



March 4, 2020

Further Support for Reducing Nicotine in Cigarettes to Non-Addictive Levels: New Studies Confirm Use of Very Low Nicotine Content Cigarettes Does Not Lead to Compensatory Smoking

Congressman Pallone Urges FDA to Move Forward with Proposal to Limit Nicotine in All Cigarettes

Williamsville, NY, March 04, 2020 (GLOBE NEWSWIRE) -- [22nd Century Group, Inc.](#) (NYSE AMERICAN: XXII), a plant biotechnology company that is a leader in reduced nicotine tobacco and hemp/cannabis plant research, announced that [two studies](#) published in *Cancer Epidemiology, Biomarkers & Prevention*, a journal of the American Association for Cancer Research (AACR), report the use of cigarettes containing very low levels of nicotine did not lead to compensatory smoking, further refuting common misperceptions about these products.

The two studies were led by Tracy T. Smith, PhD, Assistant Professor in the Department of Psychiatry and Behavioral Sciences at the Medical University of South Carolina and Hollings Cancer Center and were co-authored by other leading researchers of very low nicotine content cigarettes, including Professor Dorothy Hatsukami, PhD and Professor Eric Donny, PhD. In one study, mouth-level nicotine intake was measured from discarded filter butts from smokers who were randomly assigned to receive cigarettes with various nicotine contents, including a cigarette with very low nicotine content over a six-week period. The study concluded that there was a significant decrease in smoking intensity for very low nicotine content cigarettes.

In the second publication, unblinded participants were assessed for compensatory behavior in a controlled environment for two 4-night stays in which smokers had access to regular nicotine content research cigarettes during the first stay and very low nicotine content cigarettes during the second stay. Researchers determined that there was no evidence of compensation across any measure of smoking or smoke exposure among current smokers who used very low nicotine content cigarettes. The authors concluded that “mandated reduction in nicotine content is unlikely to result in an increase in smoking behavior to obtain more nicotine.”

These findings come at a time when the U.S. Food and Drug Administration (FDA) continues to review comments to its 2018 Advanced Notice of Proposed Rulemaking (ANPRM), whereby all cigarettes sold in the U.S. would be required to have the level of nicotine limited to minimally or non-addictive levels. A recent [letter](#) sent from Congressman Frank Pallone, Jr., Energy and Commerce Chairman (D-NJ), to FDA Commissioner Stephen Hahn urges the FDA to “move forward with proposing and finalizing regulations on this issue as soon as possible.”

In response to these developments, John Pritchard, Vice President of Regulatory Science for 22nd Century Group said, “We welcome these publications which build on the already overwhelming case for FDA’s plans to reduce nicotine in cigarettes to minimally or non-addictive levels. Almost half a million Americans die each year from smoking-related disease and more than 16 million Americans are living with a disease caused by smoking. We call on all stakeholders to play their part to end the tragic toll of tobacco on society.”

On February 14, 2020, the FDA’s Tobacco Products Scientific Committee (TPSAC) discussed 22nd Century Group’s applications for its proprietary VLN® and VLN® Menthol reduced nicotine content cigarettes. These cigarettes, made from 22nd Century’s proprietary reduced nicotine tobacco, contain 95% less nicotine than conventional cigarettes and are backed by almost a decade of [clinical studies](#) and other research costing over \$100 million dollars funded in part by several agencies of the U.S. federal government, including the FDA, and conducted primarily by independent researchers using 22nd Century’s reduced nicotine content research cigarettes. 22nd Century believes this extensive body of science overwhelmingly supports the modified exposure claims the Company is seeking from FDA as well as the FDA’s proposed rule limiting nicotine in cigarettes to minimally or non-addictive levels. 22nd Century Group believes that receiving an FDA authorization for its VLN®

brand of products will further advance FDA's stated goal of achieving a reduced nicotine product standard for all cigarettes sold in the United States and that such a measure would be game-changing for public health, the tobacco industry and adult smokers worldwide.

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About 22nd Century Group, Inc.

22nd Century Group, Inc. (NYSE AMERICAN: XXII) is a plant biotechnology company focused on technologies that allow it to regulate the level of nicotine in tobacco plants and the level of cannabinoids in hemp/cannabis plants through genetic engineering and modern plant breeding. The Company's primary mission in tobacco is to reduce the harm caused by smoking by bringing to market reduced nicotine content cigarettes with 95% less nicotine than conventional cigarettes. The Company's primary mission in hemp/cannabis is to develop proprietary hemp/cannabis plants with unique cannabinoid profiles and desirable agronomic traits.

Learn more at xxiicentury.com, on Twitter [@_xxiicentury](https://twitter.com/_xxiicentury) and on [LinkedIn](https://www.linkedin.com/company/xxiicentury).

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