Unique SAE Case Number: VLNC-Study-001-023-01

Primary Reporter Country: USA
Site Number: 001
Subject Number: 023

Initial report (received on 18-Sep-2018):

Serious Adverse Event: Subarachnoid hemorrhage

Coded Term: **Subarachnoid hemorrhage (10042320)** [MedDRA v. 21.1]

Relationship to Study Product: was not provided at the time of initial report

A 51 year-old female White/Caucasian subject 001-023 was enrolled in a Longitudinal Ambulatory Study to Assess Changes in Cigarette Consumption Behavior and Biomarkers of Exposure during a 6-Week Switch to Very Low Nicotine Cigarettes.

On (b) (6), 1 day after the last use of study product, the subject 001-023 was admitted to the hospital due to **subarachnoid hemorrhage**. The son stated that she underwent medical procedures to drain the blood in her brain. The recovery time was estimated at least 10 days according to the physician. Celerion was notified of this SAE on 17-Sep-2018.

The subject first received the study product Non-mentholated VLN cigarettes on 02-Aug-2018. The last use of the study product prior to the onset of this event was on 14-Sep-2018.

The onset date of event was on (b) (6), the day when the patient was admitted to hospital.

The severity of the SAE was assessed as **severe**.

The SAE outcome was not provided at the time of the initial report.

The action taken with study product was not provided at the time of the initial report.

The action taken to treat the SAE was reported as unknown.

At the time of the initial report no information was provided regarding relevant concomitant medications taken at the time of the event and relevant medical history.

Follow-up information (received on 21-Sep-2018):

Relationship to Study Product: **unlikely related**