

5.2 TABULAR LISTINGS OF ALL CLINICAL STUDIES

Table 5.1 – Listing of Clinical Studies

Type of Study	Study Identifier	Location of Study Report	Objective(s) of the Study	Study Design and Type of Control	Test Product(s); Dosage Regimen; Route of Administration	Number of Subjects	Healthy Subjects or Diagnosis of Patients	Duration of Treatment	Study Status; Type of Report
Phase 1	CEG-P9-153	CSR_22nd Century Group_19 DEC2018_Final_1.0.pdf	<p>The primary objective of the study was:</p> <ul style="list-style-type: none"> To evaluate the abuse liability of VLN™ cigarettes relative to own-brand cigarettes and nicotine polacrilex gum under Controlled Use and Uncontrolled Use conditions. <p>The secondary objectives of the study were:</p> <ul style="list-style-type: none"> To compare the nicotine pharmacokinetic profiles of VLN™ cigarettes relative to own-brand cigarettes and nicotine polacrilex gum under Controlled Use and Uncontrolled Use conditions. To characterize product use behavior of VLN™ cigarettes, own-brand cigarettes, and nicotine polacrilex gum. 	Crossover;	<p>Two cigarette and one gum formulations;</p> <p>Product A: VLN™ cigarette</p> <p>Product B: Own-brand non-menthol cigarette</p> <p>Product C: Nicorette® Original Flavor™;</p> <p><u>Part A:</u></p> <p><i>Ad libitum</i> use for 4 hours of one product per day for 3 days</p> <p><u>Part B:</u></p> <p>On each of the 3 days:</p> <p>10 puffs from the Product A or Product B or 10 minutes of Product C</p> <p>And</p> <p>Uncontrolled Product Use session (use of 1 unit of a product <i>ad libitum</i> for 10 minutes);</p> <p>Smoked or chewed</p>	66	Healthy Smokers	Multiple dose	Complete; Full