



April 26, 2021

## 22nd Century Delivers 3.6 Million Variable Nicotine Content Research Cigarettes for Independent Scientific Studies

*To Date, 22nd Century Has Provided More Than 31 Million Variable Nicotine Content Research Cigarettes for Numerous Independent Scientific Studies*

*Research on Nicotine Content Reduction in Cigarettes Underpins the FDA's Proposed Mandate to Reduce Nicotine Levels in All Cigarettes Sold in the U.S. to "Minimally or Non-Addictive" Levels, a Feat Already Achieved by VLN®*

*Delivery of Research Cigarettes is to Support Nicotine Cap Mandate and is Unrelated to 22nd Century's Modified Risk Tobacco Product (MRTP) Application for VLN® Cigarettes*

BUFFALO, N.Y., April 26, 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 has fulfilled an order for 3.6 million of its variable nicotine content research cigarettes. These research cigarettes are destined for use in important independent, scientific studies funded largely by the U.S. Food and Drug Administration (FDA), and other federal government health agencies. Research already completed using 22nd Century's variable nicotine content research cigarettes has revealed substantial public health benefits for implementing a national standard requiring all cigarettes to contain "minimally or non-addictive" levels of nicotine. Notably, 22nd Century's commercially focused VLN® cigarettes with 95% less nicotine already achieve this ambitious goal.

"We are proud to play a central role in supporting public health advancement by providing our variable nicotine content cigarettes for research," said James A. Mish, chief executive officer of 22nd Century Group. "We recognize that the FDA needs to carefully consider many different health aspects before introducing its mandate. It is significant that results from so many independent research studies—largely funded by U.S. government agencies—have already consistently confirmed the benefits of implementing a mandate on reduced nicotine content (RNC) cigarettes for adult smokers. That fact, along with continuing [public support from senior public health figures](#), should indicate to the FDA that **now** is the time to act and move forward with its proposed mandate to reduce the nicotine content of all cigarettes sold in the U.S. to 'minimally or non-addictive' levels. Millions of American lives would be saved by doing so. When the mandate is implemented, 22nd Century is fully prepared to deliver the solution by making our VLN® cigarettes available to adult smokers and to license our reduced nicotine technology so that every cigarette manufacturer in the industry can comply in the interest of saving lives."

In addition to growing public support, recent reports indicate that the Biden Administration is actively considering moving forward the FDA's Advanced Notice of Proposed Rulemaking ([ANPRM](#)) that will require Big Tobacco to reduce the amount of nicotine in all combustible cigarettes sold in the U.S. Considering these reports, 22nd Century is confident that the new Administration is placing a high focus on public health, particularly respiratory health, as a critical initiative. In addition, David Kessler, who was the first FDA commissioner to call for a cap on the amount of nicotine allowed in combustible cigarettes, is now a senior adviser to the Biden administration on scientific matters. That fact, along with the appointment of Xavier Becerra as Secretary of the U.S. Department of Health and Human Services, a long-time proponent of tougher regulation for the tobacco industry, are additional favorable signs.

"The lowest nicotine level style of our variable nicotine content research cigarettes accounted for a sizable portion of our recent order and were selected for a very specific reason. This style contains as little as 0.5 milligrams of nicotine per gram of tobacco, the same level in our VLN® cigarettes, and a level that the FDA has identified as 'minimally or non-addictive'. The science has already established that people who use these products reduce the number of cigarettes they consume without increasing the intensity of smoking, as well as increase their smoke-free days and double their quit attempts," said Michael Zercher, chief operating officer at 22nd Century. "Fulfilling orders of this size demonstrate 22nd Century's ability to deliver mass quantities of our reduced nicotine content

cigarettes and the technical feasibility of a product standard for all products in the U.S. to be 'minimally or non-addictive'."

Made from proprietary tobacco engineered to contain 95% less nicotine than conventional cigarette tobacco, 22nd Century's RNC cigarettes already meet the nicotine levels proposed in the FDA's Advance Notice of Proposed Rulemaking (ANPRM) for a tobacco product standard that requires all combustible cigarettes to contain "minimally or non-addictive" levels of nicotine. Numerous independent scientific studies have demonstrated that using RNC 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 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 an [Modified Risk Tobacco Product \(MRTP\)](#) designation for VLN®. The delivery of these research cigarettes is to support the nicotine cap mandate and is unrelated to 22nd Century's MRTP application for VLN®. The designation will allow 22nd Century to communicate key features of VLN® King and VLN® Menthol King, including the headline claim of "95% less nicotine." Although VLN® 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 innovative alternative to addictive, conventional 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 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.

#### **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