

VLN Cigarette Consumption Study

Confidential

Sponsor:
 22nd Century Group, Inc.

Subject ID
 001023

SAE
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

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

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

1. PROTOCOL INFORMATION:		
Protocol Short Title:	VLN Cigarette Consumption Study	IND no.: N/A
Celerion Protocol no.:	CA24914	Country: USA

2. REPORTER'S DETAILS:	
Reporter's name:	(b) (6)
Address:	621 Rose St, Lincoln, NE 68502
Site:	LNK Celerion
Email:	(b) (6) @celerion.com
Phone/Fax:	(b) (6)

3. REPORT INFORMATION: (please use the same form for initial and follow-up report, if possible)	
Initial Report:	Date: 11/7/SEP/2018 (b) (6) Reporter's name and Signature
Follow-Up No <u>1</u> :	Date: 12/1/SEP/2018 (b) (6) Reporter's name and Signature
Follow-Up No <u>2</u> :	Date: 1/0/OCT/2018 (b) (6) Reporter's name and Signature
Follow-Up No <u>3</u> :	Date: 1/8/OCT/2018 (b) (6) Reporter's name and Signature

4. SUBJECT INFORMATION:		
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

VLN Cigarette Consumption Study

Confidential

Sponsor:

Subject ID

SAE

22nd Century Group, Inc.

001023

Report Form

5. SERIOUS ADVERSE EVENT: (short term; please provide ONE diagnosis, if possible)	
intra cranial aneurysm	
6. SERIOUS ADVERSE EVENT INFORMATION:	
Awareness date:	11 7 15 SEP 20 18 dd mmm yyyy Date the investigator became aware of the event
Onset date of event:	(b) (6) dd mmm yyyy Date the event started, i.e. the first symptoms occurred
Stop date of event:	20 dd mmm yyyy Date, when the event (including symptoms) subsided, stabilized with sequelae, or date of subject's death
7. SEVERITY OF SAE:	
<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input checked="" type="checkbox"/> Severe	
8. SERIOUSNESS CRITERIA: (please tick all that apply) <input checked="" type="checkbox"/> yes <input type="checkbox"/> no (non-serious event of special interest)	
<input checked="" type="checkbox"/> Inpatient hospitalization or prolongation of existing hospitalization*	<input type="checkbox"/> Persistent or significant disability/incapacity or substantial interruption to conduct normal life functions
<input type="checkbox"/> Congenital anomaly/birth defect	<input checked="" type="checkbox"/> Life-threatening
<input type="checkbox"/> Important medical event (Please specify in the SAE description field on page 3 and only tick this criterion if no other applies)	<input type="checkbox"/> Death**
* if hospitalization: Date of admission: (b) (6) dd mmm yyyy	Date of discharge: 20 dd mmm yyyy
** if death: Date of death: 20 dd mmm yyyy	Autopsy performed? <input type="checkbox"/> yes <input type="checkbox"/> no (if yes, please provide summary of autopsy report in the SAE description on page 3)
9. SAE OUTCOME: (please tick only one)	
<input checked="" type="checkbox"/> resolved	<input type="checkbox"/> worse
<input type="checkbox"/> improved	<input type="checkbox"/> fatal
<input type="checkbox"/> unchanged	<input type="checkbox"/> unknown/lost to follow-up

VLN Cigarette Consumption Study

Confidential

Sponsor:
 22nd Century Group, Inc.

Subject ID
 001023

SAE
Report Form

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 ~~dissecting~~ aneurysm
 (b) (6) 18OCT2018

(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 10OCT2018 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.

VLN Cigarette Consumption Study

Confidential

Sponsor:

Subject ID

SAE

22nd Century Group, Inc.

001023

Report Form

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 ^{resected} ~~excised~~ ^{excised} melanoma" 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: VLNC-Study-201-023-01 Signature: (b) (6)