



December 5, 2018

## 22nd Century Files Premarket Tobacco Application (PMTA) with the FDA

***A PMTA is an important first step toward achieving potentially the first – and only – Modified Risk Tobacco Product marketing order for a combustible cigarette***

WILLIAMSVILLE, N.Y.--(BUSINESS WIRE)-- 22nd Century Group, Inc. (NYSE American:[XXII](#)), a plant biotechnology company focused on tobacco harm reduction and Very Low Nicotine tobacco, today submitted a Premarket Tobacco Application (PMTA) with the U.S. Food and Drug Administration (FDA) seeking authorization to commercialize the Company's "BRAND A" cigarette products under the proposed brand name VLN<sup>TM</sup> (the product name is subject to FDA approval). 22nd Century's proposed VLN<sup>TM</sup> cigarettes – the subject of the PMTA – are made with 22nd Century's proprietary VLN<sup>TM</sup> tobacco and, as a result, contain very low levels of nicotine.

A PMTA marketing order is a prerequisite to commercializing any new tobacco product in the United States. The Company's PMTA submission precedes the forthcoming filing of the separate, more comprehensive Modified Risk Tobacco Product (MRTP) application for 22nd Century's proposed VLN<sup>TM</sup> premium cigarettes. 22nd Century's MRTP application will request FDA authorization for the Company to state on packaging and advertising that, among other things, the proposed VLN<sup>TM</sup> cigarettes contain just 0.5mg nicotine per gram of tobacco. In contrast, a survey of the top 100 leading cigarette brands in the United States showed that conventional and highly addictive cigarettes currently sold in the United States contain an average of 19.4mg of nicotine per gram of tobacco (with an actual nicotine range of 14.7mg to 33.2mg per gram of tobacco).

22nd Century's proposed VLN<sup>TM</sup> cigarettes are modeled after the Company's Very Low Nicotine Content (VLNC) SPECTRUM® research cigarettes. 22nd Century's PMTA for the proposed VLN<sup>TM</sup> brand cigarettes references more than 50 independent studies conducted using the Company's proprietary SPECTRUM® research cigarettes. The World Health Organization (WHO) Study Group on Tobacco Product Regulation has recommended that all member countries limit the nicotine content of cigarettes to the level found in VLNC SPECTRUM® cigarettes. ([WHO Global Nicotine Reduction Strategy](#))

In March 2018, the FDA announced its plan to issue a proposed rule that, when finalized and effective, would limit the amount of nicotine in all cigarettes sold in the United States to minimally or non-addictive levels. In October 2018, Dr. Lynn Hull, Lead Pharmacologist at the Division of Individual Health Science within the FDA's Center for Tobacco Products, held a [webcast](#) highlighting and summarizing the published science surrounding VLNC cigarettes. During the webcast, Dr. Hull indicated a minimally non-addictive level of nicotine in cigarettes could be approximately between 0.2mg to 0.7mg nicotine per cigarette.

"Later this month, 22nd Century will submit to the FDA the Company's highly-anticipated MRTP application. Containing only a tiny fraction of the nicotine found in the 100 leading U.S. cigarette brands, 22nd Century's proposed VLN<sup>TM</sup> cigarettes will demonstrate conclusively that the FDA's plan to dramatically reduce nicotine in all U.S. cigarettes is immediately feasible," explained Henry Sicignano, Chief Executive Officer and President at 22nd Century Group. "As potentially the first – and only – combustible cigarettes to achieve a marketing order from the FDA under the MRTP program, 22nd Century's proposed VLN<sup>TM</sup> cigarettes will provide smokers with a nearly nicotine-free choice... and will change the tobacco industry forever."

### **About SPECTRUM® Research Cigarettes**

22nd Century developed SPECTRUM® research cigarettes in collaboration with independent researchers and officials from the National Institute on Drug Abuse (NIDA), the U.S. Food and Drug Administration (FDA), the National Cancer Institute (NCI), and the Centers for Disease Control and Prevention (CDC). Produced exclusively by 22nd Century with the Company's proprietary VLN<sup>TM</sup> tobacco plants, very low nicotine SPECTRUM®

cigarettes are the foundation for important nicotine reduction public policy initiatives around the world. The main SPECTRUM® product line consists of a series of cigarette styles that vary in nicotine yields from very low to relatively high nicotine. 22nd Century supplies SPECTRUM® research cigarettes in 24 styles, in both regular and menthol versions, with 8 different levels of nicotine.

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

22nd Century is a plant biotechnology company focused on technology which allows the increase or decrease in 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](http://www.xxiiicentury.com) and [www.botanicalgenetics.com](http://www.botanicalgenetics.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, 2017, filed on March 7, 2018, 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.*

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