



April 30, 2021

## **22nd Century Group Welcomes Ban on Menthol Cigarettes and Anticipates Further Standards as FDA Commissioner Reports Nicotine Cap on Combustibles “Still on the Table”**

*Applauds Decisive Move and Commitment by FDA to Advance Rule Banning Menthol As First Step to Reduce Addiction, Improve Quitting, Reduce Youth Initiation and Reduced Disparities; Movement on Nicotine Cap by FDA Expected to be Forthcoming*

*Tangible Action on Menthol Was Anticipated and Was Thursday's Best Outcome; Action on Nicotine Cap Was Not Expected At This Time as Only Menthol Was to Be Addressed Under Court Mandated April 29<sup>th</sup> Deadline*

*22nd Century Remains Extremely Positive Following FDA Decision; Calls for FDA to Move Forward on Nicotine Mandate and Grant VLN® Authorization to Advance Public Health*

BUFFALO, N.Y., April 30, 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 the U.S. Food and Drug Administration (FDA) for its decision to begin the rulemaking process to ban the use of menthol in highly addictive cigarettes. The ban clearly demonstrates the Agency's willingness to use its regulatory authority to aggressively address cigarette addiction and youth smoking initiation with a menthol product standard that will save lives and pave the way for a reduced nicotine product standard. With Thursday's action and the commitment made by the U.S. Health and Human Services Secretary Xavier Becerra in response to a congressional inquiry, 22nd Century is confident that further policy progress will be made on cigarette addiction. The Company encourages the FDA to quickly move forward with its proposed mandate to reduce the amount of nicotine used in all combustible cigarettes sold in the United States to 'minimally or non-addictive' levels, which will save millions of American lives and protect generations to come.

22nd Century remains highly confident that it is in the final stages of obtaining a Modified Risk Tobacco Product (MRTP) authorization for its VLN® King and VLN® Menthol King reduced nicotine content (RNC) cigarettes, the only combustible tobacco products able to meet the nicotine level in the FDA's proposed mandate. It is imperative that VLN® Menthol King cigarettes remain on the market after a menthol rule is implemented to help menthol smokers reduce their consumption and quit highly addictive menthol cigarettes while mitigating risks of illicit markets and product adulteration. 22nd Century is willing to license its RNC cigarette technology to enable the entire industry to comply with a menthol ban that allows the continued sale of reduced nicotine menthol cigarettes.

"We are absolutely thrilled with yesterday's news and anticipated and hoped for this outcome. Right now, we have the best of both worlds when it comes to a solution to improve public health," said James A. Mish, chief executive officer of 22nd Century Group. "The FDA is now making tangible movement on menthol as was expected, and just last week, the Wall Street Journal reported that the [Biden Administration is actively considering moving forward with a nicotine cap](#). Dr. Janet Woodcock, Acting FDA Commissioner, [confirmed these reports](#), saying that a low nicotine product standard is 'still on the table'. This would require Big Tobacco to reduce the amount of nicotine in all combustible cigarettes. Projections show that when the FDA implements its nicotine cap it would help five million adult smokers to quit within one year, help 33 million people to avoid becoming regular smokers, and save more than eight million American lives by the end of the century. We are fully prepared to launch our VLN® cigarettes when 22nd Century obtains MRTP authorization and, as the low nicotine product standard advances, willing to license our reduced nicotine technology to every cigarette manufacturer to enable public health to be advanced by all responsible manufacturers."

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, increasing 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, contributing to the profound tobacco-related health disparities seen in the U.S. today.

Menthol is a pharmacological active flavor additive that provides the perception of a cooling effect when used in cigarettes, which the FDA concludes, has led to more people becoming addicted to smoking. In fact, a report from the FDA estimates that nearly 18.6 million Americans smoke menthol cigarettes, and use among minorities is the highest with more than 85% of African Americans, 46% of Hispanics, and 39% of Asian smokers use menthol cigarettes, compared to roughly 29% of white smokers.

“Our African American communities have much higher rates of menthol cigarette addiction than the adult population as a whole, following decades of cynical, targeted marketing,” said John Pritchard, vice president of regulatory science at 22nd Century Group. “We are firmly committed to playing our part to end the appalling health disparities created and compounded by cigarette addiction across the U.S. Our VLN® King and Menthol King cigarettes have been developed for current adult smokers who are seeking to reduce their consumption of nicotine. The FDA has already [established that](#) the same product is ‘appropriate for the protection of public health’ under the PMTA pathway, concluding that, ‘among several key considerations, the potential to reduce nicotine dependence in addicted adult smokers, who may also benefit from decreasing nicotine exposure and cigarette consumption.’ The Agency has determined that non-smokers, including youth, 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.”

22nd Century believes that banning menthol cigarettes as well as the announced proposals for a product standard on flavored cigars are important steps. However, the public health benefits of menthol regulation are dwarfed by those that would be achieved from making all cigarettes non-addictive. 22nd Century’s VLN® cigarettes contain 95% less nicotine than traditional cigarettes and are 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.

#### **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](http://xxiicentury.com), on Twitter [@xxiicentury](https://twitter.com/xxiicentury), and on [LinkedIn](#).

#### **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.

#### **Investor Relations & Media Contact:**

Mei Kuo  
Director, Communications & Investor Relations  
22nd Century Group, Inc.  
(716) 300-1221  
[mkuo@xxiicentury.com](mailto:mkuo@xxiicentury.com)



Source: 22nd Century Group, Inc