



April 30, 2019

22nd Century's Pre-Market Tobacco Application for VLN™ Cigarettes Advances with Completed FDA Inspection

FDA Inspection is an important milestone for 22nd Century's VLN™ Cigarettes

WILLIAMSVILLE, N.Y.--(BUSINESS WIRE)-- 22nd Century Group, Inc. (NYSE American:[XXII](#)), a plant biotechnology company that is a world leader in tobacco harm reduction, Very Low Nicotine Content tobacco, and hemp/cannabis research, announced today that last week the U.S. Food and Drug Administration (FDA) conducted a comprehensive inspection of the Company's manufacturing facility in North Carolina as a part of the FDA's review of 22nd Century's Pre-Market Tobacco (PMT) application for the Company's VLN™ cigarettes. 22nd Century's proposed VLN™ cigarettes are made with the Company's proprietary Very Low Nicotine Content (VLNC) tobacco.

In December of 2018, the Company submitted Modified Risk Tobacco Product (MRTP) and related PMT applications to the FDA for the Company's VLNC cigarettes. Together, these important applications seek the FDA's authorization to commercialize the Company's VLN™ cigarettes and to communicate to consumers that VLN™ cigarettes contain at least 95% less nicotine as compared to the 100 leading cigarette brands in the United States.

The FDA's inspection was a highly anticipated component of the third phase of the FDA's four phase review process for the PMT application. The FDA's stated goal for the inspection was "to verify the information and data contained in the [PMT] application." As such, the FDA inspectors witnessed production of 22nd Century's proprietary VLN™ cigarettes. In addition, FDA inspectors reviewed 22nd Century's raw material receiving and storage procedures, quality control processes, manufacturing equipment and systems, tobacco processing methods, and finished-products analyses procedures.

Concurrent with the FDA's review process for 22nd Century's MRTP and PMT applications, the FDA is pursuing a proposed rule that, when finalized and effective, would limit the amount of nicotine in **all** cigarettes sold in the United States to "minimally-addictive or non-addictive levels." Officials from the FDA have previously indicated a "minimally-addictive or non-addictive" level of nicotine in cigarettes could be achieved at approximately 0.3 to 0.7 mg nicotine per gram of tobacco. The World Health Organization (WHO) has similarly recommended that all member nations adopt "a [tobacco] policy of limiting the sale of cigarettes to brands with a nicotine content that is not sufficient to lead to the development and/or maintenance of addiction." Importantly, in its published report, [Global Nicotine Reduction Strategy](#), the WHO referred specifically to 22nd Century and to the Company's proprietary VLNC tobacco.

22nd Century's proposed VLN™ cigarettes – with a target concentration of 0.5 mg nicotine per gram tobacco – fall squarely within the nicotine range that public health officials anticipate will be mandated by the FDA, and that will simultaneously enable the WHO to advance its global nicotine reduction agenda. For these reasons, when 22nd Century's proprietary VLNC cigarettes achieve MRTP status, they could serve as a powerful tool and precedent in support of the FDA's broader national nicotine reduction mandate.

"Our extraordinary VLN™ cigarettes contain at least 95% less nicotine than any of the 100 leading cigarette brands in the U.S.," explained Henry Sicignano III, President and Chief Executive Officer of 22nd Century Group. "The FDA's inspection of our manufacturing facility is another important milestone in the FDA review process that we expect will ultimately result in VLN™ cigarettes becoming the world's first FDA-approved MRTP combustible tobacco cigarettes."

About 22nd Century Group, Inc.

22nd Century is a plant biotechnology company focused on technology which allows it to increase or decrease the level of nicotine in tobacco plants and the level of cannabinoids in hemp/cannabis plants through genetic

engineering and plant breeding. The Company's primary mission in tobacco is to reduce the harm caused by smoking. The Company's primary mission in hemp/cannabis is to develop proprietary hemp/cannabis strains for important new medicines and agricultural crops. Visit www.xxiiicentury.com for more information.

Cautionary Note Regarding Forward-Looking Statements: This press release contains forward-looking information, including all statements that are not statements of historical fact regarding the intent, belief or current expectations of 22nd Century Group, Inc., its directors or its officers with respect to the contents of this press release, including but not limited to our future revenue expectations. The words "may," "would," "will," "expect," "estimate," "anticipate," "believe," "intend" and similar expressions and variations thereof are intended to identify forward-looking statements. We cannot guarantee future results, levels of activity or performance. You should not place undue reliance on these forward-looking statements, which speak only as of the date that they were made. These cautionary statements should be considered with any written or oral forward-looking statements that we may issue in the future. Except as required by applicable law, including the securities laws of the United States, we do not intend to update any of the forward-looking statements to conform these statements to reflect actual results, later events or circumstances, or to reflect the occurrence of unanticipated events. You should carefully review and consider the various disclosures made by us in our annual report on Form 10-K for the fiscal year ended December 31, 2018, filed on March 6, 2019, including the section entitled "Risk Factors," and our other reports filed with the U.S. Securities and Exchange Commission which attempt to advise interested parties of the risks and factors that may affect our business, financial condition, results of operation and cash flows. If one or more of these risks or uncertainties materialize, or if the underlying assumptions prove incorrect, our actual results may vary materially from those expected or projected.

View source version on businesswire.com: <https://www.businesswire.com/news/home/20190430005551/en/>

22nd Century Group
James Vail, Director of Communications
716-270-1523
jvail@xxiiicentury.com

Source: 22nd Century Group, Inc.