



January 18, 2022

## **22nd Century Launching the First Reduced Nicotine Cigarette Authorized by the FDA That Helps You Smoke Less**

- FDA Mandates Addition of Extra Claim “Helps You Smoke Less” on Packaging
- U.S. Pilot Market Launch with Major Retail Partner by March 2022

BUFFALO, N.Y., Jan. 18, 2022 (GLOBE NEWSWIRE) -- On December 23, 2021 the FDA announced an historic landmark decision in the fight against smoking when it authorized VLN® King and VLN® Menthol King from 22nd Century Group, Inc. (Nasdaq: [XXII](#)) as the first and only reduced nicotine content (RNC) cigarettes under its Modified Risk Tobacco Product (MRTP) designation. Scientific studies show the Company’s VLN® reduced nicotine content cigarettes “help you smoke less.” 22nd Century is now moving aggressively to bring VLN® to market. A pilot launch will begin in its first major metropolitan market by March 2022 and then marketing and distribution is expected to expand to a full nationwide launch.

The FDA decision on VLN® is a major event for public health in the fight to reduce the harm caused by smoking. Not only did 22nd Century receive the MRTP authorization based on its application requests, the FDA proactively added an extra and incredibly valuable claim of “Helps You Smoke Less” mandated on every package to educate the consumer about the product’s benefit.

VLN® King and VLN® Menthol King are the only FDA authorized reduced nicotine content combustible cigarettes in the U.S. tobacco products market, estimated at approximately \$80 billion in size.

“The FDA’s MRTP authorization of VLN® ushered in a new reality – a combustible cigarette carrying an authorized harm reduction claim supported by extensive scientific and clinical studies, most of which were funded by federal health agencies,” said James A. Mish, Chief Executive Officer. “VLN is the only reduced harm product of its kind, and we are confident based on the research that it can absolutely be successful on its own or in combination with other harm reduction products. With an estimated 1,300 deaths per day associated with U.S. smoking, our products that can help people smoke less offer a truly a game-changing prospect for millions of American adults who currently smoke.”

22nd Century intends to commence its pilot market launch in March 2022 in order to test and optimize its marketing mix educating smokers about the benefits of reduced nicotine content VLN® King and VLN® Menthol King cigarettes. The pilot will help the Company better understand how adult smokers will use this unique and revolutionary product prior to advancing to national distribution, providing an unmatched tool for helping adult smokers find an off-ramp from nicotine addiction.

“22nd Century has secured a well-known national retail partner for VLN®’s pilot market launch phase,” said Mish. “We intend to deploy and test a wide array of marketing materials aimed at adult smokers looking for ways to help them smoke less. These will include marketing at the point of sale, direct materials sent to self-identified adult smokers interested in VLN® and online resources such as our new product site at [tryvln.com](http://tryvln.com).”

Research indicates that nearly 70% of the estimated 34 million adult smokers in the U.S. want to quit and more than 60% of adult smokers in our research have told us they are likely to try VLN®, including many adult smokers not seeking to quit.

Additionally, 22nd Century is engaged in ongoing discussions with other potential partners – both retail and strategic – interested in helping to introduce reduced nicotine content products using 22nd Century’s proprietary tobacco to adult smokers.

While 22nd Century owns or controls the intellectual property that makes VLN® tobacco possible, the company has reiterated its willingness and expectation to license the technology to strategic partners to help ensure availability to the maximum number of adult smokers in the U.S. and worldwide as quickly as possible in support

of broader public health goals established by the U.S. FDA and other agencies.

The Company intends to update its progress toward the launch of its pilot market over the coming weeks.

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

22nd Century Group, Inc. (Nasdaq: [XXII](#)) is a leading agricultural biotechnology company focused on tobacco harm reduction, reduced nicotine tobacco and improving health and wellness through plant science. With dozens of patents allowing it to control nicotine biosynthesis in the tobacco plant, the Company has developed proprietary reduced nicotine content (RNC) tobacco plants and cigarettes, which have become the cornerstone of the [FDA's Comprehensive Plan](#) to address the widespread death and disease caused by smoking. The Company received the first and only FDA MRTP authorization of a combustible cigarette in December 2021. In tobacco, hemp/cannabis, and hop plants, 22nd Century uses modern plant breeding technologies, including genetic engineering, gene-editing, and molecular breeding to deliver solutions for the life science and consumer products industries by creating new, proprietary plants with optimized alkaloid and flavonoid profiles as well as improved yields and valuable agronomic traits.

Learn more at [xxiicentury.com](http://xxiicentury.com), on Twitter [@\\_xxiicentury](#), and on [LinkedIn](#).

Learn more about VLN® at [tryvln.com](http://tryvln.com).

#### **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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A photo accompanying this announcement is available at:  
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Source: 22nd Century Group, Inc

**VLN(R) Packages**



**VLN(R) Reduced Nicotine Content Cigarettes from 22nd Century Group**