

**Elzbieta Banasiewicz**

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**From:** Darlene F. Hodge on behalf of Dr. Stanislaw R. Burzynski  
**Sent:** Tuesday, January 06, 2009 10:47 AM  
**To:** Elzbieta Banasiewicz  
**Subject:** FW: Paul Zimmerman's Response

FYI.  
Thanks.  
-----Darlene  
Ext. 636

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**From:** swb [mailto:swb555@gmail.com]  
**Sent:** Tuesday, January 06, 2009 10:29 AM  
**To:** Dr. Stanislaw R. Burzynski; Tomasz Janicki; Barbara Tomaszewski  
**Cc:** Chuck Cade  
**Subject:** Paul Zimmerman's Response

Dear Dr. Burzynski, CONGRATULATIONS! Sam

----- Forwarded message -----

**From:** Zimmerman, Paul F <paul.zimmerman@fda.hhs.gov>  
**Date:** Tue, Jan 6, 2009 at 10:12 AM  
**Subject:** RE: Burzynski Research Institute Phase III study  
**To:** swb555@gmail.com

Dear Dr. Beenken,

Regarding the IND 43742 submission dated 10-20-08, for protocol changes to the protocol titled "A Randomized Phase 3 Study of Combination Antineoplaston Therapy [Antineoplastons A10 (Atengenal) and AS2-1 (Astugenal)] Plus Radiation Therapy vs. Radiation Therapy Alone in Subjects with Newly-Diagnosed, Diffuse, Intrinsic Brain Stem Glioma", our reviewers have indicated that the appropriate corrections have been made as requested. The study may proceed.

Thanks,  
Paul

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**From:** swb [mailto:swb555@gmail.com]  
**Sent:** Tuesday, January 06, 2009 10:24 AM  
**To:** Zimmerman, Paul F  
**Subject:** Burzynski Research Institute Phase III study

Dear Dr. Zimmerman,

I understand that you have been away over the Holidays. I trust that they were enjoyable. I am forwarding an email to you that I originally sent on Decemeber 23 and may be buried in a backlog of emails. I appreciate your considering it. A simple "yes" or "no" answer would be very helpful.

Best regards,

SAM

1/6/2009

Samuel W. Beenken, MD  
Consultant for the Burzynski research instiotute  
----- Forwarded message -----  
From: swb <swb555@gmail.com>  
Date: Tue, Dec 23, 2008 at 11:36 AM  
Subject: Burzynski Research Institute  
To: "Zimmerman, Paul F" [paul.zimmerman@fda.hhs.gov](mailto:paul.zimmerman@fda.hhs.gov)

Dear Mr. Zimmerman:

I am writing regarding the Burzynski Research Institute's Phase III study of ANP therapy + RT in children with diffuse, intrinsic brainstem glioma. As part of the SPA Agreement Letter, the Division requested some minor modifications to the protocol, which were made. Copies of the amended protocol were forwarded to yourself and to Dr. Justice. It is now the understanding of the Burzynski Rresearch Institute that there is no further approval process and the Institute may initiate the study at any time.

I would appreciate a brief confirmation that the Institite's current understanding is correct. That confirmation could be addressed via email to myself and/or to Dr. Burzynski ([srb@burzynskiclinic.com](mailto:srb@burzynskiclinic.com)). I will follow-up this email with a phone call.

Thank you very much for your help!

Sincerely,

Samuel W. Beenken, MD  
Consultant to the Burzynski Research Institute