



April 1, 2021

## Multiple Former FDA Commissioners Voice Support for Reduced Nicotine Mandate; Proposed Legislation Would Be Game-Changing for 22nd Century

- *22nd Century's Proprietary VLN<sup>®</sup> King and VLN<sup>®</sup> Menthol King Poised to Play a Central Role in Making FDA's Reduced Nicotine Mandate Feasible*
- *MRTTP Authorization of VLN<sup>®</sup> King and VLN<sup>®</sup> Menthol King Will Serve as a Major Catalyst for the FDA to Accelerate Rule*
- *Containing 95% Less Nicotine than Traditional Cigarettes, VLN<sup>®</sup> is the Only Combustible Tobacco Product that Complies with the FDA's Proposed Nicotine Cap*

WILLIAMSVILLE, N.Y., April 01, 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, announced today that it continues to be confident on the renewal of the FDA's proposed reduced nicotine mandate that would make all cigarettes "minimally or non-addictive." By way of support, four former U.S. Food and Drug Administration (FDA) commissioners, Robert M. Califf, M.D. MACC; Scott Gottlieb, M.D.; Peggy Hamburg, M.D.; and, Jane Henney, M.D., spoke on a recent [panel](#) and were vocal in their endorsement of the mandate to limit the amount of nicotine in cigarettes to levels already achieved by 22nd Century's reduced nicotine content cigarettes, [VLN<sup>®</sup>](#).

During the panel discussion, Dr. Gottlieb, who first established the FDA's [Comprehensive Plan for Tobacco and Nicotine Regulation](#) in 2017, remarked: "[c]ertainly if a Republican administration can begin a process to regulate nicotine in combustible tobacco, I suspect that it's going to be taken forward by a Democratic administration." Dr. Hamburg also pointed out that, "[n]ow is the time...to really address a whole range of [tobacco] issues that [the] FDA is now empowered to act on."

"Coming from such a group of experienced and authoritative assembly of public health figures, the comments made during the STAT webcast are a powerful endorsement of the FDA's plan to implement a reduced nicotine product standard," said James A. Mish, chief executive officer at 22nd Century. "Over the past year, COVID-19 has brought the criticality of respiratory health to the forefront of public concerns. The FDA has the authority and responsibility to change the trajectory of public health in the U.S., save millions of lives, and protect future generations from addiction by enacting a reduced nicotine mandate. We believe that the Agency will advance their Comprehensive Plan and soon announce its simple, yet powerful reduced nicotine product standard. This will be a grand slam for 22nd Century."

22nd Century shares the former FDA Commissioners' enthusiasm. With the recent change in administration at the White House, and Democratic control of both the Senate and the House of Representatives, the Company believes there will be a high focus on improving public health moving forward. The Biden administration is placing public health as a top priority and recently issued a [proclamation](#) "strongly committing to improving the prevention and treatment of cancer." In addition, the appointment of Xavier Becerra as Secretary of the U.S. Department of Health and Human Services (HHS), a long-time proponent of tougher regulation for the tobacco industry, further points to a favorable political climate for the renewal of the reduced nicotine mandate that is projected to [help](#) more than five million people to quit smoking within the first year of implementation and save more than eight million American lives by the end of the century.

Made from tobacco engineered by 22nd Century to contain 95% less nicotine than traditional cigarettes, VLN<sup>®</sup> is the only combustible product that complies 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<sup>®</sup>. The designation will allow 22nd Century to communicate key features of VLN<sup>®</sup> King and VLN<sup>®</sup> Menthol King, including a headline claim of "95% less nicotine." Although VLN<sup>®</sup> 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 innovative 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<sup>®</sup> cigarettes within 90 days of receiving authorization from the FDA and believes that a MRTP designation will serve as a catalyst for its VLN<sup>®</sup> brand and tobacco franchise. The Company also remains willing to license its technology to enable every cigarette manufacturer to comply with the FDA's proposed nicotine cap that will significantly reduce the harm caused by smoking and protect future generations from ever becoming addicted to cigarettes.

#### **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](#), 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)



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