categorized as SD. Please refer to the amended protocol definition of SD in Appendix 1, the patient notes (appendix 17) and the attached monitoring report confirming the review of data to substantiate the assessment response of SD is being maintained (appendix 18).

***Regarding Subject 012252 / Protocol BT-10:** The Agency asserts that the Tumor Measurements CRF indicates, based on MRIs taken on 4/20/2009 and 8/7/2009, that the subject had a less than 50% change in tumor size compared to baseline, and that this state was maintained for a minimum of 12 weeks. However, the Steroids Report CRF shows that the subject was not on either a stable or decreasing dose of corticosteroids. Therefore, the subject did not meet the criteria for Stable Disease.*

BRI Response:

The patient initiated ANP on 2/12/2009. The 84 day time period elapsed on 3/6/10. The ensuing MRI of 6/3/09 shows stable disease. The subsequent MRI of 8/7/09, as indicated in the Agency's warning letter, is still showing stable disease. However, it is unnecessary to fulfill the criteria of maintaining stable disease for a minimum of twelve weeks. As per our previous response to the 483 letter dated April 2013, this patient was categorized as SD. Please refer to the amended protocol definition of SD in Appendix 1, the patient notes (appendix 19) and the attached monitoring report confirming the review of data to substantiate the assessment response of SD is being maintained (appendix 20). Between the indicated dates of 4/20/2009 and 8/7/2009, the subject was on decreasing dose of corticosteroids. Please note that the starting dose of Decadron on 4/17/2009 was 6 mg PO daily and was gradually tapered to 1.5 mg PO daily on 7/29/2009 and maintained as such until the MRI date of 7/9/2009.

***Regarding (III) 1 d Subject 011373 / Protocol BT-10:** The Agency states that the Tumor Measurements CRF shows that a baseline MRI was taken on April 12, 2007. The subject began receiving investigational drug on April 13, 2007, and had additional MRIs taken on May 18, July 6, and July 19, 2007. The Tumor Measurements CRF documents that a change of less than 50% in tumor size, compared to baseline, was*

maintained from May 18 through July 19, 2007; however, there are no confirmatory MRIs or PET scans after July 19, 2007, and there is; therefore, no evidence that the reduction was maintained for a minimum of 12 weeks. In addition, the Steroids Report CRF shows that the subject was not on either a stable or decreasing dose of corticosteroids. Therefore, the subject did not meet the criteria for Stable Disease.

BRI Response:

Patient started ANP on 4/13/2007. The eighty-four day time period elapsed on subsequent MRI of 7/6/2007 indicating SD maintained by patient for a minimum of 12 weeks. The patient was diagnosed with brainstem glioma intrinsic diffuse on 3/11/2007. Measurements were made based upon the non-enhanced portion of tumor. We believe that the Agency misinterpreted our internal tumor measurement report, which erroneously indicated that scans were not available. The scans are available upon request and indicate that we measured only the enhanced portion of the tumor. A data correction form clarifies that the CRF wording has been amended (appendix 21). The information reviewed and for this type of diagnosis, the non-enhanced images are used for evaluation.

For the MRIs of 7/8/2007 and 7/19/2007, the contrast was not used based on the radiologist decision (see attached radiologist – without contrast). For this reason the tumor measurements are based on non-enhanced images and indicate the same tumor measurements on 4/12/2007, 5/18/2007, 7/6/2007 and 7/19/2007, confirming SD. We believe the FDA inspector misunderstood the use of internal abbreviations used on the imaging sheets (i.e. NE refers to non-enhanced).

Regarding steroid usage, please note that at the end of the period of time the patient was on decreasing doses of Decadron. Initially the subject was taking 12 mg daily of Decadron, which subsequently reduced to 6 mg and a further reduction to 5 mg daily.

As per our previous response to the 483 letter dated April 2013, this patient was categorized as SD and is based upon the non enhancing portion of the tumor. Please refer to the amended protocol definition of SD in Appendix 1, the patient notes (appendix 22) and the attached monitoring report confirming the review of data to substantiate the assessment response of SD is being maintained (appendix 23).

The agency indicated that our response related to monitoring the clinical investigator's provision of informed consent is inadequate. Specifically, the Informed Consent Document (ICD) did not include or reference a separate treatment billing agreement as part of the informed consent process. We understand that the ICD may give an impression that the subject may not have been apprised of costs at the time of informed consent.

As described in the flow diagram (appendix 24), a financial discussion occurs prior to the presentation of the ICD. Treatment options are discussed and details of costs presented. Though a number of patients opt to sign the ICD at this time, they may or may not have opted to proceed with signing a treatment billing agreement in order to give them the time to consult with family members, insurance carrier, etc. according to their personal circumstances. The Financial Billing Agreement summarizes what has already been discussed and confirms as to what the patient's financial obligations would be. The

Financial Billing Agreement can be signed at a later date separate from the informed consent and should not to be interpreted as part of the informed consent process.

As corrective action in order to ensure that there is no misunderstanding about when and what financial information is provided to the subject, we will ensure the addition of a statement and an attachment detailing costs that will be included with each ICD. The financial information document detailing the costs will be signed and dated concurrently to the signing of the ICD for all subsequent subjects and will be appended accordingly to this document. The additional cost could vary from patient to patient depending on the individual patient, and for this reason is not provided with this correspondence.

Regarding: 2. Failure to obtain from an investigator sufficient financial information to allow the sponsor to submit complete and accurate certification or disclosure statements required under 21 CFR part 54 [21 CFR 312.53(c)(4)].

BRI Response:

As corrective action, we are corresponding with physicians whose 1572 Form we have on file, who were described by the Agency as "sub-investigators" who have or had been associated with patients on antineoplastons. In these letters we are asking them to complete and sign the requisite Financial Disclosure. We will send you regular status reports on the fulfillment of this effort.

We are also providing you with an affidavit certifying that we have not entered into any financial arrangement with the listed investigators whereby the value of compensation to the Investigator could be affected by the outcome of the study as defined in 21 CFR 54.2 (a). We are thus certifying that each listed investigators required to disclose to the sponsor whether the investigator had a proprietary interest in the product or a significant equity in the Sponsor as defined in 21 CFR 54.2 (b). We further are certifying that no listed investigator was the recipient of any payments of other sorts as defined in 21 CFR 54.2 (f). Please see appendix 25.

Regarding: The Agency has requested that the Informed Consent Checklist be revised to reflect applicable regulations. Attached is the updated SOP 410, dated 12/16/2013, entitled "Review and Approval of Site Regulatory Documents for Submission", which supersedes version of 05/15/2012.

BRI Response:

Corrective action has been made to Attachment 410A of the aforementioned SOP (appendix 26) and represents the updated Informed Consent Checklist. We have included an introductory statement to the Informed Consent Checklist:

> "For studies that are subject to the requirements of the FDA regulations, the informed consent documents should meet the requirements of 21 CFR 50.20 and contain the information required by each of the eight basic elements of 21 CFR 50.25(a), and each of the six elements of 21 CFR 50.25(b) that is appropriate to the study. IRBs have the final authority for ensuring the adequacy of the information in the informed consent document."

We have also removed reference to 45 CFR 46.408 (c), whereby an IRB may waive the requirement to obtain parental permission in a clinical investigation.

Regarding: In your correspondence you requested whether BRI was planning to submit its proposed protocol amendments to FDA, since you feel that the described protocol changes reflect a significant change in the design of the protocols and as a result, BRI would be required to submit the protocol changes to FDA for review [21 CFR 312.30(b)(1)(ii) and (2)(i)(a)].

BRI Response:
Though we did not believe the protocol amendments required review by the Agency, we will request clarification from the Division of Oncology 2 and if so required we will submit said amendments and thereafter inform the FDA Office of Scientific Investigation.

In summary, we provide here our responses and planned actions to the listed observations. The appendices are associated documents and additional information referenced in the responses. We plan to submit our next update to the FDA on or before February 15, 2014 and monthly thereafter, until all our corrective actions are completed.

Should you have any additional questions, please do not hesitate to contact me.

Respectfully,

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