Background
Cigarette smoking is causally linked to the development of cardiovascular diseases (CVD). Cigarette smoke (CS) contains 93 chemicals categorized as harmful and potentially harmful constituents (HPHCs) by the U.S. Food and Drug Administration. Twelve HPHCs have been identified in CS. The HPHCs, synthetic, and tobacco-based nanoparticles (THS) contained in CS are modulators of endothelial dysfunction, oxidative inflammation, platelet function, and atherosclerotic stress in CVD. To reduce the risk of CVD and other smoking-related diseases, Philip Morris International has developed the Tobacco Heating System (THS, 2.2), which heats a tobacco plug in a controlled manner; never allowing the temperature to exceed 350°C, preventing the combustion process from taking place, thereby generating an aerosol containing no or minimal levels of HPHCs (particulate/aerosols are reduced by >90% in THS 2.2 aerosol vs. CS).

Clinical Study: Clinical Risk Endpoints in THS Switchers
A randomized, controlled, 2-arm parallel group, multicenter, U.S. study was conducted over six months in adult smokers who switched from cigarettes to THS 2.2, compared to those who continued to smoke CS, to demonstrate favorable changes in THS 2.2 compared to CS in terms of primary endpoints: biomarkers of oxidative stress, inflammation, endothelial function, platelet function, and atherosclerotic stress in CVD. THS 2.2-exposed mice were monitored (n = 408) in THS 2.2 (n = 488).

Methods

Results

Conclusions
The results of this THS 2.2 translational assessment program demonstrate that:
• THS 2.2 aerosol contains no or minimal levels of chemicals, Additionally, conventional/tobacco constituents are reduced by >90%.
• The effects of THS 2.2 aerosol on the adhesion of monocyte cells to human coronary endothelial cells in vitro are significantly reduced.
• Switching to THS 2.2 halted the progression of CS-induced atheromalous changes. THS 2.2 aerosol had minimal adverse effects in the ApoE-/- mouse study.

In humans, all primary endpoints linked to smoking-related diseases shifted favorable, in the same direction as the smoking cessation effect observed in the literature, after six months of switching from cigarettes to THS 2.2.

PMI has completed 17 non-clinical studies and 9 clinical studies, including the studies presented herein. The totality of evidence available to date, from non-clinical and clinical studies, indicates that switching to THS 2.2 has the potential to reduce the risk of smoking-related diseases, such as CVD.

References

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