VLN Cigarette Consumption Study — **Confidential**

Sponsor: 22nd Century Group, Inc.

Subject ID 0 0 1 0 2 3

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: 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: 21 SEP 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

(dd / mmm / yyyy)

4. SUBJECT INFORMATION:

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

Gender:
- [x] female
- [ ] male

Race:
- [x] 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)*

Subarachnoid hemorrhage

6. SERIOUS ADVERSE EVENT INFORMATION:

Awareness date: 17 SEP 2018 (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:

☐ 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) (dd mmm yyyy) Date of discharge: __ __ 20__ (dd mmm yyyy)

** if death: Date of death: __ __ 20__ (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 ☐ worse

☐ improved ☐ fatal

☐ unchanged ☐ 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.

On (b) (6) Subject 001023 was admitted to the hospital. According to her son, it was for a Subarachnoid hemorrhage. The son stated that she underwent medical procedures to drain the blood in her brain. The physician said that there's at least a 10 day recovery time. Celerion was notified of this SAE on 17SEP2018

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Sponsor: **Subject ID** **SAE**

22nd Century Group, Inc. 001023 **Report Form**

15. INVESTIGATOR'S SIGNATURE:

Investigator's name: PHILIP MATHEW

Investigator's signature: (b) (6) Date: 17 SEP 2018 (dd mmm yyyy)

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

Received date: 21-Sep-2018 Time: 20:36 Tracked: ☒

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