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

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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

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 BioExp (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 (SAEs) (sudden and diabetic ketoacidosis) and was not randomized. Following randomization, 14 AEIs in 52 subjects (65.9%) in THS2.2, 32 AEIs in 26 subjects (48.6%) in CC, and 49 AEIs in 23 subjects (95.0%) 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, 70% of all SAEs were reported after randomization.

CONCLUSIONS

• Switching from CC to THS2.2 used resulted in substantial reductions in exposure to selected harmful and potentially harmful constituents compared to CC, which allowed 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 magnitude of the decrease of the BioExp levels in THS2.2 were close to those observed in SA.
• The interpretation of the observed SA effect is limited as only 95 subjects were available at 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 toward smoking abstinence supports the clinical relevance of the reduction in exposure.

*100% Considering that the THS2.2 effect can not be greater than SA, values are set at 100%.
* 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.