

September 21, 2018

Philip Morris International response to Reuters

- Our intent is to give the 40 million American men and women who smoke an opportunity to make an informed choice for a potentially better option than continued smoking.
- The statements made by the authors are selective, incorrect, and misleading.
- The totality of evidence available on IQOS supports that it is likely to present less risk of harm compared to continued smoking. This includes a significant reduction in inflammatory response and favorable changes in lung function. This evidence has been submitted to the U.S. Food and Drug Administration in connection with our pending applications to market IQOS in the U.S.
- IQOS is not risk free and the best option for every smoker is to quit. However, we believe switching completely to IQOS is a much better choice for current adult smokers than continuing to smoke cigarettes.
- PMI's assessment program is inspired by standards and practices long adopted by the pharmaceutical industry and in line with guidance of the U.S. FDA Center for Tobacco Products. We adhere to internationally recognized practices on Good Laboratory and Clinical Practices.
- The inflammatory responses observed in PMI non-clinical studies are small compared with the effects of cigarette smoke, and mostly occur at the highest IQOS exposure (>100 sticks/day), which is not representative of human exposure. Furthermore, these inflammatory responses are transient and adaptive in nature, and, they are not indicative of IQOS exposure-related immunomodulatory effects.
- Data from PMI's latest Exposure Response clinical study (submitted to the FDA on June 8 2018, as part of PMI's Modified Risk Tobacco Product Application for IQOS) include endpoints for inflammation and pulmonary effects, and clearly show statistically significant favorable changes after switching to IQOS as compared to continued smoking, even in a condition of dual-use.
- The totality of evidence, including a significant reduction in inflammatory response and favorable changes in lung function, supports that IQOS, while not risk free, is likely to present less risk of harm compared to continued smoking.
- PMI welcomes independent public review of our data. However, any review of scientific results needs to take into consideration the study design and limitations of a study and bring the results into context of other available evidence in order to draw conclusions. Specifically when assessing the potential benefits of switching from smoking cigarettes to using a candidate Modified Risk Tobacco Product, the results have to be considered in the context of both continued smoking and smoking cessation, as these represent both the highest and lowest risk of smoking-related disease for a current adult smoker.