

## VLN Cigarette Consumption Study

Confidential

Sponsor:

Subject ID

SAE

22nd Century Group, Inc.

001023

Report Form

## Serious Adverse Event Report Form

Please send this report immediately to Assign Safety Desk via:

Fax: +43 (0) 512 281514 77 or e-mail: [SafetyDesk@assigndmb.com](mailto:SafetyDesk@assigndmb.com)

(24h Safety Hotline: +43 (0) 676 844033835)

All dates should be provided as DD/MMM/YYYY.

<b>1. PROTOCOL INFORMATION:</b>		
Protocol Short Title:	VLN Cigarette Consumption Study	IND no.: N/A
Celerion Protocol no.:	CA24914	Country: USA
<b>2. REPORTER'S DETAILS:</b>		
Reporter's name:	(b) (6)	
Address:	621 Rose St., Lincoln, NE 68502	
Site:	LNK Celerion	
Email:	(b) (6) @celerion.com	
Phone/Fax:	(b) (6)	
<b>3. REPORT INFORMATION:</b> (please use the same form for initial and follow-up report, if possible)		
Initial Report:	Date: 11/7/SEP/2018 dd mmm yyyy	(b) (6) Reporter's name and Signature
Follow-Up No <u>1</u> :	Date: 12/1/SEP/2018 dd mmm yyyy	(b) (6) Reporter's name and Signature
Follow-Up No <u>2</u> :	Date: 1/0/OCT/2018 dd mmm yyyy	(b) (6) Reporter's name and Signature
Follow-Up No <u>3</u> :	Date: 1/8/OCT/2018 dd mmm yyyy	(b) (6) Reporter's name and Signature
<b>4. SUBJECT INFORMATION:</b>		
Date of birth: (b) (6) dd mmm yyyy	Race: <input checked="" type="checkbox"/> White/Caucasian <input type="checkbox"/> Black/African American <input type="checkbox"/> Asian <input type="checkbox"/> Native Hawaiian/other Pacific Islander <input type="checkbox"/> American Indian/Alaska Native <input type="checkbox"/> Other:	Height: 1.61 cm
Gender: <input checked="" type="checkbox"/> female <input type="checkbox"/> male		Weight: 67.6 kg

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## 5. SERIOUS ADVERSE EVENT: (short term; please provide ONE diagnosis, if possible)

intra cranial aneurysm

## 6. SERIOUS ADVERSE EVENT INFORMATION:

Awareness date: 11/7/SEP/2018 Date the investigator became aware of the event  
 Onset date of event: (b) (6) Date the event started, i.e. the first symptoms occurred  
 Stop date of event: 2/0/ Date, when the event (including symptoms) subsided, stabilized with sequelae, or date of subject's death

## 7. SEVERITY OF SAE:

☐ Mild ☐ Moderate ☒ Severe
8. SERIOUSNESS CRITERIA: (please tick all that apply) ☒ yes ☐ no (non-serious event of special interest)

☒ Inpatient hospitalization or prolongation of existing hospitalization\* ☐ Persistent or significant disability/incapacity or substantial interruption to conduct normal life functions  
☐ Congenital anomaly/birth defect ☒ Life-threatening  
☐ Important medical event ☐ Death\*\*  
 (Please specify in the SAE description field on page 3 and only tick this criterion if no other applies)

\* if hospitalization: Date of admission: (b) (6) Date of discharge: 2/0/

\*\* if death: Date of death: 2/0/

Probable cause of death: Autopsy performed? ☐ yes ☐ no  
 (if yes, please provide summary of autopsy report in the SAE description on page 3)

## 9. SAE OUTCOME: (please tick only one)

☒ resolved ☐ worse  
☐ improved ☐ fatal  
☐ unchanged ☐ unknown/lost to follow-up

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## 10. STUDY PRODUCT INFORMATION:

Study product name	First use			Last use prior to SAE		
	dd	mmm	yyyy	dd	mmm	yyyy
<input type="checkbox"/> Subject's usual brand non-mentholated filtered king size cigarettes			20			20
<input type="checkbox"/> Subject's usual brand mentholated filtered king size cigarettes			20			20
<input checked="" type="checkbox"/> Non-mentholated VLN cigarettes	02	AUG	2018	14	SEP	2018
<input type="checkbox"/> Mentholated VLN cigarettes			20			20

## 11. ASSESSMENT OF CAUSALITY:

☐ likely
 ☐ probably
 ☐ possibly
 ☒ unlikely
 ☐ unrelated

## 12. ACTION TAKEN WITH STUDY PRODUCT: (please tick only one)

☒ Unchanged
 ☐ Interrupted
 ☐ Reduced
 ☐ Withdrawn

## 13. ACTION TAKEN TO TREAT SAE:

☐ none  
☐ drug therapy started  
☐ diagnostic test performed  
☒ non-drug therapy started  
☒ unknown  
☒ other (please specify): Surgically treated ~~drained~~ aneurysm  
 (b) (6) 18OCT2018

## 14. SERIOUS ADVERSE EVENT DESCRIPTION:

Describe event fully. Include baseline medical status (medical history, signs and symptoms, diagnosis, diagnostic test results, clinical course, treatment (all drugs/procedures used as interventions for SAE), outcome, hospital course for hospitalizations, etc. Please do not attach test results and hospital records but provide a short summary of relevant findings. Please also provide rationale for relationship assessment.

18OCT2018: This Follow-up 3 form is to clarify previous answers in prior SAE form submissions. First, on page 2 of the previous SAE form the SAE was marked "resolved" with no stop date. The subject returned on 18OCT2018 and appeared in good health. However, we don't know exact stop date of SAE because we're awaiting medical records. Please note on this SAE form I ticked "yes" in "Seriousness criteria" and listed all that apply.



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Second, please note that "Action taken with study product" is changed to "unchanged". The subject was no longer on VLN cigarettes at time of SAE. Thirdly, I added "Surgically <sup>resected</sup> ~~excised~~ metastasis" to "Action taken to treat SAE". At this time we are not aware of any medical history, signs and symptoms, diagnosis, clinical course, treatment, or concomitant medications at this time. Follow up 4 SAE form will be submitted upon arrival of medical records.

15. INVESTIGATOR'S SIGNATURE:

Investigator's name: PHILIP MATHEW

Investigator's signature:

(b) (6)

Date:

18 OCT 20 18  
dd mmm yyyy

FOR DRUG SAFETY DEPARTMENT ONLY - NOT TO BE FILLED IN BY REPORTER:

Received date: 18-Oct-2018

Time: 17:10

Tracked: ☒

Case Number: VLN Study - 001-023-01

Signature:

(b) (6)