



PHILIP MORRIS INTERNATIONAL

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## PMI'S LATEST CLINICAL RESULTS: FINDINGS ARE A STEP FURTHER TOWARDS CONFIRMING RISK REDUCTION

- Likely the first ever clinical study of this magnitude to directly assess risk-reduction potential of a smoke-free product in people who switch to it.
- Six-month Clinical Study met primary objective: shows improvements in the biological response of people who switch to *IQOS* compared to continued smoking.
- Results submitted to the US FDA on June 8 to add to the extensive body of evidence already presented to the Agency.

LAUSANNE, Switzerland – June 15, 2018 Philip Morris International ([PMI](#)) (NYSE: PM) announces today the positive results from a new clinical study on *IQOS*, the company's most advanced smoke-free product. The Exposure Response Study (ERS) measured the biological response of people who switch to *IQOS* for six months compared with continued smoking. The study met its primary objective, demonstrating that after six months, eight measures of biological response (the primary clinical risk endpoints) improved in those who switched to *IQOS*.

PMI's Scientific Assessment Program has rigorously tested *IQOS* over more than 7 years and has demonstrated that switching to our most advanced smoke-free product is likely to present less risk of harm than continuing to use cigarettes. Numerous aerosol chemistry and physics measurements demonstrate that *IQOS* aerosol contains an average of 90-95% lower levels of harmful constituents. Our results also show that these reduced emissions translate to reduced toxicity in the laboratory and to reduced exposure in clinical studies. The ERS contributes an important new facet to PMI's research: it begins to explore the impact of all of these promising results by measuring the biological response of people who switch to *IQOS* compared with those who continue to smoke.

"These results are very encouraging. We believe this study on *IQOS* is the first ever clinical study of this magnitude to directly assess the risk-reduction potential of a smoke-free product in people who switch to it. Everything we've seen, including these new results, continues to point in the direction of risk reduction," said Frank Luedicke, PMI's Chief Medical Officer. "We are sharing the results with the scientific community at multiple conferences over the next few months and we look forward to their feedback."

On June 8<sup>th</sup>, PMI submitted the ERS results to the US FDA to add to the extensive body of evidence already presented to the agency in support of PMI's pending application for authorization of *IQOS* as a modified risk tobacco product. FDA is in the process of reviewing both PMI's modified risk tobacco product and their premarket tobacco applications, but has not yet reached conclusion. The topline ERS results have already been presented at recent conferences, including the [18<sup>th</sup> International Symposium on Atherosclerosis](#) in Toronto, Canada on June 8-12, and the [1<sup>st</sup> Scientific Summit on Tobacco Harm Reduction: Novel products.](#)

[Research & Policy](#) on June 9<sup>th</sup>. The results will also be presented today at the [Global Forum on Nicotine](#) in Warsaw, Poland and other conferences in the coming months.

#### About the Study

The ERS was a six-month randomized, controlled, two-arm parallel group, multicenter US study in adults who switched from smoking cigarettes to *IQOS* as compared to continuing to smoke cigarettes. The study followed 984 people who were randomized to either continue smoking cigarettes (n= 488), or switch to *IQOS* (n=496) for six months. The ERS assessed a set of eight primary and numerous secondary clinical risk endpoints, which were selected because of their association with smoking-related diseases. These endpoints are negatively impacted by smoking and based on literature are expected to improve within six months of smoking cessation.

The study met its primary objective: all eight of the primary clinical risk endpoints moved in the same direction as observed for smoking cessation in the group who switched to *IQOS*, with statistically significant changes in five of the eight endpoints compared with on-going smoking. These clinical risk endpoints are associated with diseases including heart and lung diseases, covering multiple organ systems, disease pathways, and biological mechanisms such as inflammation and oxidative stress.

The study was designed to address key questions related to the impact of switching to *IQOS*, as it is actually used. The study included people who had no intention to quit smoking and allowed them to freely use *IQOS* as well as other tobacco and nicotine containing products. The study met its primary objective and also saw favorable changes in the secondary clinical risk endpoints, even though there was a proportion of the *IQOS* users in the study who concomitantly used cigarettes. For more information on the ERS go to [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (Identifier: NCT02396381). The full results will be submitted for publication in a peer-reviewed journal.

#### About PMI's Research

These results contribute to the totality of evidence on *IQOS* and were produced as part of PMI's extensive research and assessment program. This program is inspired by the well-recognized practices of the pharmaceutical industry and in line with the draft guidance of the U.S. FDA for Modified Risk Tobacco Product (MRTP) Applications. Over 430 PMI R&D experts are working to develop and assess new smoke free products, and have published over 250 peer-reviewed scientific publications and book chapters to-date.

PMI has spent more than USD 4.5 billion to develop, substantiate and build manufacturing capacity for a wide portfolio of smoke-free products. To date, PMI's portfolio includes 2,900 granted patents worldwide, and a pipeline of 4,600 pending patent applications. PMI is the 58<sup>th</sup> largest patent filer in the EU, and the only tobacco company in the top 100 on this list. Under agreements with PMI, PM USA, an affiliate of Altria Group, Inc., is licensed to sell *IQOS* in the U.S. should PMI receive a marketing authorization order from the FDA.

#### Philip Morris International: Who We Are

We are a leading international tobacco company engaged in the manufacture and sale of cigarettes and other nicotine-containing products in markets outside the United States of America. We're building our future on smoke-free products. Through multidisciplinary capabilities in product development, state-of-the-art facilities and scientific substantiation, we aim to ensure that our smoke-free products meet adult consumer preferences and rigorous regulatory requirements. Our vision is that these products ultimately replace cigarettes. For more information, see our [PMI](#) and [PMIScience](#) websites.