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

PMI SCIENCE
PHILIP MORRIS INTERNATIONAL

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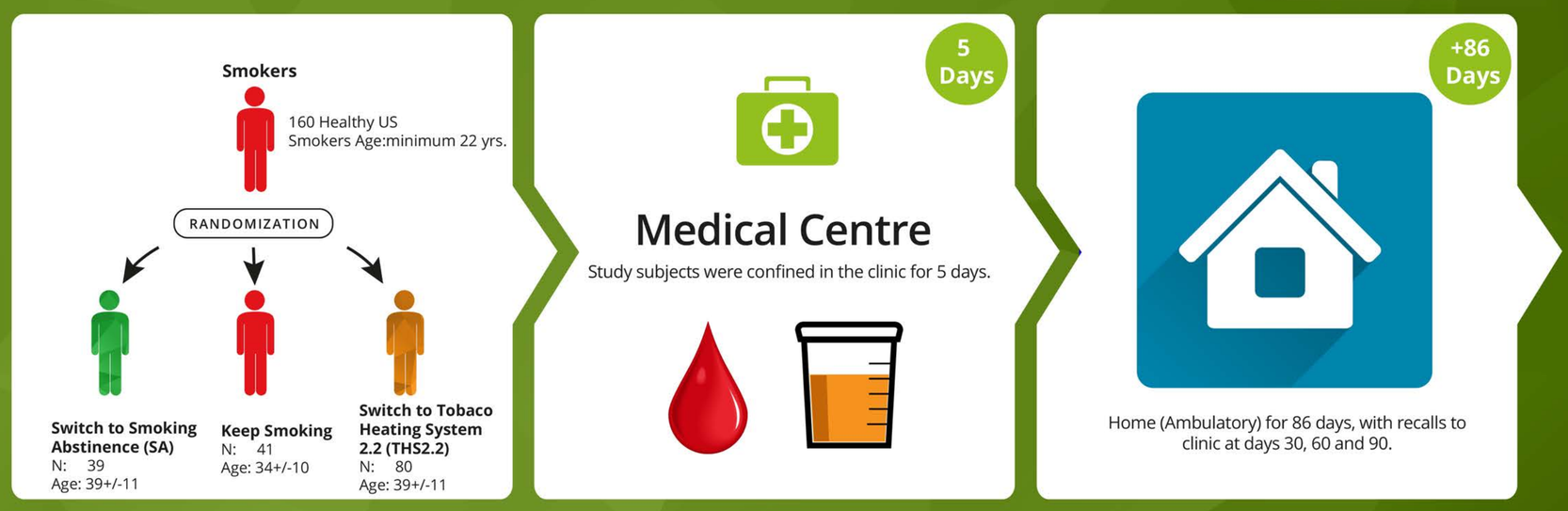
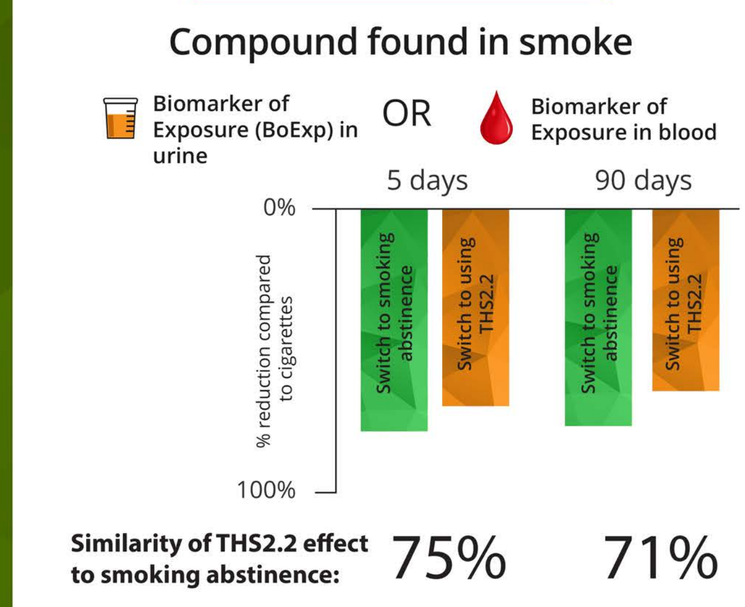


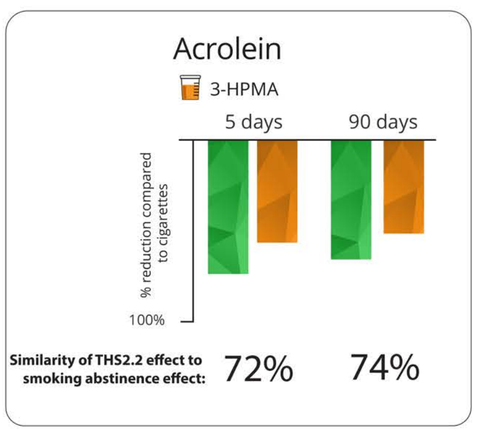
How to interpret the data

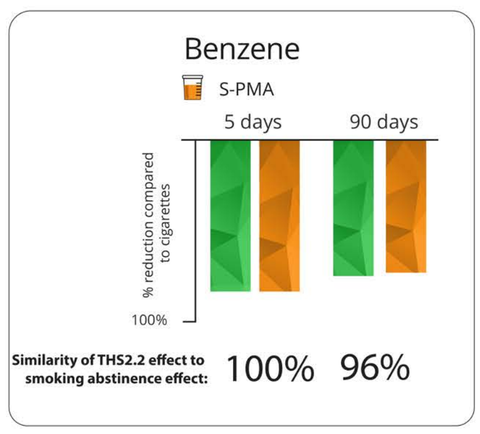


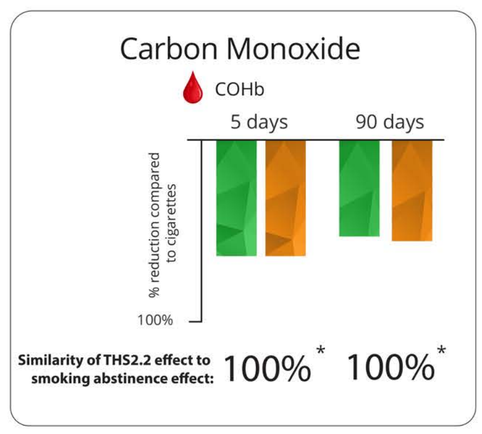
% Reduction: The levels of biomarkers measured in the sample compared to smoking.

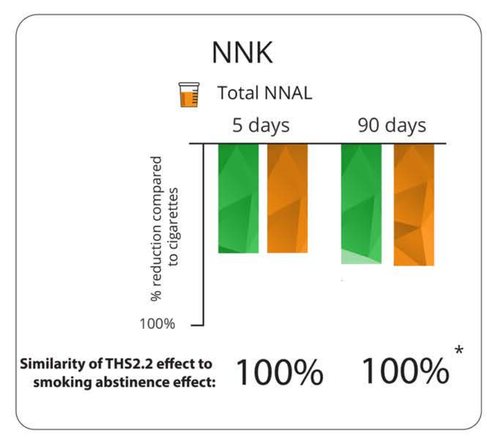
Smoking Abstinence effect: The similarity of levels of biomarkers measured in the THS2.2 group compared to smoking abstinence.

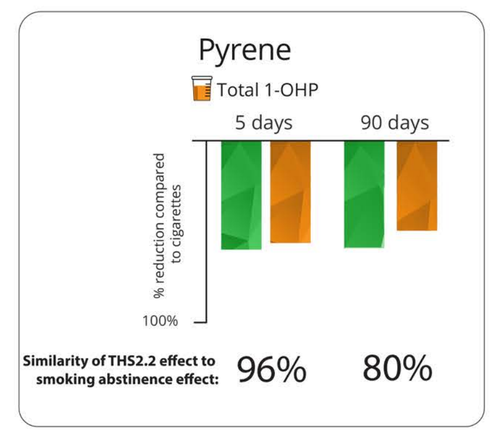
Biomarkers of Exposure

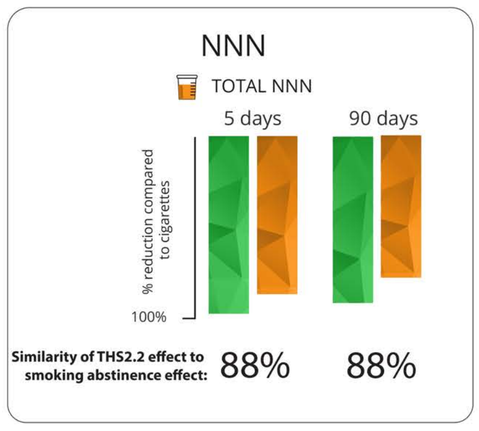


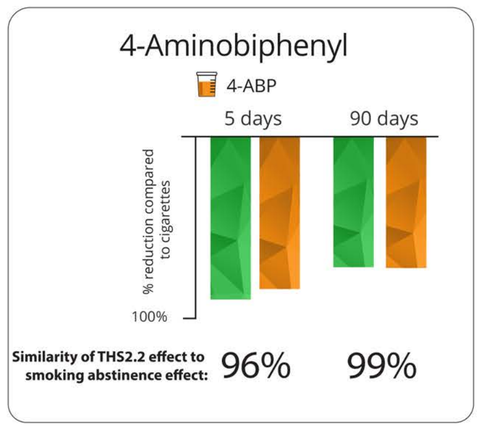


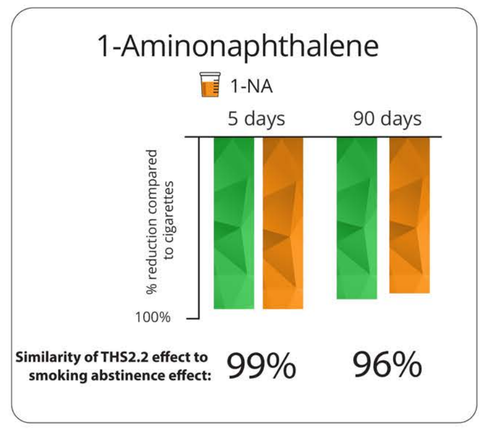


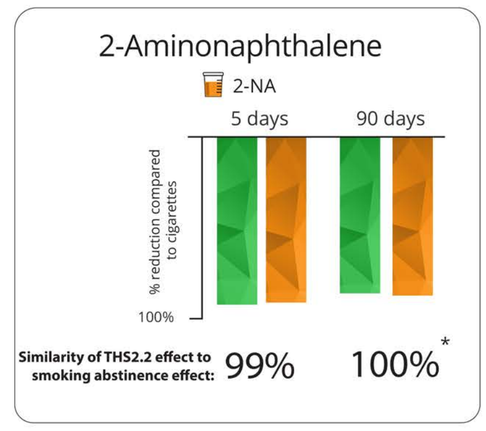


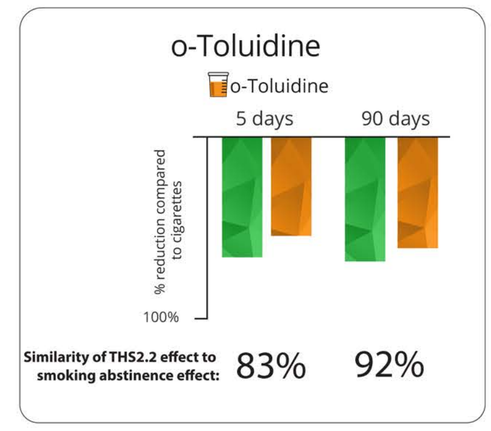


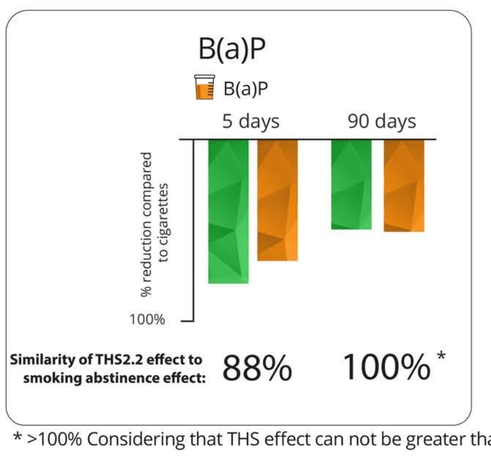


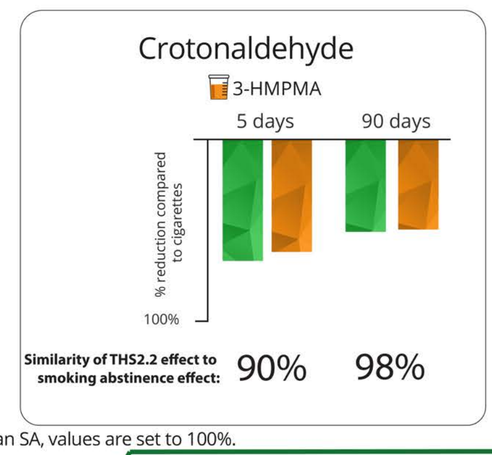


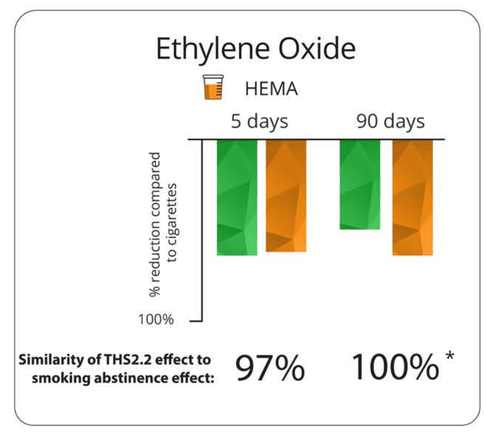


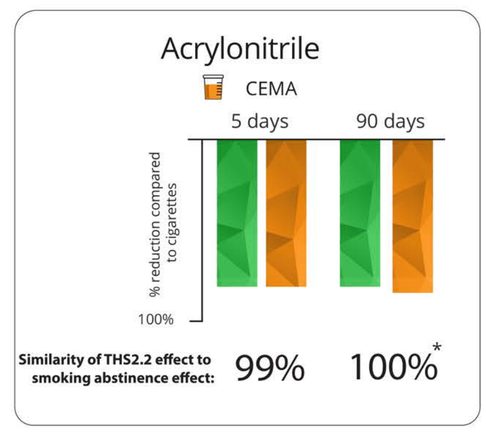


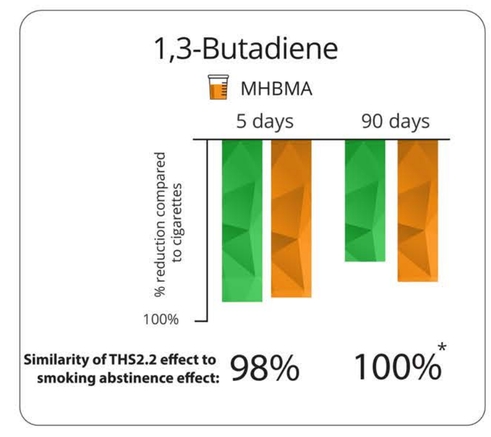












* >100% Considering that THS effect can not be greater than SA, values are set to 100%.

The biomarker S-BMA was also measured, however this biomarker indicated that it is not sensitive enough to discriminate between the different groups; Data not shown.

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

High density lipoprotein-cholesterol, total white blood cell count, forced expiratory volume in 1 second, soluble intercellular molecule adhesion-1, 8-epi-prostaglandin F2α , and 11-dehydro-thromboxane B2 were measured as clinical risk endpoints (CREs) . Due to the study design, targeting to the assessment of BoExp (limited sample size), and adherence to the allocated regimen, the variability of the CRE results did not allow a conclusive interpretation of the results although most CREs started to show favorable changes shifting in the direction of SA.

SUBJECTIVE EFFECTS

Subjective effects of smoking were assessed by means of the brief version of the Questionnaire of Smoking Urges, the revised version of the Minnesota Nicotine Withdrawal Symptoms, and the modified Cigarette Evaluation Questionnaire. Product evaluation at Day 90 showed slightly less satisfaction for THS2.2 compared to cigarette (CC). However, THS2.2 achieved an equally efficient suppression of urge to smoke compared to CC over the entire exposure period. THS2.2 was well tolerated.

SAFETY

Prior to randomization, 84 adverse events (AEs) were observed in 62 (37.6%) of 165 subjects enrolled. One subject reported 2 serious adverse events (SAE) (sinusitis and diabetic ketoacidosis) and was not randomized. Following randomization, 114 AEs in 52 subjects (65.0%) in THS2.2, 32 AEs in 20 subjects (48.8%) in CC and 49 AEs in 23 subjects (59.0%) in SA were reported with decreased hemoglobin and increased lymphocyte count as most frequently reported AEs. Seven mild AEs in THS2.2 were reported as related to THS2.2. No SAE was reported after randomization.

CONCLUSIONS

- Switching from CC to THS2.2 use resulted in substantial reductions in exposure to selected harmful and potentially harmful constituents (except S-BMA, which showed similar levels for the THS2.2, CC and SA groups indicating that it is not a sensitive marker to discriminate between smoking and SA; data not shown) sustained throughout the 3-month exposure period. The kinetics and the magnitude of decrease of the BoExp levels in THS2.2 were close to those of observed in SA.
- The interpretation of the preserved SA effect is limited as only 9 subjects were compliant to SA.
- Similar exposure to nicotine between the THS2.2 and CC, comparable reduction in urge-to-smoke and satisfaction show that users adapted quickly to the new product, indicating that THS2.2 could be an acceptable substitute for CC.
- 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 the US in 2013/14 according to ICH GCP, approved by an IRB and registered on ClinicalTrials.gov (NCT01989156).

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*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 the U.S.: A comparison with continued cigarette use or smoking abstinence"