Your abstract submission has been received

Click here **to print this page now.**

You have submitted the following abstract to the 2018 ASCO Annual Meeting (June 1-5, 2018). Receipt of this notice does not guarantee that your submission was complete, free of errors, or accepted for presentation. Abstract notifications will be sent to the First Author by March 30, 2018.

Absence of Indicators of Hypercoagulability and Anti-phospholipid Syndrome in BXQ-350 First in Human Study.

Charles A Cruze, Olivier Rixe, John Charles Morris, Vinay K. Puduvalli, John L. Villano, Trisha Michel Wise-Draper, Angela Johnson, Robert Wesolowski; Bexion Pharmaceutical, Covington, KY; University of New Mexico Comprehensive Cancer Center, Albuquerque, NM; University of Cincinnati Cancer Institute, Cincinnati, OH; Ohio State University Comprehensive Cancer Center, Columbus, OH; Markey Cancer Center, University of Kentucky, Lexington, KY; CTI Clinical Trial & Consulting, Covington, KY; The Ohio State University Comprehensive Cancer Center, Arthur G. James Cancer Hospital, Columbus, OH

****Note: The appearance of your abstract here is an approximation of how the abstract would appear in print, if accepted.**

Background: Saposin C is a lysosomal activator protein that can be combined with a phosphatidylserine lipid to create a nanovesicle that targets cancer cells. Similar lipid nanovesicle preparations are linked to altered coagulation and anti-phospholipid syndrome (APS), thus coagulation parameters and immune markers for APS were explored in the first-in-human (FIH) trial of BXQ-350.

Methods: Data from 17 solid tumor/high grade glioma patients (59% M, 24-67 yrs) in the Phase 1a trial of BXQ-350 nanovesicles at IV doses of 0.7-2.4 mg/kg (NCT02859857) were examined for effects on plasma fibrinogen (PF), coagulation factors, prothrombin time (PT), aPPT, INR, and cardiolipins IgG, IgA, and IgM at days 1, 8, 15, 22, 29, 57, 85, 113, 141, and 171 (or off-study date). Mean and change from baseline (Day 0) ±2.0 units are reported.

Results: No clinically significant changes in coagulation or baseline PT or INR ±2.0 were observed. For doses 1.1-2.4 mg/kg, subclinical increases occurred at Day 57-171, including PF peak at Day 57 of 1.1 mg/kg (155±142.8 mg/dL) and Day 171 of 2.4 mg/kg (128.8±79.6 mg/dL). Subclinical aPTT peak was also observed Day 171 of 2.4 mg/dL (13.7±20.3 s), but not at other doses. No DLTs or severe adverse events related to BXQ-350 were reported.

Conclusions: Therapeutic BXQ-350 nanovesicle dosages did not cause APS or clinically significant hypercoagulability in humans. Further, AEs related to BXQ-350 were not due to hypercoagulability.

Table. Δ Coagulability Factors

mg/kg	Day	PF	aPTT	IgG	IgM	IgA
1.1	1	-	-	-	-	11.4±0
	8	35±132.5	-	-	-	-
	15	20.3±35.7	-	-	-	-
	22	22.3±111.3	11.5±16	-	3±0	9.8±0
	29	42.5±7.8	2.7±1.8	-	-	-
	57	155±142.8	-	-	-	-
	171	47.5±193	-	-	3.6±4	1±0.7

1.4	1	-	-	-	-	9.8±0
	8	82±195.1	-	975±0	18±0	241±0
	15	58.7±99.1	-	-	-	-
	22	42.7±64.1	-	-	9±0	-
	29	75.5±30.4	7.6±11.9	-	-	-
	57	15.5±50.2	-	-	-	-
	171	36.7±54.6	8.7±15.9	-	-	-
1.8	1	-	-	6±0	6.1±5.9	-
	8	14.3±47	-	5±0	-	9.8±0
	15	25±84.2	4.4±8.3	-	-	-
	22	5.7±96	1.2±2.4	4±0	-	-
	29	14±92.5	6.4±6	-	-	-
	57	47.5±57.3	-	-	-	-
	113	0	-	4±0	6±0	-
	171	38.7±27.8	-	8±0	3.3±2.9	-
2.4	1	-	0	7.4±8.7	7±0	
	8	13.2±35.7	-	8.9±6.5	-	11.2±0
	15	14.2±34.8	6±11.3	-	-	-
	22	13±32.2	-	3.6±3	7±0	-
	85	55±51.5	2.6±3.8	-	-	-
	171	128.8±79.6	13.7±20.3	10±5.7	6±1.4	-

Title:
Absence of Indicators of Hypercoagulability and Anti-phospholipid Syndrome in BXQ-350 First in Human Study.

Submitter's E-mail Address:
ajohnson@ctifacts.com

Is this a late-breaking data submission?
No

Is this abstract a clinical trial?
Yes

Is this clinical trial registered?
Yes

Registry Name:
Clinicaltrials.gov

Registration Number:
NCT02859857

Research Funding Source:
Pharmaceutical/Biotech Company

Research Funding Source Name:
Bexion Pharmaceutical

Would like to be considered for a Merit Award:
No

Have the data in this abstract been presented at another major medical meeting?
No

Has this research been submitted for publication in a medical journal?
No

Type of Research:
Phase I
Research Category:
Clinical
Continued Trial Accrual:
Yes
Received Grant funding:
No
Relevant to geriatric oncology:
No
Sponsor:
John L. Villano, MD, PhD

First Author

Presenting Author
Charles A Cruze, PhD
Bexion Pharmaceutical
632 Russell Street
Covington, KY 41011
Phone Number: 513-777-2574
Email: ccruze@bexionpharma.com

Click to view Conflict of Interest Disclosure

Second Author

Olivier Rixe, MD, PhD
University of New Mexico Comprehensive Cancer Center
1201 Camino de Salud NE
Albuquerque, NM 87131
Email: orixe@salud.unm.edu

Click to view Conflict of Interest Disclosure

Third Author

John Charles Morris, MD
University of Cincinnati Cancer Institute
3125 Eden Avenue
ML 0562
Cincinnati, OH 45267
Phone Number: 513-558-2158
Email: morri2j7@ucmail.uc.edu

Click to view Conflict of Interest Disclosure

Fourth Author

Vinay K. Puduvalli, MD
Ohio State University Comprehensive Cancer Center
320 W 10th Ave
Starling Loving Hall Ste M410
Columbus, OH 43210
Phone Number: 614-688-7592
Fax Number: 713-794-4999
Email: Vinay.Puduvalli@osumc.edu
Alternate Email: brenda.adkins@osumc.edu

Click to view Conflict of Interest Disclosure

Fifth Author

John L. Villano, MD, PhD
Markey Cancer Center, University of Kentucky
800 Rose St
CC447
Lexington, KY 40536
Phone Number: 859-323-0405
Email: jlvillano@uky.edu

Click to view Conflict of Interest Disclosure

Sixth Author

Trisha Michel Wise-Draper, MD, PhD
University of Cincinnati Cancer Institute
231 Albert Sabin Way
Suite
Cincinnati, OH 45267
Phone Number: 513-558-2826
Email: wiseth@uc.edu

Click to view Conflict of Interest Disclosure

Seventh Author

Corresponding Author
Angela Johnson, BA, MS, PMP
CTI Clinical Trial & Consulting
100 E Rivercenter Blvd
1710 Cherokee Dr
Covington, KY 41011
Phone Number: 910-540-9890
Email: ajohnson@ctifacts.com

Click to view Conflict of Interest Disclosure

Eighth Author

Robert Wesolowski, MD
The Ohio State University Comprehensive Cancer Center, Arthur G. James Cancer Hospital
B401 Starling Loving Hall
320 W 10th Ave
Columbus, OH 43210
Phone Number: 614-366-8541
Fax Number: 614-293-4372
Email: robert.wesolowski@osumc.edu
Alternate Email: Robert Wesolowski@osumc.edu

Click to view Conflict of Interest Disclosure

If necessary, you can make changes to your abstract between now and the deadline of Tuesday, February 13, 2018

- To access your submission in the future, use the direct link to your abstract submission from one of the automatic confirmation emails that were sent to you during the submission.
- *Or* point your browser to /asco/reminder.cgi to have that URL mailed to you again. Your username/password are 217541/441061.

Any changes that you make will be reflected instantly in what is seen by the reviewers. You DO NOT need to go through all of the submission steps in order to change one thing. If you want to change the title, for example, just click "Title" in the abstract control panel and submit the new title.

When you have completed your submission, you may close this browser window.

Tell us what you think of the abstract submission process

Home Page