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22nd Century Group's FDA Advisory Committee Meeting for Reduced Nicotine Content Cigarettes Brings New Standard for the Tobacco Industry

22nd Century Group seeks Modified Risk Tobacco Product marketing authorization for its VLN[®] and VLN[®] Menthol Reduced Nicotine Tobacco Products

WILLIAMSVILLE, N.Y.--(BUSINESS WIRE)-- [22nd Century Group](#), Inc. (NYSE American: XXII)—a plant biotechnology company that is a leader in tobacco harm reduction, reduced nicotine tobacco, and hemp/cannabis plant research—will present the Company's Modified Risk Tobacco Product (MRTP) application for its reduced nicotine content cigarettes to the U.S. Food and Drug Administration's [Tobacco Product Scientific Advisory Committee](#) (FDA TPSAC) on Friday, February 14, 2020. This meeting will be the first TPSAC meeting to review a combustible tobacco product application, and the first time it has reviewed a modified exposure claim application.

Committee experts from across public health and medicine will hear from 22nd Century Group and the FDA about 22nd Century's MRTP application and will then discuss specific areas of interest to the FDA. The Company's MRTP applications seek a reduced exposure marketing authorization from the FDA to allow 22nd Century's reduced nicotine content cigarettes to be marketed under the brand name "VLN[®]" with pack and advertising claims stating that the cigarettes contain "95% Less Nicotine" than conventional tobacco cigarettes, as well as related claims.

Mike Zercher, President of 22nd Century Group, explained: "The presentation of our MRTP application to the FDA's Scientific Advisory Committee is yet another milestone in the Company's mission to make available reduced nicotine content products to adult smokers." Zercher continued: "22nd Century is poised to significantly disrupt the \$100 billion U.S. tobacco industry. Our research shows VLN[®] strongly appeals to adult smokers, and importantly from a public health perspective, former and never smokers have little interest in the product."

John Pritchard, Vice President of Regulatory Science for 22nd Century Group, who will lead the Company's presentation to TPSAC, explained: "Over recent years, 22nd Century has invested millions of dollars and countless hours to create and submit comprehensive, science-based applications to FDA for these first-of-their-kind tobacco products. These applications are supported by well over \$100 million of independent clinical research conducted at leading institutions and major universities in the United States and elsewhere.

"Late last year, we secured an FDA [authorization](#) for our Moonlight[®] and Moonlight[®] Menthol brand of reduced nicotine content cigarettes by meeting the PMTA regulatory requirements," continued Pritchard. "This week, we look forward to presenting an overview of our modified exposure claim application to the FDA's scientific advisory committee. We believe that all adult smokers have the right to know that our VLN[®] products have 95% less nicotine than conventional cigarettes; an authorization under the MRTP regulatory pathway will enable this. Moreover, receiving an FDA authorization for VLN[®] will further advance FDA's stated goal of achieving a reduced nicotine product standard for all cigarettes sold in the United States, which would be truly game-changing for public health."

22nd Century's reduced nicotine cigarettes enable smokers to experience the same taste and smell as they would smoking conventional cigarettes but with minimal exposure to nicotine. The FDA's own [assessment](#) of its [plan](#) to regulate nicotine to levels already achieved in VLN[®] would lead to 5 million additional adult smokers quitting one year after implementation with over 8 million American lives saved by the end of this century.

The public is invited to attend the Tobacco Product Scientific Advisory Committee meeting in Building 31 at the FDA White Oak Campus (Silver Spring, MD). The meeting also will be [webcast](#). Meeting details can be found on the FDA's website at <https://www.fda.gov/advisory-committees/tobacco-products-scientific-advisory->

[committee/2020-tpsac-meeting-materials-and-information#agenda](#)

About 22nd Century Group, Inc.

22nd Century Group is a plant biotechnology company focused on technologies that allow it to regulate the level of nicotine in tobacco plants and the level of cannabinoids in hemp/cannabis plants through genetic engineering and modern plant breeding. The Company's primary mission in tobacco is to reduce the harm caused by smoking by bringing to market reduced nicotine content cigarettes with 95% less nicotine than conventional cigarettes. The Company's primary mission in hemp/cannabis is to develop proprietary hemp/cannabis plants with unique cannabinoid profiles and desirable agronomic traits. Visit <https://xxiicentury.com> for more information.

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