22nd Century Technology is a “Game Changer”

FDA plan to reduce nicotine in cigarettes to non-addictive levels “could save more lives than any other act of a governmental agency in all of human history.”

68% of surveyed adults in the United States believe government should mandate that all cigarettes have very low, non-addictive levels of nicotine.

CLARENCE, N.Y.--(BUSINESS WIRE)-- 22nd Century Group, Inc. (NYSE American: XXII), a plant biotechnology company that is focused on tobacco harm reduction, announced today that a growing number of independent scientists specializing in tobacco harm reduction are publicly proclaiming that the FDA’s recently announced plan to reduce nicotine to non-addictive levels in cigarettes will drastically improve public health.

Noted experts have proclaimed that Very Low Nicotine cigarettes will “end the combustible tobacco epidemic” and “could save more lives than any other act of a governmental agency in all of human history.”

Dr. Neal Benowitz, a tobacco science expert and a professor at the University of California, San Francisco School of Medicine, wrote an article published on August 15, 2017 in the Annals of Internal Medicine entitled “Comprehensive Nicotine Regulation to End the Combustible Tobacco Epidemic.” In the perspective article, Dr. Benowitz states that an FDA-mandated 95% reduction in nicotine content would “make it impossible to compensate by smoking cigarettes more intensively or smoking more per day.” Like many other health experts, Dr. Benowitz recognizes that compensatory smoking does not occur when the nicotine content of combustible cigarettes is reduced by 95% as compared to conventional cigarettes. 22nd Century is the only company in the world that is capable of growing tobacco with nicotine levels of just 0.4mg per gram of tobacco – a 95% reduction in nicotine.

The vast majority of public health advocates, tobacco control experts, and scientists have widely embraced the FDA’s proposed nicotine policy. In fact, outside of “Big Tobacco” companies, few critics of the nicotine reduction plan have emerged and the FDA has now strongly affirmed its regulatory authority for cigarette product standards. On August 16, 2017, Scott Gottlieb, M.D., the Commissioner of the FDA and Mitchell Zeller, J.D., the Director of FDA’s Center for Tobacco Products, released an article entitled, “A Nicotine-Focused Framework of Public Health.” Published in The New England Journal of Medicine (NEJM), the article spells out the FDA’s regulatory authority for mandating non-addictive levels of nicotine in combustible cigarettes. Gottlieb and Zeller point to the 2009 Tobacco Control Act that authorizes the FDA to establish tobacco product standards that are appropriate for the protection of public health. The NEJM article states, the agency has “clear authority” [emphasis added] to reduce nicotine levels. On the issue of compensatory smoking, the authors state that, “FDA will be led by the science” and they reference several independent clinical studies that suggest minimum compensation when smokers use 22nd Century’s proprietary Very Low Nicotine research cigarettes. Gottlieb and Zeller reference a recent 6-week study by Donny, et al. that showed that “cigarettes with lower nicotine content reduced nicotine exposure and dependence, as well as the number of cigarettes smoked, as compared with cigarettes with standard nicotine levels.” [emphasis added]

In their concluding paragraph, Commissioner Gottlieb and Director Zeller highlight the ultimate goal of a nicotine mandate: “The public health benefits of implementing a nicotine-reduction policy for combustible cigarettes could be enormous: we would expect smoking-related morbidity and premature mortality to decrease considerably.”

Dr. Benowitz, Commissioner Gottlieb and Director Zeller are not alone in their determination to regulate nicotine. In a May 2017 survey conducted by Harris Poll online, 68% of more than 2,000 adults across the United States voiced support for government to mandate that all cigarettes have very low, non-addictive levels of nicotine. A similar percentage of surveyed adults in Japan (73%), Australia (77%), Canada (76%) and the United Kingdom (76%) also agreed that their governments should mandate very low, non-
On August 22, 2017, Stanford professor, Robert N. Proctor, Ph.D., authored an editorial published in Tobacco Control entitled, "FDA’s new plan to reduce the nicotine in cigarettes to sub-addictive levels could be a game-changer." Professor Proctor reasons that limiting cigarettes to non-addictive levels of nicotine is a moral imperative when he asserts: “Smokers would be able to start or quit at will, without suffering the robbery of choice that defines addiction.” The Tobacco Control editorial argues, convincingly, that the new FDA plan “could save more lives than any other act of a government agency in all of human history. The magnitude of the harms is that great. We hear a lot about tobacco endgames: this one could be a game-changer.” [emphasis added]

In recognition and acceptance of this inevitable, upcoming paradigm shift in the combustible tobacco market, the Chief Executive Officer of Philip Morris International (PMI), Andre Calatzopoulos, stated in an article published by Reuters on August 22, 2017 and entitled “Philip Morris International CEO Cheers U.S. FDA Tobacco Proposal,” that PMI was actually “extremely encouraged” by the FDA’s recent proposal to lower nicotine levels in cigarettes and called it “one of the best articulated positions in many years” that does not require “litigation or anything of this nature.”

“More than $100 Million of independent research has demonstrated that 22nd Century’s proprietary Very Low Nicotine tobacco could save many millions of lives and will prevent future generations of young people from becoming addicted to cigarettes,” explained Henry Sicignano, III, President and Chief Executive Officer of 22nd Century Group. “22nd Century’s technology is proven. The FDA plan is already feasible. The time to implement a mandate of Very Low Nicotine tobacco in all combustible cigarettes sold in the United States has arrived.”

About 22nd Century Group, Inc.

22nd Century is a plant biotechnology company focused on genetic engineering and plant breeding which allows the increase or decrease of the level of nicotine in tobacco plants and the level of cannabinoids in cannabis plants. The Company’s primary mission in tobacco is to reduce the harm caused by smoking. The Company’s primary mission in cannabis is to develop proprietary hemp/cannabis strains for important new medicines and agricultural crops. Visit www.xxiicentury.com and www.botanicalgenetics.com for more information.

Cautionary Note Regarding Forward-Looking Statements: This press release contains forward-looking information, including all statements that are not statements of historical fact regarding the intent, belief or current expectations of 22nd Century Group, Inc., its directors or its officers with respect to the contents of this press release, including but not limited to our future revenue expectations. The words “may,” “would,” “will,” “expect,” “estimate,” “anticipate,” “believe,” “intend” and similar expressions and variations thereof are intended to identify forward-looking statements. We cannot guarantee future results, levels of activity or performance. You should not place undue reliance on these forward-looking statements, which speak only as of the date that they were made. These cautionary statements should be considered with any written or oral forward-looking statements that we may issue in the future. Except as required by applicable law, including the securities laws of the United States, we do not intend to update any of the forward-looking statements to conform these statements to reflect actual results, later events or circumstances, or to reflect the occurrence of unanticipated events. You should carefully review and consider the various disclosures made by us in our annual report on Form 10-K for the fiscal year ended December 31, 2016, filed on March 8, 2017, including the section entitled “Risk Factors,” and our other reports filed with the U.S. Securities and Exchange Commission which attempt to advise interested parties of the risks and factors that may affect our business, financial condition, results of operation and cash flows. If one or more of these risks or uncertainties materialize, or if the underlying assumptions prove incorrect, our actual results may vary materially from those expected or projected.


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