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FDA Publishes Advance Notice of Proposed Rulemaking (ANPRM) on Lowering Nicotine in Cigarettes

22nd Century CEO to discuss FDA's nicotine reduction plan with institutional investors in New York, Chicago and Boston

CLARENCE, 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, announced today that the U.S. Food and Drug Administration ("FDA") has published in the [Federal Register](#) the FDA's Advance Notice of Proposed Rulemaking ("ANPRM") to lower nicotine in cigarettes to minimally or non-addictive levels. Henry Sicignano III, President and Chief Executive Officer of 22nd Century Group, will meet this week with institutional investors in New York, Chicago and Boston to discuss the industry-wide implications of the FDA's sweeping new plan.

First announced in July 2017, the FDA's new policy on tobacco and nicotine regulation aims to mandate the reduction of nicotine in cigarettes to minimally or non-addictive levels. The ANPRM is a pivotal first step in the FDA's rule-making process. The ANPRM states that the FDA will receive initial public comments until June 14, 2018. The ANPRM also describes the independent science that supports the FDA's proposed nicotine reduction mandate.

The ANPRM indicates that the FDA desires to receive input on a maximum allowable nicotine level. However, the ANPRM already references previously completed independent research that found: "an absolute limit of 0.4 to 0.5 mg of nicotine per cigarette should be adequate to prevent or limit the development of addiction in most young people. At the same time, it may provide enough nicotine for taste and sensory stimulation." The ANPRM also cites the results of independent clinical studies, including the clinical trial by Dr. Eric Donny, *et al.*, that was published in the October 2015 issue of *The New England Journal of Medicine* that found: "Those participants using cigarettes with the lowest nicotine content (0.4 mg per gram nicotine/gram of tobacco filler), demonstrated reduced dependence... with minimal evidence of withdrawal-related discomfort or safety concerns." *22nd Century provided all of the proprietary Very Low Nicotine cigarettes that made this study possible.*

With ownership or control of patents on the genes in the tobacco plant that regulate nicotine production, 22nd Century is able to grow tobacco with up to 97% less nicotine than tobacco used in conventional cigarettes. Since 2011, 22nd Century has supplied more than 24 million proprietary SPECTRUM® research cigarettes for the National Institute on Drug Abuse (NIDA) to use in independent clinical studies in which agencies of the U.S. federal government have invested more than \$100 million. The Company's SPECTRUM product line consists of a series of 24 cigarette styles (11 regular and 13 menthol versions) that have 8 different levels of nicotine – from very low to high.

The ANPRM specifically mentions 22nd Century, by name, in reference to the Company's proprietary Very Low Nicotine tobacco and the Company's continued provision of Very Low Nicotine cigarettes for use in independent scientific research funded by agencies of the U.S. federal government: "To provide consumers with reduced risk tobacco products, companies like 22nd Century are using genetic engineering and plant breeding to produce very low nicotine tobacco for incorporation into cigarettes. In 2014, the company was granted patents for its process to virtually eliminate the nicotine in tobacco plants. Further, low nicotine cigarettes are produced and distributed for research purposes by Research Triangle Institute (RTI), under a contract for the NIDA's Drug Supply Program. 22nd Century is acting as a vendor for RTI for this contract manufacturing SPECTRUM [research] cigarettes that contain 0.4 mg nicotine/gram (g) of tobacco filler."

In [commenting on the ANPRM](#), FDA Commissioner Dr. Scott Gottlieb said, "This milestone places us squarely on the road toward achieving one of the biggest public health victories in modern history and saving millions of lives in the process."

"The release of the ANPRM marks the first step in the rule-making process" explained Dr. James Swauger, Senior Vice President of Science and Regulatory Affairs at 22nd Century Group. "We look forward to contributing information to help the FDA plan for a nicotine product standard requiring all cigarettes sold in the United States to be minimally or non-addictive."

In addition, a [Special Report](#) published last week in *The New England Journal of Medicine* detailed the results of modeling work intended to characterize the public health benefit associated with implementing a "policy that would require the reduction of nicotine in cigarettes to minimally addictive levels." The special report reviewed projected outcomes following a mandate that would set a maximum level for nicotine in cigarettes, roll-you-own tobacco, non-premium cigars, and pipe tobacco. The report projected that a reduced nicotine product standard could result in an additional 5 million smokers quitting smoking in the first year alone, and up to 13 million smokers quitting within 5 years. The model also forecast that by the end of the century, 33 million people, mostly youth and young adults, would avoid becoming regular smokers and there would be 8 million fewer smoking-related deaths within that time.

The authors of such report concluded: "Our findings show that reducing the nicotine level in cigarettes has the potential to substantially reduce the enormous burden of smoking-related death and disease. We estimate that a nicotine product standard for cigarettes in the United States could save millions of lives and tens of millions of life-years over the next several decades."

"We are enormously proud that the independent science that supports the FDA's proposed rule to reduce nicotine in cigarettes to minimally or non-addictive levels has been made possible by clinical research using 22nd Century's proprietary SPECTRUM research cigarettes," explained Henry Sicignano III, President and Chief Executive Officer of 22nd Century Group "We intend to play an active role in the FDA rule-making process and we look forward to making 22nd Century's proprietary Very Low Nicotine cigarettes available to smokers across the United States and around the globe."

About 22nd Century Group, Inc.

22nd Century is a plant biotechnology company focused on technology which allows the Company 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.xxiicentury.com and 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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22nd Century Group
James Vail, 716-270-1523
Director of Communications
jvail@xxiicentury.com

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