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## 22nd Century Reports on New Responses to the FDA's Nicotine Reduction Plan

***Scientists highlight reduced consumption; refute claims of compensation; support an immediate reduction in nicotine level***

WILLIAMSVILLE, N.Y.--(BUSINESS WIRE)-- 22nd Century Group, Inc. (NYSE American: [XXII](#)), a plant biotechnology company that is a leader in tobacco harm reduction and Very Low Nicotine tobacco, today highlights two important submissions to the U.S. Food and Drug Administration (FDA). Altogether, nine separate researchers authored these particular submissions in response to the FDA's Advance Notice of Proposed Rulemaking ([ANPRM](#)) to require that nicotine levels in combustible cigarettes be lowered to minimally or non-addictive levels. 22nd Century's proprietary VLN™ tobacco cigarettes were used by the FDA in formulating the Agency's plan to dramatically reduce the nicotine content of cigarettes. 22nd Century is the only company in the world now growing multiple varieties of Very Low Nicotine flue-cured and burley tobacco varieties to satisfy the FDA's planned mandate that will reduce drastically the nicotine levels of *all cigarettes sold in the United States*.

The open comment period for the FDA's ANPRM on a nicotine product standard for cigarettes ends July 16, 2018. To date, major medical associations, government agencies, tobacco insiders, and the public at large have submitted nearly [5,000 public comments](#) to the FDA.

Noted scientific researchers Neal Benowitz, M.D., Eric Donny, Ph.D., Kathryn Edwards, Ph.D., Dorothy Hatsukami, Ph.D., Tracy Smith, Ph.D., and Clifford Watson, Ph.D. [coauthored a letter](#) from the University of California – San Francisco (UCSF) that identified a “minimally addictive” nicotine content for cigarettes as follows:

*“The amount of nicotine needed to make cigarettes minimally addictive appears to be 0.4 to 0.5 mg nicotine per gram of tobacco in the tobacco rod. This represents a reduction of nicotine content of 95% or more compared to currently available commercial cigarettes.”*

22nd Century's SPECTRUM® Very Low Nicotine research cigarettes contain less than 0.5 mg nicotine per gram of tobacco – exactly the level specified in the UCSF submission. The above-noted researchers also conclusively refuted claims that Very Low Nicotine cigarettes could cause smokers to increase their smoking:

*“Effectively compensating to maintain nicotine exposure is virtually impossible when switching to cigarettes with minimally addictive nicotine content.”*

In another [recent submission](#) to the FDA regarding the FDA's ANPRM to limit dramatically the nicotine content of cigarettes, noted scientific researchers Megan Piper, Ph.D., David Drobos, Ph.D., and Natalie Walker, Ph.D. address the issues of smoking dependence and smoking abstinence when smokers switch exclusively to Very Low Nicotine content cigarettes. Citing a number of scientific studies investigating nicotine dependence, these researchers explain:

*“...there is direct evidence that smoking reduced nicotine cigarettes is associated with reduced dependence (both self-reported dependence and dependence related criteria such as withdrawal, cravings) and ultimately smoking abstinence.”*

In conclusion, Drs. Piper, Drobos, and Walker cite scientific clinical evidence to show that an immediate switch to Very Low Nicotine content cigarettes results in:

*“1) a reduction in validated dependence measures...; 2) a reduction in cigarettes smoked; 3) a reduction in biomarkers of nicotine exposure; and 4) a reduction in withdrawal symptoms”*

“The scientists responsible for many of the independent clinical trials using 22nd Century's proprietary VLN™

cigarettes continue to refute the objections raised to the FDA's nicotine reduction plan and hasten the road to final implementation of the life-saving mandate," explained Henry Sicignano, III, President and Chief Executive Officer of 22nd Century Group. "When the FDA's plan is enacted, 22nd Century's Very Low Nicotine tobacco varieties could form the foundation for, quite literally, ALL tobacco cigarettes sold in the United States."

#### **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 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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