



April 29, 2021

Congresswoman Gwen Moore Adds Voice to Groundswell of Support for Reducing Nicotine in Cigarettes, Encourages HHS Secretary Becerra to Take Action to Save Lives and End Health Disparities

When Mandate is Implemented, 22nd Century is Fully Prepared to Deliver VLN® Reduced Nicotine Content Cigarette, the Only Combustible Product in Line with FDA’s Proposed Nicotine Cap

BUFFALO, N.Y., April 29, 2021 (GLOBE NEWSWIRE) -- 22nd Century Group, Inc. (NYSE American: [XXII](#)), a leading plant-based biotechnology company focused on tobacco harm reduction, very low nicotine content tobacco, and hemp/cannabis research, applauds Congresswoman Gwen Moore (D-WI-04) for proactively encouraging the federal government to introduce new legislation that would reduce the level of nicotine content allowed in any cigarette sold in the United States to “minimally or non-addictive” levels. In a letter to U.S. Department of Health and Human Services (HHS) Secretary Xavier Becerra, Rep. Moore states that smoking continues to kill and disable Americans and asked that the HHS use its authority under the Tobacco Control Act to put an end to the damages smoking inflicts on the population.

“22nd Century fully supports Representative Moore, and we are in complete agreement with her powerful message to Secretary Becerra. We appreciate the addition of her voice to those of our leading [public health officials](#) urging the federal government to implement a mandate to reduce the amount of nicotine content allowed in combustible cigarettes to ‘minimally or non-addictive’ levels, as proposed in 2017 by the FDA (U.S. Food and Drug Administration) in its [Comprehensive Plan for Tobacco and Nicotine Regulation](#),” said James A. Mish, chief executive officer of 22nd Century Group. “This development represents more positive news for 22nd Century and all those interested in improving public health. Earlier this month, the [New Zealand Ministry of Health - Manatū Hauora](#) issued a proposal to reduce nicotine content in all cigarettes sold in that country. And in the U.S., there are reports that the [Biden Administration is actively considering introducing a new rule](#) that would require Big Tobacco to reduce the amount of nicotine in all combustible cigarettes sold here. When a rule is published, 22nd Century is fully prepared to partner with the FDA to launch our VLN® reduced nicotine content (RNC) cigarette brand, and license our RNC tobacco technology to every cigarette manufacturer in the industry.”

In her letter to Secretary Becerra, Moore states, “The negative health effects of nicotine addiction and smoking fall more heavily on minority and low-income communities. Nowhere is this disparity greater than among low-income African-Americans.” Supporting her point, she cites statistical data from a paper in the *American Psychological Association Journal of Consulting and Clinical Psychology* that reports that 16.7% of African Americans in the U.S. are smokers, compared to 13.7% who are white. Representative Moore’s call to action comes during National Minority Health Month, which was created to build awareness about the disproportionate burden of premature death and illness in minority populations.

Moore also laments the fact that after FDA Commissioner Scott Gottlieb launched the Agency’s initiative to reduce the level of nicotine in tobacco products in 2017, it was dropped as a priority in 2019. That decision was made despite a Centers for Disease Control and Prevention (CDC) report in the same year showing that eight in 10 cigarette smokers favor a rule requiring cigarette makers to reduce the amount of nicotine in cigarettes. As head of HHS, Secretary Becerra has oversight of all operational divisions within HHS, including the FDA, and he has the authority to direct the FDA to move forward with the nicotine mandate proposed under Commissioner Gottlieb.

“It has never been clearer that cigarette addiction disproportionately harms our minority and most vulnerable communities, and extensive research supports Representative Moore’s statements that African Americans

continue to pay a heavy price, with high levels of cigarette addiction in their communities. This is no coincidence; such communities have been targeted by Big Tobacco using appropriated cultural themes and aggressive marketing and sales promotion,” said John Pritchard, vice president of regulatory science for 22nd Century Group. “With smoking rates as high as 40% in low-income communities, the time for willful ignorance is over. The FDA has the authority to address these shameful disparities: Big Tobacco and its proxies must stand aside to enable an equal, healthy and more just society for all.”

22nd Century’s VLN® cigarettes were engineered to contain 95% less nicotine than traditional cigarettes, and VLN® is the only combustible product that is in line with the FDA’s proposed nicotine cap. Numerous independent scientific studies, funded largely by the FDA, the National Institutes of Health (NIH), and other U.S. federal government agencies, have demonstrated 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.

The Company believes that it is in the final stages of the FDA’s application process to obtain a Modified Risk Tobacco Product (MRTP) designation for VLN®. The designation will allow 22nd Century to communicate key features of VLN® King and VLN® Menthol King, including a headline claim of “95% less nicotine.” Although it contains just 0.5 milligrams of nicotine per gram of tobacco, VLN® tastes, smells, and smokes like a conventional cigarette. This disruptive product is an alternative to addictive, traditional cigarettes and will help adult smokers reduce their exposure to nicotine. 22nd Century is fully prepared and eager to launch its VLN® cigarettes within 90 days of receiving authorization from the FDA and believes that an MRTP designation will serve as a catalyst for its VLN® brand and tobacco franchise. The Company remains willing to licensing its technology to every cigarette manufacturer so that Big Tobacco can join in the effort to reduce the harm caused by smoking and protect future generations from ever becoming addicted to cigarettes.

Reprint of the original letter below:

April 8, 2021

*The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201*

Dear Secretary Becerra:

I write to request, as part of the Administration's commitment to use all available tools to combat the damage to our communities by tobacco use especially among our youth, that the Department of Health and Human Services (HHS) and Federal Drug Administration (FDA) use existing authority under the Tobacco Control Act to reduce the level of nicotine in tobacco products. Even during the current COVID pandemic, the Center for Disease Control and Prevention (CDC) continues to recognize that cigarette smoking is the leading cause of preventable disease, disability, and death in the United States. Smoking continues to kill and disable Americans because of the addictive nature of nicotine contained in tobacco products.

The negative health effects of nicotine addiction and smoking fall more heavily on minority and low-income communities. Nowhere is this disparity greater than among low-income African Americans. The March 11, 2021, issue of the American Psychological Association Journal of Consulting and Clinical Psychology cites statistics showing that smoking is more prevalent among Black adults than among whites - 13.7% for whites and 16.7% for Blacks. The article says the smoking rates are as high as 40% in disadvantaged urban low-income African-American communities (smoking rates are also high among other low-income groups including whites, but the disparity is greatest in low-income Black communities). At a March 12, 2021, forum with four former FDA commissioners hosted by STAT News, former Commissioner Robert Califf stated: "tobacco use is becoming one of the most important markers of disparities in our economy and health care system."

In 2017, then FDA Commissioner Scott Gottlieb undertook an initiative to significantly reduce the level of nicotine in tobacco products as part of FDA's policy to improve public health by tackling addiction to tobacco. At that time, Dr. Gottlieb stated: "[t]he overwhelming amount of death and disease attributable to tobacco is caused by addiction to cigarettes - the only legal consumer product that used as intended will kill half of all long-term users." Unfortunately, when Dr. Gottlieb left FDA in April 2019, the agency dropped this initiative from its agenda.

*Following FDA's decision to drop reduction of nicotine in tobacco products as a priority, the American Heart Association strongly protested the change in policy. In November 2019 it said:
We are deeply disappointed the administration appears to have delayed or abandoned a plan to lower the amount of nicotine in traditional cigarettes to minimally addictive or non-addictive levels. Lowering nicotine levels in combustible tobacco products would dramatically reduce their appeal, causing tobacco use to plummet, reducing tobacco-related illness and death as a result.*

I applaud your leadership as Attorney General of California when you led the effort among state Attorneys General to advocate for stronger nicotine regulation in response to FDA's Advance Notice of Proposed Rulemaking (Notice), 83 Fed. Reg. 11818-43 (March 16, 2018), issued while Dr. Gottlieb was commissioner.

I share your commitment to the fight to reduce health disparities and to reduce the damage that tobacco use causes in our country. I urge you to move forward with the initiative to reduce nicotine in tobacco products and implore you to restore that initiative as a high priority for HHS and FDA during your term as Secretary.

Thank you for your full and fair consideration of this request.

*Sincerely,
Gwen Moore
Member of Congress*

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.

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

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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