



April 20, 2021

## 22nd Century Fully Prepared to Deliver the Solution as Biden Administration Considers Requirement to Lower Nicotine Level for All Cigarettes Sold in U.S.

- *Company's Confidence Continues to Grow on Implementation of Proposed Nicotine Cap and Menthol Ban*
- *Company is Fully Prepared to Launch its VLN<sup>®</sup> Reduced Nicotine Content Cigarettes; Willing to License Reduced Nicotine Technology to Big Tobacco to Save Millions of American Lives*
- *Science Behind Benefits of Reduced Nicotine Content Cigarettes Is Conclusive; No Signs of Compensatory Smoking*

BUFFALO, N.Y., April 20, 2021 (GLOBE NEWSWIRE) -- 22nd Century Group, Inc. (NYSE American: [XXII](#)), a leading plant-based, biotechnology company that is focused on tobacco harm reduction, very-low nicotine content tobacco, and hemp/cannabis research, reports that it is fully prepared to partner with the U.S. Food and Drug Administration (FDA) to launch its VLN<sup>®</sup> reduced nicotine content cigarette brand and license its reduced nicotine content (RNC) tobacco technology to every cigarette manufacturer. This follows reports in the media ([WSJ](#)) that the Biden Administration is actively considering moving forward the Advance Notice of Proposed Rulemaking ([ANPRM](#)) that will require Big Tobacco to reduce the amount of nicotine in all combustible cigarettes sold in the United States to be "minimally or non-addictive" – a level already achieved in the first—and only—combustible RNC cigarette product already authorized for sale by the FDA, which contains 95% less nicotine than conventional cigarettes.

22nd Century remains confident that the new Administration is placing a high focus on public health, particularly respiratory health, as a critical initiative, while the battle with COVID-19 continues and new variants arise. Smokers who contract COVID-19 are more likely to be hospitalized, admitted to the ICU, suffer worse outcomes, or die from the virus. [If implemented, FDA's nicotine cap would help 5 million adult smokers quit within one year, help 33 million people – mostly youth and young adults – avoid becoming regular smokers, and save more than 8 million American lives by the end of the century.](#) The renewed interest by FDA follows recent statements by President Biden and the Administration supportive of a nicotine cap, including its war on cancer, the appointment and confirmation of Xavier Becerra as the new Secretary of HHS, and a [groundswell of support](#) for a reduced nicotine cap from multiple former FDA Commissioners.

"A nicotine cap by the FDA has been in the works since the Obama Administration. During that time, 22nd Century has consistently proven beyond any doubt with our VLN<sup>®</sup> cigarettes that a cigarette that contains nicotine levels that the FDA has identified as 'minimally or non-addictive' is technically feasible. Moreover, given the millions of Americans who smoke and will suffer and die from cigarette addiction, this mandate is necessary and appropriate," said James A. Mish, chief executive officer of 22nd Century Group. "As **the only company** with the ability to offer a combustible tobacco product that can meet the FDA's mandate today, we look forward to helping with this critical public health initiative. Numerous independent research studies—largely funded by U.S. government agencies—have consistently confirmed the benefits of implementing a mandate on reduced nicotine content cigarettes for adult smokers. Once this rule is in place, we are fully prepared to provide the solution by making our VLN<sup>®</sup> cigarettes available to adult smokers, and we remain willing to license our technology to every cigarette manufacturer in the industry to give them the opportunity to join us in our efforts to reduce the harm caused by smoking and to protect future generations from ever becoming addicted to cigarettes."

The FDA is being sued by a group of tobacco control and public health groups for its failure to advance regulation against menthol in highly addictive tobacco products. As part of this action, the Agency must respond to an earlier [citizens' petition to ban menthols](#) no later than April 29, 2021. FDA was also petitioned by leading public health experts to advance its nicotine cap as part of FDA's wider [Comprehensive Plan for Tobacco and Nicotine Regulation](#), announced in 2017.

According to the Centers for Disease Control and Prevention (CDC), studies have shown that menthol in cigarettes likely leads people – especially young people – to experiment with smoking, which could increase the risk of becoming nicotine dependent. Further, research has shown that adults who smoke menthol cigarettes make more attempts to quit smoking and have a harder time quitting, and that menthol cigarettes contribute to the profound tobacco-related health disparities seen in the U.S. 22nd Century believes that making all menthol cigarettes non-addictive is a good solution but that making **all** cigarettes non-addictive is an even better solution. 22nd Century's reduced nicotine content (RNC) cigarettes, VLN<sup>®</sup> King and VLN<sup>®</sup> Menthol King, contain levels of nicotine content that are "minimally or non-addictive", unlike conventional cigarettes that are "designed to create and sustain addiction to nicotine." Whatever is decided, 22nd Century is fully prepared to deliver the solution.

As part of the FDA's Comprehensive Plan, the Agency included a proposed a product standard to reduce the nicotine content in all cigarettes sold in the U.S. to "minimally or non-addictive" levels. A reduction in the amount of nicotine content allowed in cigarettes is supported by a [report](#) published by the CDC that found that 80% of adult smokers favor requiring cigarette makers to lower nicotine levels in cigarettes, so that they are less addictive.

The ANPRM that President Biden's Administration is considering moving forward was issued in March of 2018, and the comment period closed in June of 2018. The FDA will likely issue a notice of proposed rulemaking (NPRM) as the next step in the rulemaking process before a final rule is published. The Agency's proposed mandate is well studied and is backed by what 22nd Century estimates to be more than \$100 million in independent scientific studies, funded largely by the FDA, the National Institutes of Health (NIH), and other U.S. federal government agencies.

These numerous clinical studies have demonstrated, conducted using 22nd Century's reduced nicotine content research cigarettes, that using reduced nicotine content tobacco cigarettes helps smokers reduce their nicotine exposure and dependence, smoke fewer cigarettes per day, increase their number of smoke-free days, and double their quit attempts – [all with minimal or no evidence of nicotine withdrawal or compensatory smoking](#) .

Although many alternative nicotine products are available to smokers -- including vape, IQOS, and nicotine pouches, patches, and gum -- cigarette smoking remains the leading cause of preventable disease, disability and death in the U.S., accounting for one in every five deaths.

Despite the tobacco industry's stated claims of wanting to create a world without cigarettes, including Altria's slogan of "[moving beyond smoking](#)" and "[from tobacco company to tobacco harm reduction company](#)," and Philip Morris International's "[delivering a smoke-free future](#)" mantra, Big Tobacco seems to be interested only in products that create and sustain addiction **regardless of the costs to society and public health** . Rather than joining the FDA's efforts to combat cigarette addiction, Big Tobacco has continued to mislead the public by raising points that are long disproved by extensive research, such as, "perhaps users will smoke cigarettes to get the same amount of nicotine."<sup>1</sup> They have also maintained that it is not possible to comply with the planned FDA reduced-nicotine mandate; this is the same industry that swore under oath that nicotine was not addictive.

Research behind the impact RNC cigarettes is extensive, conclusive, and solid, and it demands immediate action that is based on science. Public health researchers have conclusively refuted the common misperception that RNC cigarettes could cause smokers to increase their smoking, [saying](#), "Effectively compensating to maintain nicotine exposure is virtually impossible when switching to cigarettes with minimally addictive nicotine content," [and](#), "[M]andated reduction in nicotine content is unlikely to result in an increase in smoking behavior to obtain more nicotine."

In a [submission](#) to the FDA regarding the FDA's ANPRM to dramatically limit the nicotine content of cigarettes, noted scientific researchers Megan Piper, PhD, David Drobos, PhD, and Natalie Walker, PhD address the issues of smoking dependence and smoking abstinence when smokers switch exclusively to RNCs. Citing a number of scientific studies investigating nicotine dependence, these researchers explain, "...there is direct evidence that smoking reduced nicotine cigarettes is associated with reduced dependence (both self-reported dependence and dependence related criteria, such as withdrawal, cravings) and ultimately smoking abstinence."

22nd Century has proven that it is technically feasible to make a cigarette with "minimally or non-addictive" levels of nicotine, and the Company remains willing to license its RNC tobacco technology to every cigarette manufacturer, including Altria, Reynolds American, and other Big Tobacco companies, so that the entire industry can join 22nd Century's effort to reduce the harm caused by smoking and protect future generations from ever becoming addicted to cigarettes.

In December of 2019, the FDA authorized 22nd Century to sell its RNC cigarettes under the Premarket Tobacco Product Applications (PMTA) pathway. The FDA [concluded](#) that "following a rigorous science-based review", the Agency determined that these reduced nicotine products are, "appropriate for the protection of the public health"

due to its, “potential to reduce nicotine dependence in addicted adult smokers, who may also benefit from decreasing nicotine exposure and cigarette consumption.” The FDA also determined that, “[y]outh are also unlikely to start using the products, and those who experiment are less likely to become addicted than people who experiment with conventional cigarettes.”

Made from proprietary tobacco engineered to contain 95% less nicotine than conventional cigarette tobacco, 22<sup>nd</sup> Century’s RNC cigarettes are the only combustible tobacco products able to meet the nicotine levels proposed in the FDA’s ANPRM for a tobacco product standard reduce the nicotine content of all combustible cigarettes. The Company believes that it is in the final stages of the FDA’s application process to obtain a MRTP designation for its RNC cigarette, VLN<sup>®</sup> King and VLN<sup>®</sup> Menthol King. The designation will allow 22nd Century to communicate key features of the products including the headline claim of “95% less nicotine.” It will also distinguish the product from highly addictive, conventional cigarettes. Although it contains just 0.5 milligrams of nicotine per gram of tobacco, VLN<sup>®</sup> tastes, smells, and smokes like a conventional cigarette. This disruptive product is an alternative to addictive, conventional cigarettes and will help adult smokers reduce their exposure to nicotine. Based on perception studies conducted by 22nd Century, 60% of smokers are likely to use RNC cigarettes, indicating that they are ready for something new to help them change their relationship with nicotine. 22nd Century is fully prepared and eager to launch its VLN<sup>®</sup> cigarettes within 90 days of receiving authorization from the FDA and believes that an MRTP designation will serve as a catalyst for its VLN<sup>®</sup> brand and tobacco franchise.

1. Stated Emmanuel Babeau, Chief Financial Officer of Philip Morris International on April 20, 2021 on their Q1 2021 Earnings Call.

#### **About 22nd Century Group, Inc.**

22nd Century Group, Inc. (NYSE American: XXII) is a leading plant biotechnology company focused on technologies that alter the level of nicotine in tobacco plants and the level of cannabinoids in hemp/cannabis plants through genetic engineering, gene-editing, and modern plant breeding. 22nd Century’s primary mission in tobacco is to reduce the harm caused by smoking through the Company’s proprietary reduced nicotine content tobacco cigarettes – containing 95% less nicotine than conventional cigarettes. The Company’s primary mission in hemp/cannabis is to develop and commercialize proprietary hemp/cannabis plants with valuable cannabinoid profiles and desirable agronomic traits.

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#### **Cautionary Note Regarding Forward-Looking Statements**

Except for historical information, all of the statements, expectations, and assumptions contained in this press release are forward-looking statements. Forward-looking statements typically contain terms, such as “anticipate,” “believe,” “consider,” “continue,” “could,” “estimate,” “expect,” “explore,” “foresee,” “goal,” “guidance,” “intend,” “likely,” “may,” “plan,” “potential,” “predict,” “preliminary,” “probable,” “project,” “promising,” “seek,” “should,” “will,” “would,” and similar expressions. Actual results might differ materially from those explicit or implicit in forward-looking statements. Important factors that could cause actual results to differ materially are set forth in “Risk Factors” in the Company’s Annual Report on Form 10-K filed on March 11, 2021. All information provided in this release is as of the date hereof, and the Company assumes no obligation to and does not intend to update these forward-looking statements, except as required by law.

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