

22nd Century Provides Corporate Update On Its VLN® MRTP Renewal Process – The First and Only Combustible Tobacco Product Authorized by the FDA Specifically to Help Smokers Smoke Less

Jul 10, 2025

Extensive Clinical Data Continues to Demonstrate VLN® Reduced Nicotine Content Tobacco Helps Reduce Smoking and Increase Quit Attempts

Growing List of VLN® Based Cigarette Brands Bring Non-Addictive Alternatives to the Fight Against Smoking

MOCKSVILLE, N.C., July 10, 2025 (GLOBE NEWSWIRE) -- 22nd Century Group, Inc. (Nasdaq: XXII), the only tobacco products company that has for 27 years led and continues to lead the fight against the harms of smoking driven by nicotine addiction today announces a corporate update regarding its Modified Risk Tobacco Product renewal process for its innovative VLN® reduced nicotine content products - the first and only combustible cigarette authorized by the U.S. Food and Drug Administration specifically to reduce the health harms of smoking.

Originally authorized in December 2021 and due for renewal in December 2026, a growing list of brands are using VLN® tobacco containing 95% less nicotine than conventional, highly addictive cigarettes. Decades of independent clinical research studies and an extensive list of peer reviewed publications that were included as part of the FDA's MRTP authorization process have demonstrated that smoking VLN® reduced nicotine content cigarettes lowers the amount of addictive nicotine consumed, can reduce the rate of smoking, increase quit attempts by smokers and reduce the health harms of smoking. Based on independent clinical research studies included in the original MRTP decision, FDA authorized VLN® claims include:

- "95% less nicotine"
- "Helps reduce your nicotine consumption"
- "Greatly reduces your nicotine consumption"
- "Helps you smoke less"

"Our MRTP authorization for VLN® cigarettes stands apart as one of the most unique and innovative tools in the tobacco industry leading the fight in Tobacco Harm Reduction to reduce the health harms of smoking. Nicotine is a highly addictive substance and the FDA's clinically documented affirmation that reducing the nicotine content of combusted tobacco to nonaddictive levels can reduce smoking behaviors, leading to more quit attempts and improved public health outcomes, could be the most important public health decision in decades," said Larry Firestone, Chief Executive Officer of 22nd Century Group. "With a growing list of brands, products and patented tobacco plant varieties under the VLN® umbrella, we intend to give smokers as many low nicotine alternatives as possible to help them control their nicotine intake to potentially use less tobacco and achieve their personal health goals."

"Additionally, Our VLN® cigarette is the only product that meets the FDA's guideline for low nicotine based on its proposed low nicotine mandate issued in January 2025." Said Firestone. "While the FDA's mandate has not yet become a final ruling, we expect that the FDA will fully support our MRTP renewal for VLN®."

The renewal process is part of 22nd Century's ongoing R&D programs that continue to advance reduced nicotine content in tobacco and support the introduction of additional VLN® based products that give tobacco users further health oriented non-addictive alternatives to conventional tobacco products, as well as to new nicotine delivery products that are designed to create and sustain nicotine addiction.

About 22nd Century Group, Inc.

22nd Century Group is the pioneering nicotine harm reduction company in the tobacco industry enabling smokers to take control of their nicotine consumption.

We created our flagship product, the VLN[®] cigarette, to give traditional cigarette smokers an authentic and familiar alternative that helps them take control of their nicotine consumption. VLN[®] cigarettes have 95% less nicotine than the traditional cigarette and have been proven to allow consumers to greatly reduce their nicotine consumption. Instead of offering new ways of delivering nicotine to addicted smokers, we offer smokers the option to take control of their nicotine consumption and make informed and more productive choices, including the choice to avoid addictive levels of nicotine altogether.

Our proprietary reduced nicotine tobacco blends are made possible by comprehensive and patented technologies and tobacco plants that regulate nicotine biosynthesis activities in the tobacco plant, resulting in full flavor and high yield with 95% less nicotine. Our extensive patent portfolio has been developed to ensure we have the only low nicotine combustible cigarette in the United States and critical international markets.

VLN[®] is a registered trademark of 22nd Century Limited LLC.

Learn more at xxiicentury.com, on [X \(formerly Twitter\)](#), on [LinkedIn](#), and on [YouTube](#).

Learn more about VLN[®] at 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, including but not limited to our full year business outlook. 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. Forward-looking statements include, but are not limited to, statements regarding (i) our cost reduction initiatives, (ii) our expectations regarding regulatory enforcement, including our ability to receive an exemption from new regulations, (iii) our financial and operating performance and (iv) our expectations for our business interruption insurance claim. 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 20, 2025, and in the Company's Quarterly Reports filed on May 13, 2025. 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

Matt Kreps

Investor Relations

22nd Century Group

mkreps@xxiicentury.com

214-597-8200