

A close-up photograph of several microscope objective lenses, showing their metallic surfaces and engraved markings. The lenses are arranged in a cluster, with some in the foreground and others slightly out of focus in the background. The background is a solid blue color.

A randomised, controlled, single-centre, open-label study to assess aspects of abuse liability of a glo heating device with two variants of an alternative non-tobacco, nicotine-containing consumable

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Role of Heated Products for Tobacco Harm Reduction



THR

Tobacco Harm Reduction (THR) Initiative

Encourage adult smokers, who would otherwise continue to smoke, to switch to scientifically substantiated alternatives with reduced risk profile



**Smokeless
Products**

Smokeless Products

Tobacco and nicotine products that do not operate through a combustion process, and therefore do not produce smoke, and thereby emit fewer and lower numbers of toxicants as compared with combustible cigarettes



HTP

Heated Tobacco Products (HTP)

Tobacco rod is heated rather than combusted, which reduces the toxicant content of the resulting aerosol as compared to cigarette smoke*

* Comparison with smoke from a scientific standard reference cigarette (approximately 9mg of tar) in terms of the average of the 9 harmful components the World Health Organization recommends to reduce in cigarette smoke

Herbal Heated Products

Herbal Heated Products: a new product category with potential to support THR



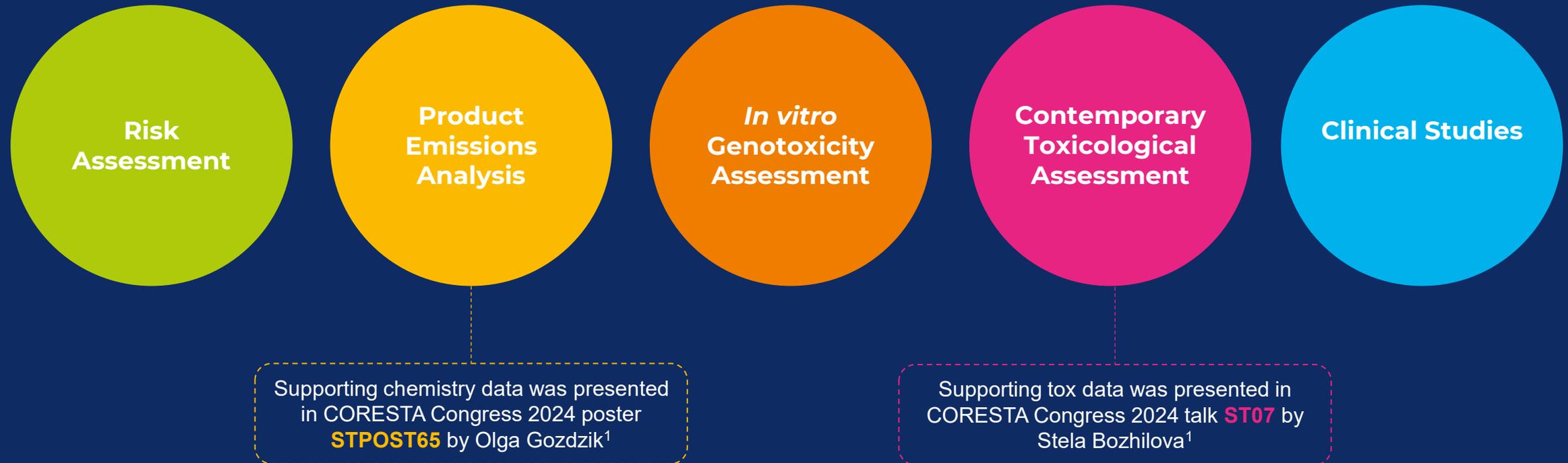
HHP

Herbal Heated Products (HHPs)

- Tobacco-free, contains herbal material (such as a novel rooibos substrate) with added nicotine and flavourings

Herbal Heated Products: a new product category with potential to support THR

Integrated Testing Approach



Study objectives

Primary objective

To assess abuse liability of a glo heating device with two varieties of rooibos substrate, and one heated tobacco product through assessment of in-the-moment Product Liking (PL) subjective measures over 4 hours after the start of Investigational Product (“IP”) use

Secondary objectives

To assess plasma nicotine uptake over the first 4 hours after the start of IP use

To assess C_{max} and T_{max} values for plasma nicotine uptake over 4 hours after the start of IP use

To assess subjective measures (Product Effects [PE], Urge to Smoke [UTS], Overall Product Liking [OPL] and Overall Intent to Use Again [OIUA]) over the 4 hours after the start of IP use

Study Design

Study Products



HTP/HHP variants

- glo Hyper X2 device
 - HTP-Neo Redberry Click (1.7% nicotine)
 - HHP-Veo Sunset Click (1.6% nicotine)
 - HHP-Veo Scarlet Click (1.6% nicotine)



Combustible Cigarette

- Participants' usual brand

Nicotine replacement therapy (NRT) gum

- Nicorette® Mint 4 mg nicotine gum

Study Endpoints

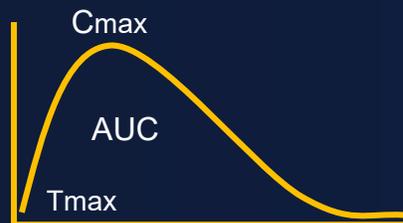


Primary Endpoints

- In-the-moment product liking

Secondary Endpoints

- Nicotine pharmacokinetics
- Product effects
- Urge to smoke
- Overall product liking
- Overall intent to use again



Study Population



Characteristics

- N=36
- Healthy adults 21-60 years
- 50:50 male:female

HTPs users who also smoke

- 6-months use history

Study Location

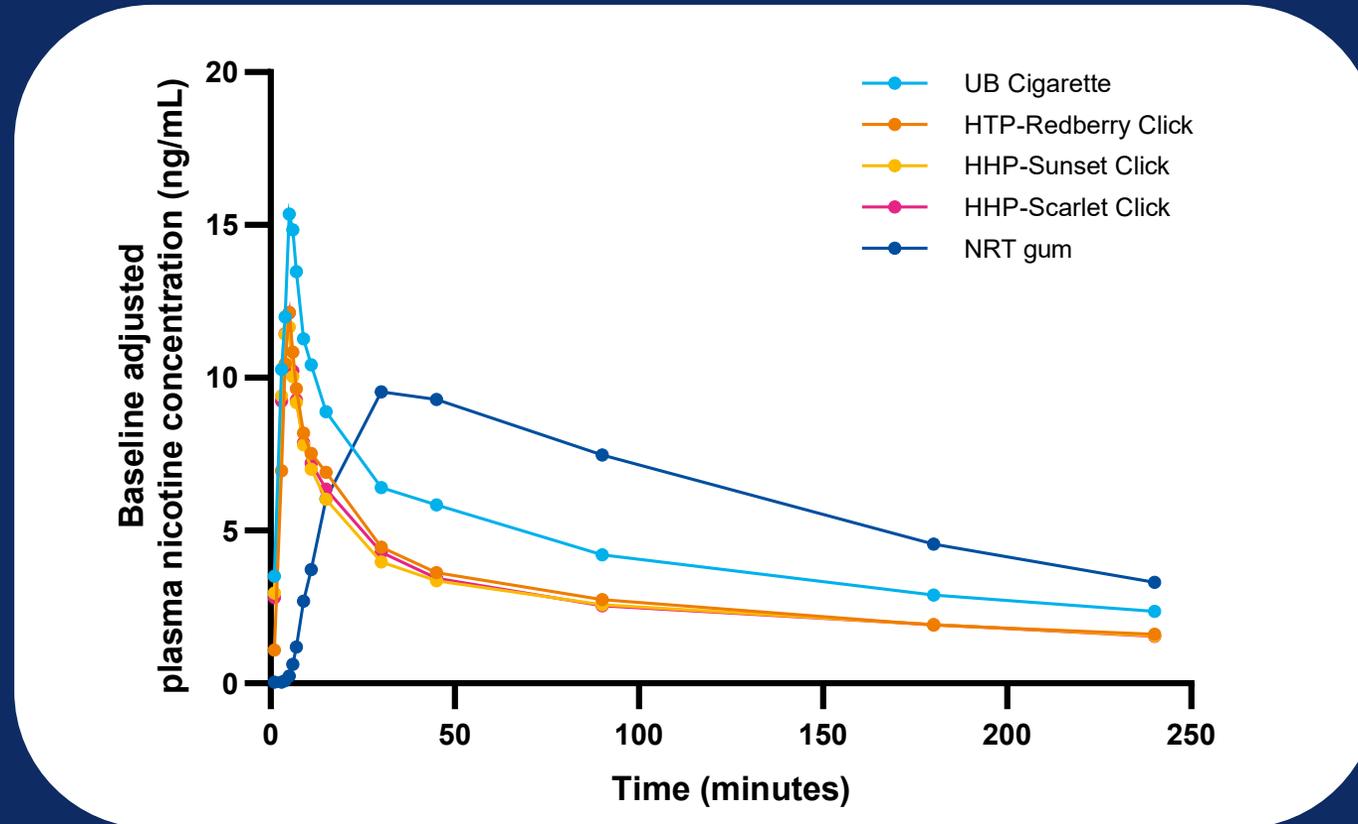
- Verona, Italy

6 days
In clinic

12 hrs
wash out period

4 hrs
blood draws
-5, 1, 3, 4, 5, 6, 7, 9, 11,
15, 30, 45, 90, 180 &
240 min

Plasma nicotine uptake



- HTP/HHP variants show similar nicotine uptake patterns to UB cigarette
- HTP/HHP variants had lower peak concentration (C_{max}) than UB cigarette
- NRT gum took longer time to reach peak concentration (T_{max}) ~30 minutes

Plasma nicotine uptake parameters

Parameter	UB cigarette	HTP-Redberry Click	HHP-Sunset Click	HHP-Scarlet Click	NRT gum	IP vs UB cigarette	IP vs NRT gum
AUC ₀₋₁₅ (min*ng/mL)	153.5 (110.2)	112.1 (79.7) ^{a, b}	111.8 (81.4) ^{a, b}	114.7 (61.6) ^{a, b}	30.8 (16.8)	0.019 ^B 0.003 ^C 0.039 ^D	<0.001 ^B <0.001 ^C <0.001 ^D
AUC ₀₋₂₄₀ (min*ng/mL)	1054.4 (447.4)	709.8 (310.8) ^{a, b}	676.4 (301.4) ^{a, b}	686.4 (263.8) ^{a, b}	1423.3 (507.7)	<0.001 ^B <0.001 ^C <0.001 ^D	<0.001 ^B <0.001 ^C <0.001 ^D
C _{max} (ng/mL)	17.3 (14.9)	13.8 (12.3) ^a	13.7 (12.3) ^a	14.2 (10.2)	10.8 (3.4)	0.032 ^B 0.011 ^C 0.082 ^D	0.525 ^B 0.301 ^C 0.783 ^D
T _{max} (min)	6.14	6.01 ^b	5.02 ^{a, b}	5.02 ^{a, b}	45.0	0.629 ^B 0.001 ^C 0.034 ^D	<0.001 ^B <0.001 ^C <0.001 ^D

LS means presented for AUC and C_{max}; medians are presented for T_{max}

^B compared to HTP-Redberry Click

^C compared to HHP-Sunset Click

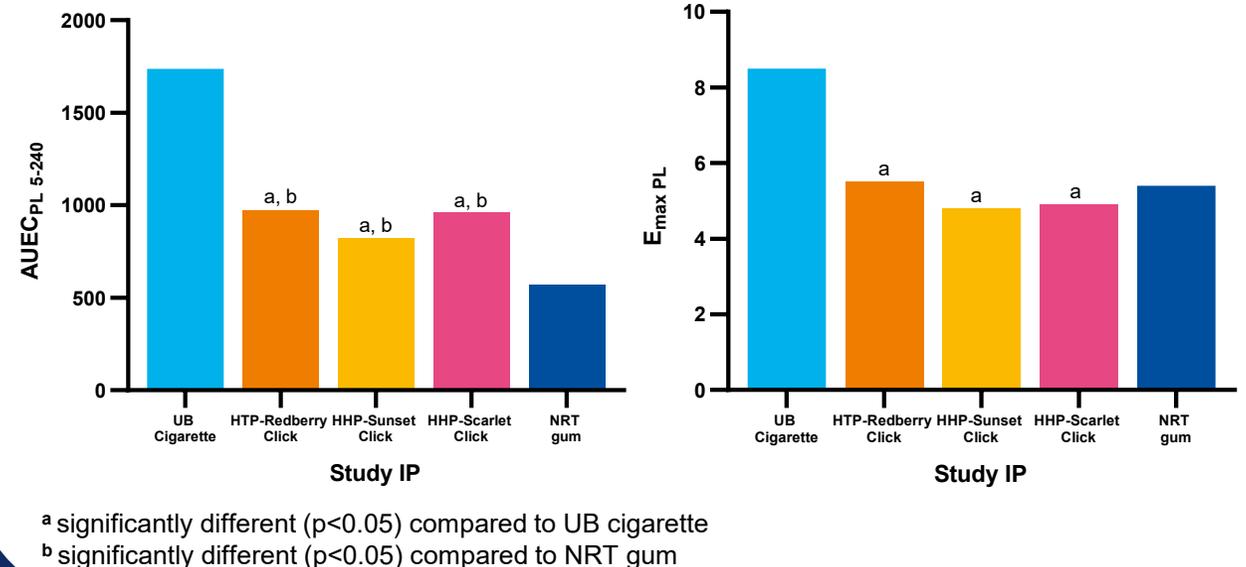
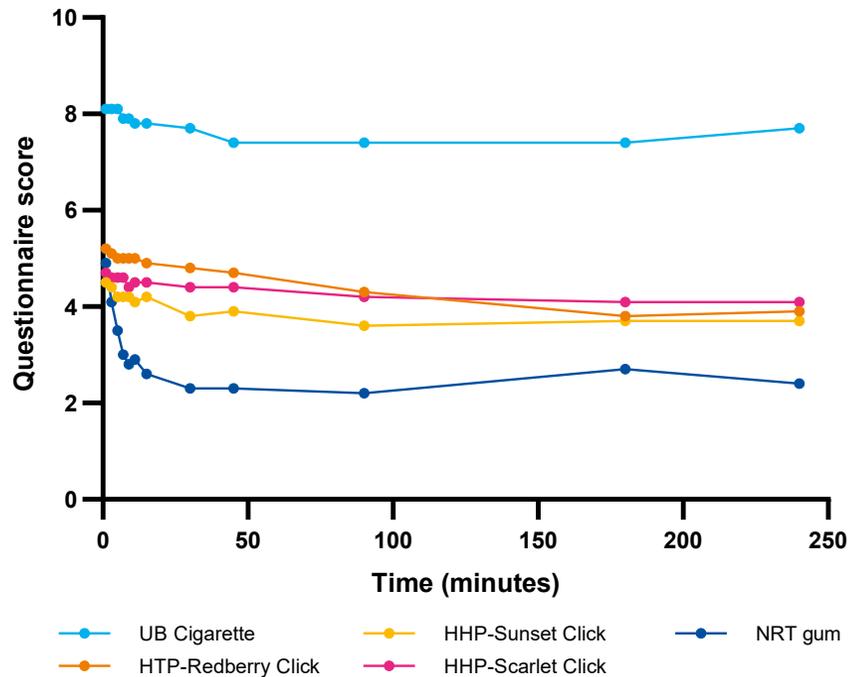
^D compared to HHP-Scarlet Click

^a significantly different compared to UB cigarette

^b significantly different compared to NRT gum

In-the-moment product liking

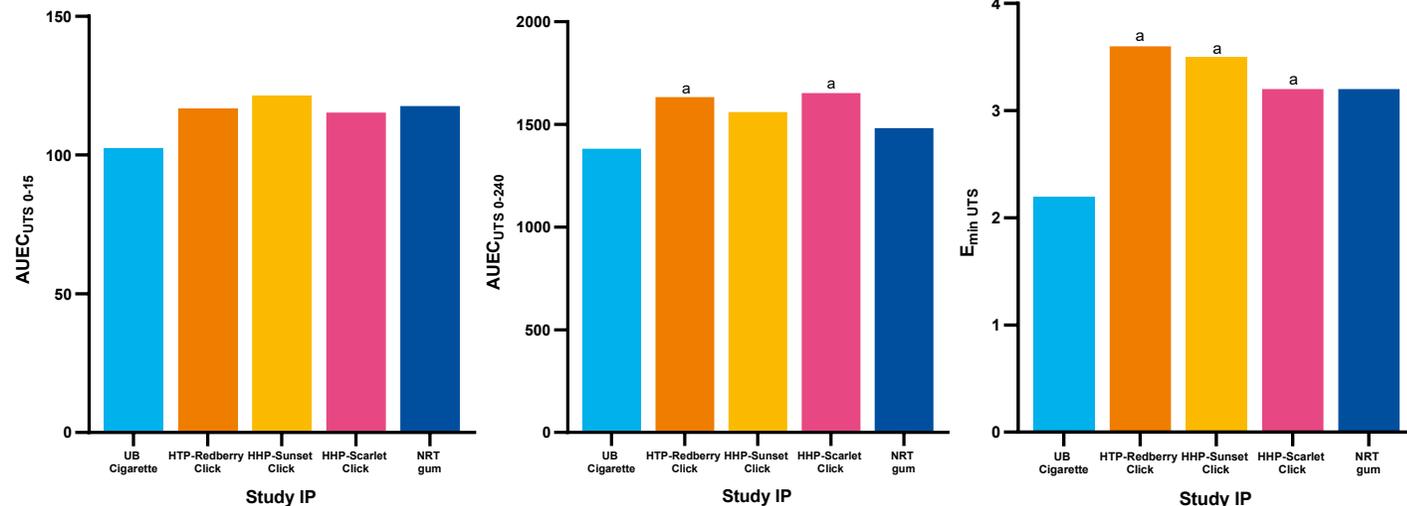
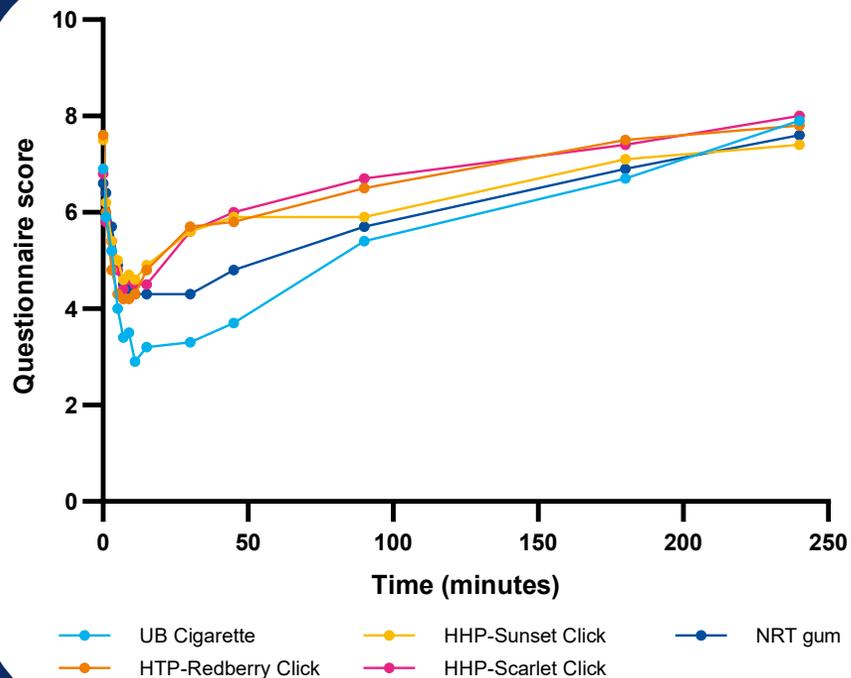
At this moment, how much do you like the product?



- Product liking for HTP/HHP variants was significantly lower than UB cigarette and significantly higher than NRT gum
- Maximum effect for HTP/HHP variants was significantly lower than UB cigarette and similar to NRT gum

Urge to smoke (UTS)

How strong is your current urge to smoke your usual brand cigarette?



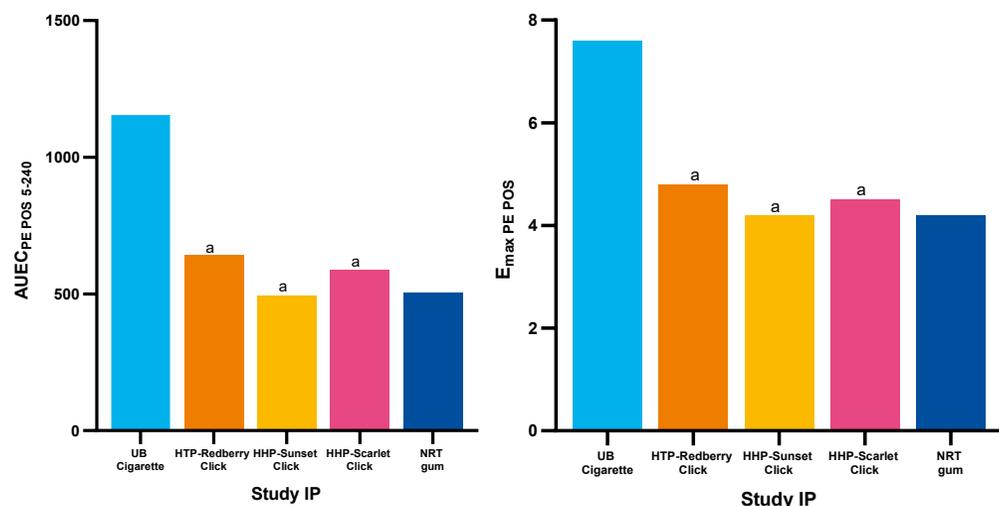
^a significantly different ($p < 0.05$) compared to UB cigarette

- UTS parameters for HTP/HHP variants were more similar to NRT gum than to UB cigarette during the first 15 minutes of product use (not significant)
- Effect of minimum UTS for HTP/HHP variants was significantly greater than UB cigarette but similar to NRT gum

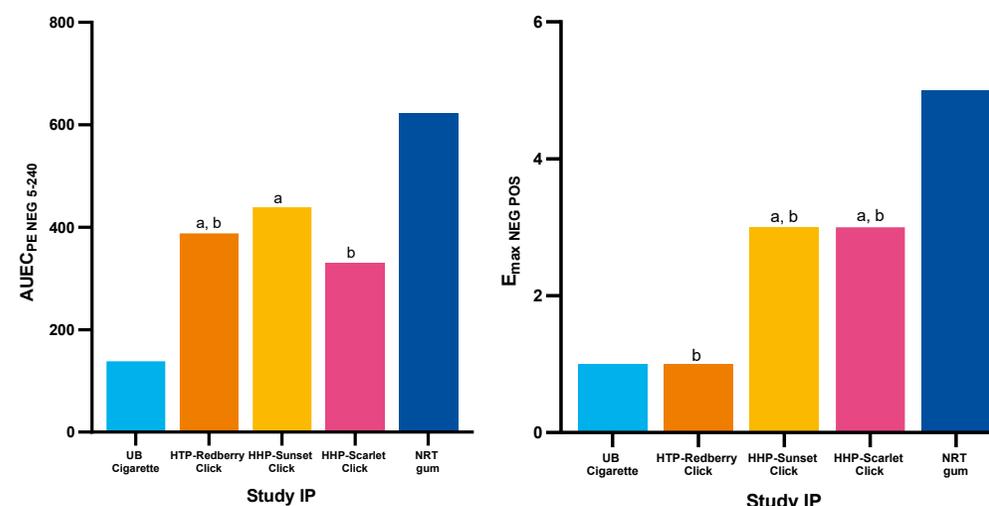
Positive effects (PE) and negative effects (NE)

Rate the degree to which you feel positive effects of the product at this moment

Rate the degree to which you feel negative effects of the product at this moment



^a significantly different (p<0.05) compared to UB cigarette



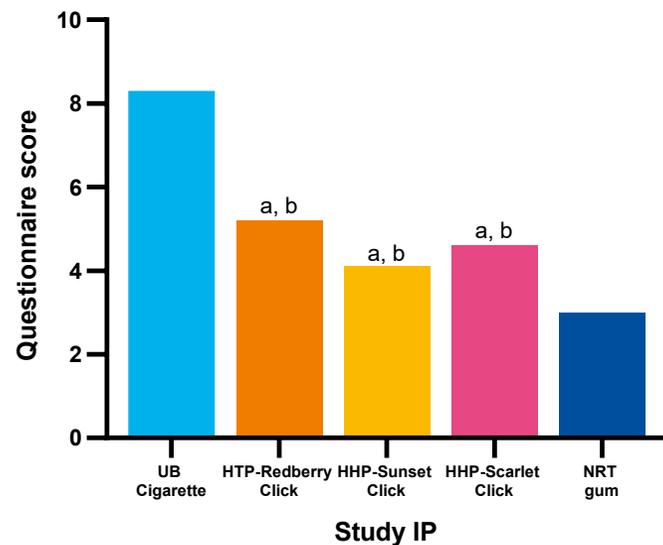
^a significantly different (p<0.05) compared to UB cigarette

^b significantly different (p<0.05) compared to NRT gum

- Both overall maximum PEs for HTP/HHP variants were similar to NRT gum but significantly lower than UB cigarette
- Maximum negative PEs for HTP/HHP variants were significantly lower than NRT gum and significantly higher than UB cigarette, except for HTP (E_{max} was similar to UB cigarette)

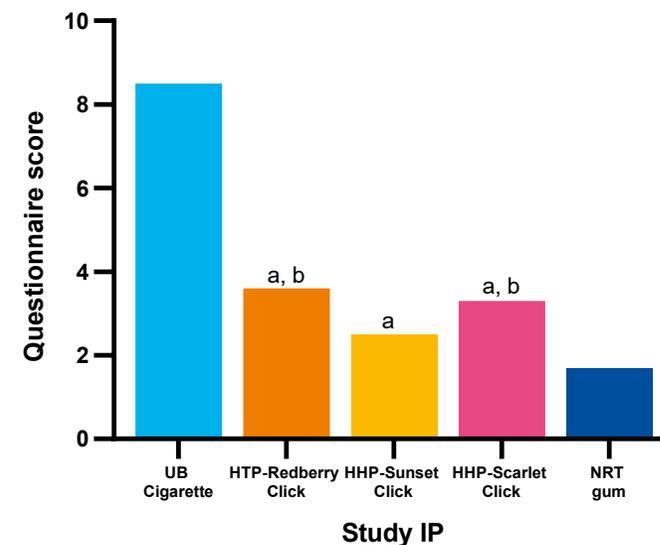
Overall product liking and overall intent to use again

Overall, how much did you like the product?



^a significantly different ($p < 0.05$) compared to UB cigarette
^b significantly different ($p < 0.05$) compared to NRT gum

Rate the degree to which you would like to use the product again



^a significantly different ($p < 0.05$) compared to UB cigarette
^b significantly different ($p < 0.05$) compared to NRT gum

- Overall product liking for HTP/HHP variants were significantly lower compared to UB cigarette and higher than NRT gum
- Overall intent to use again for HTP/HHP variants were significantly lower compared to UB cigarette, HTP-Redberry Click and HHP-Scarlet Click overall intent to use again were significantly higher than NRT gum

Safety assessments – Adverse Events (AE)

Parameter	UB cigarette (n [%]) a	HTP-Redberry Click (n [%]) a	HHP-Sunset Click (n [%]) a	HHP-Scarlet Click (n [%]) a	NRT gum (n [%]) a	Total (n [%]) a
No. of adverse events	4 (11.8) 7	-	3 (9.1) 6	-	3 (9.4) 3	10 (27.8) 17
No. of pre-IP adverse events	N/A	N/A	N/A	N/A	N/A	1 (2.8) 1*
No. of TEAEs	4 (11.8) 7	-	3 (9.1) 6	-	3 (9.4) 3	9 (25.0) 16
No. of TEAEs related to IP	-	-	2 (6.1) 4	-	2 (6.3) 2	4 (11.1) 6
No. of TEAEs by severity						
Mild	2 (5.9) 2	-	3 (9.1) 6	-	2 (6.3) 2	6 (16.7) 10
Moderate	2 (5.9) 4	-	-	-	1 (3.1) 1	3 (8.3) 5
Severe						

TEAE = treatment emergent adverse event; IP = investigational product; n = no. of participants with AE; a = number of adverse events

* One serious adverse event (one participant): Salpingitis, reported after screening but before enrollment therefore unrelated to IP use

- Majority of AEs were mild in severity, commonly reported AEs: cough, nausea, and headache
- AEs expected for a nicotine pouch study

Conclusions



1

The abuse liability profile of the studied glo heating device and HHP variants fell between that of participants' UB cigarette and a commercially-available NRT gum

2

This study indicates the evaluated glo heating device with HHP variants may provide consumers with a level of nicotine similar to that provided by combustible cigarettes, but with a lower abuse liability profile. The studied glo device with HHP variants may provide a satisfactory complete alternative to cigarettes for adult cigarette smokers who would otherwise continue to smoke.

3

The studied glo heating device and HHP variants were well-tolerated, the adverse event profile was similar to that commonly observed during clinical studies of tobacco- or nicotine-containing products



Thank You & Questions?

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