Actual Use Study of a Heated Tobacco Product (glo™)

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OUTLINE

1. Objectives
2. Method & Study Design
3. Results
4. Conclusion
Objectives

Describe the acceptance of the HTP IP (i.e., glo™) and the pattern of CC consumption in the context of the glo™ availability among current daily cigarette smokers.

**PRIMARY ENDPOINT 1**

Determine number and proportion of subjects who meet the definition of “established users” of the glo™ (defined as using ≥100 neo sticks) over the 6 weeks of the AUP.

**PRIMARY ENDPOINT 2**

Determine number and proportion of subjects among “established users” who reduce their cigarettes per day (CPD) consumption by at least 50% at the end of the AUP.

**PRIMARY ENDPOINT 3**

Descriptive weekly average CPD consumption per subject among all subjects.
Methods & Study Design

Key Inclusion Criteria:
Adult smokers (defined as ≥ 5 CC/day, smoked 100 CC in lifetime and at least 20/30 days smoked in the past month). Must indicate “an intention to use” glo™ and able and willing to comply with all study requirements.

Study IP:
Heated Tobacco Product (glo™) is an alternative to combustible TNPs that can be used with non-combusted neosticks to heat rather than burn tobacco.
DEMOGRAPHICS

Enrolled = 1180*

Full Analysis Set = 1120**
- Fulfilment of all eligibility criteria
- ≥1 documented use of CC in the BAP
- ≥1 documented use of glo in the AUP

Completed = 1073***

Race
White 58%
Black 36%
Other 6%

Sex
Male 42%
Female 58%

Age (Years)
21-30 7%
31-49 61%
50-60 32%

Subject TNP Use 30 days prior to SEV
Poly CC and more than one other TNP 50.6%
Exclusive CC 22.8%
Dual CC and Vaping 16.8%
Dual CC and Other Combustible Tobacco Products 8.8%
Dual CC and Oral 0.7%
Dual CC and HTP 0.2%

* 1229 subjects attended the SEV, 49 screen fails occurred
** 60 enrolled subjects not included in the FAS as did not meet the criteria
*** 47 subjects were terminated early mainly due to lost to follow-up, followed by non-compliance with eDiary
## COMPLIANCE RATES

<table>
<thead>
<tr>
<th>Numbers of Subjects fulfilling compliance criteria</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of subjects with eDiary entries available for at least 6 days of the one-week baseline period</td>
<td>1094 (97.7%)</td>
</tr>
<tr>
<td>Number of subjects with eDiary entries available for at least 6 days per week during the six-week Actual Use Period</td>
<td>877 (78.3%)</td>
</tr>
<tr>
<td>Number of subjects who did not miss any Site Visit</td>
<td>1014 (90.5%)</td>
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## SAFETY REPORTING

Less than 1% of subjects reported an AE
Primary Endpoints

- **61%**
  - Proportion of Established Users of Glo™
  - 660 subjects met the definition of established users* of Glo™ by Week 6

- **35%**
  - 50% CPD Consumption Reduction
  - 236 established users of Glo™ reduced their CPD consumption by at least 50% or more by Week 6

- **12→9**
  - Average CPD Reduction
  - Average CPD of all completed subjects (n=1073) decreased from 12.4 at baseline to 8.99 at Week 6

* Established users defined as using ≥100 neo sticks over AUP.

Note: Results are based on preliminary data
GLO™ USE

4.5 Neo Sticks Per Day at Week 6 (All Completed Subjects)
6.8 Neo Sticks Per Day at Week 6 (Established Users)

INTENT TO USE GLO™ AGAIN

Subjects were asked about their intent to use glo™ again at the end of the study on a scale of 1-10 (1 being definitely would not use it and 10 being definitely would use).

- 130 subjects (12.1%) reported they would ‘definitely use it again’.
- 573 subjects (53.4%) reported they would use it again (6-10).

COMPLETLY QUIT CC

- 41 subjects (3.8%) reported to have completely quit CC at the end of the study
- 34 subjects (3.2%) were exclusively using glo™ at the end of the study
By Week 6, the use of all 4 variants was evenly distributed.
By week 6, most subjects used 1 or 2 neo stick variants (compared to 2, 3 and 4 neo stick variants at week 1).

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**Neo Sticks Variant Combination Used During AUP**

- 1 Neo Stick Variant: n = 1115
- 2 Neo Stick Variants: n = 1045
- 3 Neo Stick Variants: n = 1001
- 4 Neo Stick Variants: n = 973

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**Percentage of subjects by week**

- Week 1:
  - 1 Neo Stick Variant: 35%
  - 2 Neo Stick Variants: 25%
  - 3 Neo Stick Variants: 15%
  - 4 Neo Stick Variants: 10%

- Week 2:
  - 1 Neo Stick Variant: 30%
  - 2 Neo Stick Variants: 30%
  - 3 Neo Stick Variants: 20%
  - 4 Neo Stick Variants: 20%

- Week 3:
  - 1 Neo Stick Variant: 25%
  - 2 Neo Stick Variants: 25%
  - 3 Neo Stick Variants: 20%
  - 4 Neo Stick Variants: 20%

- Week 4:
  - 1 Neo Stick Variant: 20%
  - 2 Neo Stick Variants: 20%
  - 3 Neo Stick Variants: 15%
  - 4 Neo Stick Variants: 15%

- Week 5:
  - 1 Neo Stick Variant: 15%
  - 2 Neo Stick Variants: 15%
  - 3 Neo Stick Variants: 10%
  - 4 Neo Stick Variants: 10%

- Week 6:
  - 1 Neo Stick Variant: 10%
  - 2 Neo Stick Variants: 10%
  - 3 Neo Stick Variants: 5%
  - 4 Neo Stick Variants: 5%
PRODUCT USE EXPERIENCE

NEO STICKS LIKING

- Liking rates increased over AUP
- Consistent across all four neo stick variant types

GLO™ MISUSE

615 subjects reported using the product in a manner that differs from product use instructions

Most frequent glo™ Misuse:

- Left glo unattended while charging
- Reuse of neo stick
- Tried to light and smoke a neo stick
CIGARETTE USE CHANGE FROM BASELINE

All Study Completers

- Mean CPD decreased during AUP
- By Week 6 CPD reduction was 29%

All Completers & Established Users of glo™

- ~20% of all completers and ~14% of established users did not reduce at all
- ~50% of all completers and established users reduced up to 50%
- ~24% of all completers and ~34% of established users reduced more than 50%
Conclusions

- **61%** of participants became established users of glo™
- **35%** of established users reduced their CC consumption by ≥ 50%
- On average, CC consumption was reduced by **29%**
- neo stick variants were rated highly on the liking scale
- High compliance rates (eDiary completion and site visit rates)
  - Low attrition rate (4%)
  - Low AEs reported (<1% subjects)
- glo™ has the potential to positively impact public health
- Study results have informed the acceptance of glo™ and CC consumption patterns
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Thank you. Any Questions?