Comparing The Levels Of Harmful Compounds In Smokers That Either Continue To Smoke, Quit Or Switch To THS2.2 Menthol*  

Presented by: Yin Boll  
C. Haziza 1, N. Lama 1, A. Donelli 1, P. Picavet 1, G. Baker 1, J. Ancerewicz 1, M. Benzimra 1, M. Franzon 1, M. Endo 2, F. Ludicke 1.  
1 Philip Morris Products S.A. Neuchatel, Switzerland (part of Philip Morris International group of companies) 2 Osaki Hospital, Tokyo Heart Centre, Tokyo, Japan

How to interpret the data

**Similarity of THS effect to smoking abstinence:** 75% 71%

5 Days 90 Days

<table>
<thead>
<tr>
<th>Compound found in smoke</th>
<th>Biomarker of Exposure in urine</th>
<th>OR</th>
<th>Biomarker of Exposure in blood</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Biomarkers of Exposure

**Clinical risk measurements were selected based on:**

1. Their association with smoking-related disease  
2. Those showing a relationship between the number of cigarettes smoked and their levels  
3. Those that show reversibility upon smoking cessation

Clinical risk measurements chosen were: High Density Lipoprotein-Cholesterol (CVD), total white blood cell count (Inflammation), forced expiratory volume in 1 second (COPOS), soluble intercellular adhesion molecule 1 (CVD), B-epi-prostaglandin F2α (Inflammation) and 11-dehydro-thromboxane B2 (11-DTX-B2, CVD). In spite of the variability due to the limited sample size (which was powered to assess the biomarkers of exposure), the data showed favorable shifts in the direction of smoking abstinence for all the clinical risk measurements. 70% of the smoking abstinence was achieved an equally efficient suppression of urge to smoke compared to CC. THS2.2 was well tolerated.

**SUBJECTIVE EFFECTS**
A number of additional measurements were recorded, including by the use of questionnaires. These measurements were Daily Product Use, Nicotine Exposure, the brief version of the Questionnaire of Smoking Urge, the revised version of the Minnesota Nicotine Withdrawal Symptoms, and the modified Cigarette Evaluation Questionnaire. There was a similar exposure to nicotine between THS2.2 and cigarette (CC) and, in general, the THS2.2 group exhibited identical trends to the CC group. Product evaluation at Day 90 showed that the level of satisfaction for THS2.2 was comparable to CC. Similarly, THS2.2 achieved an equally efficient suppression of urge to smoke compared to CC. THS2.2 was well tolerated.

**SAFETY**
No serious adverse events were reported during the study. Prior to randomization, 22 adverse events (AEs) were reported in 16 (9%) out of the 175 subjects enrolled. Post-randomization, 49 AEs in 32 subjects (18%) in the THS2.2 were reported in 14 subjects for both the CC (33%) and SA (35%) groups were reported. Decreased hemoglobin and decreased levels of neutrophils were the most frequently reported AEs. All AEs were of mild or moderate severity. One mild AE was judged to be related to the THS (chamara). No serious adverse events were reported during the study.

**CONCLUSIONS**
- Switching from CC to THS2.2 resulted in substantial reductions in exposure sustained throughout the 3-month study period.
- The kinetics and the magnitude of decrease of the biomarkers of exposure levels in THS were similar to those observed in SA.
- Similar exposure to nicotine between THS and CC and comparable reduction in urge-to-smoke and satisfaction show switches quite adapt to THS.
- The directional favorable shift of clinical risk measurements towards smoking abstinence supports the clinical relevance of the reduction in exposure.

* * * * * *

Competing Financial Interests: The research described in this poster was sponsored by Philip Morris International. The study was conducted in Japan in 2015/14 according to ICH-GCP, approved by an IRB and registered on ClinicalTrials.gov (NCT01979095).

* For more detailed information please refer to original poster “Reduced exposure to harmful and potentially harmful constituents after 90 days of use of tobacco heating system 2.2 menthol in Japan: a comparison with continued cigarette use or smoking abstinence”