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: 17 SEP 2018 (b) (6) Reporter's name and Signature

Follow-Up No 1: Date: 10 OCT 2018 (b) (6) Reporter's name and Signature

Follow-Up No ___: Date: ___ ___ 20__ _____ Reporter's name and Signature

Follow-Up No ___: Date: ___ ___ 20__ _____ Reporter's name and Signature

4. SUBJECT INFORMATION:

Date of birth: (b) (6) (dd mmm yyyy)

Gender:
- ☑ female
- ☐ male

Race:
- ☑ White/Caucasian
- ☐ Black/African American
- ☐ Asian
- ☐ Native Hawaiian/other Pacific Islander
- ☐ American Indian/Alaska Native
- ☐ Other:

Height: 161 cm

Weight: 62.6 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:	1 1 SEP 2 0 1 8 (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:	2 0 (dd mmm yyyy)	*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 *(Please specify in the SAE description field on page 3 and only tick this criterion if no other applies)*
- ☐ Death**

* if hospitalization: Date of admission: (b) (6) (yyyy) Date of discharge: 2 0 (dd mmm yyyy)

** if death: Date of death: 2 0 (dd mmm yyyy)

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

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10. STUDY PRODUCT INFORMATION:

Study product name	First use dd	First use mmm	First use yyyy	Last use prior to SAE dd	Last use prior to SAE mmm	Last use prior to SAE yyyy
☐ Subject's usual brand non-mentholated filtered king size cigarettes			20			20
☐ Subject's usual brand mentholated filtered king size cigarettes			20			20
☑ Non-mentholated VLN cigarettes	02	AUG	2018	14	SEP	2018
☐ 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):

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.

10 OCT 2018 : Subject returned on 10-OCT-2018 to sign medical release form. Dr. Mathew discussed events leading up to the SAE. Subject reports sudden onset of unconsciousness on (b) (6) . Upon regaining consciousness, she noticed she had vomited and had a severe headache. She was evaluated at the hospital but then transported via ambulance to a larger ICU hospital and was surgically treated for an

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intracranial aneurysm.

15. INVESTIGATOR'S SIGNATURE:

Investigator's name: PHILIP MATHEW

Investigator's signature: (b) (6)

Date: 10 OCT 2018 (dd mmm yyyy)

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

Received date: 10-Oct-2018 Time: 21:38 Tracked: ☒

Case Number: VLNC-Study-001-023-01 Signature: (b) (6)