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22nd Century Announces the Immediate Feasibility of the FDA's Nicotine Reduction Plan

Reynolds American and Phillip Morris unable to comply with the FDA's plan "for 20-years"

WILLIAMSVILLE, New York--(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, yesterday responded to the Advance Notice of Proposed Rulemaking (ANPRM) by the U.S. Food and Drug Administration (FDA) to develop a rule that will require all cigarettes sold in the United States to contain only minimally or non-addictive levels of nicotine. When the Company's response is posted online by the FDA at www.regulations.gov, the corresponding tracking number will be: **1k2-94b8-wdcp**. 22nd Century's complete response to the FDA's ANPRM is currently available at: www.xxiiicentury.com/ANPRM.

22nd Century's public comments to the FDA's ANPRM describe how the FDA's proposed rule to require that all cigarettes sold in the United States contain only minimally or non-addictive levels of nicotine is supported by rigorous independent science. The Company also demonstrates that the planned mandate is exceedingly practical and urgently needed in the interests of public health.

The FDA's stated goal to render cigarettes minimally or non-addictive is *immediately* feasible. 22nd Century has produced and delivered tens of millions of the Company's Very Low Nicotine Content (VLNC) SPECTRUM® research cigarettes since 2011 for use in numerous independent clinical studies funded by more than \$100 million from agencies of the United States federal government. The results of these independent clinical studies show that upon switching to 22nd Century's VLNC SPECTRUM® cigarettes, smokers: (1) reduce their cigarette consumption, (2) experience lessened withdrawal symptoms, and (3) increase their attempts to quit smoking. These peer-reviewed and published studies provide a solid scientific foundation for the FDA's proposed nicotine reduction mandate. VLNC cigarettes are so promising that independent [researchers estimate](#) that in the first year after implementation of the FDA's rule to limit cigarettes to minimally or non-addictive levels of nicotine, approximately 5 million people would stop smoking and, in as few as five years after implementation of the FDA's plan, more than 13 million people would stop smoking.

In preparation for the prompt implementation of the new FDA rule, 22nd Century is already growing increased amounts of the Company's VLN™ tobacco in order to be able to supply a sufficient quantity of the Company's proprietary VLN™ tobacco seeds to grow enough VLN™ tobacco for the entire U.S. tobacco industry in just one growing season.

In contrast, Reynolds American (a subsidiary of [British American Tobacco](#)) is apparently incapable of matching 22nd Century's achievements and meeting a standard for minimally or non-addictive tobacco cigarettes. In Reynolds American's July 13, 2018 response to the FDA's ANPRM, Michael Ogden, Ph.D., Senior Vice President of RAI Services (which is part of Reynolds American), explains:

"At the present time... the science lags behind on this important issue and additional methods, possibly used in conjunction with traditional breeding practices, would need to be developed. RAIS believes that the industry is at least 20 years away from producing tobacco at a commercial scale that would meet the range of low-level nicotine discussed in the ANPRM."

Conversely, 22nd Century already has an extensive portfolio of patented technologies and unique VLN™ tobacco plants in burley and flue-cured varieties and is continuing to develop new VLN™ varieties with improved agronomic traits. RAIS' comments on the ANPRM went on to recognize 22nd Century's leadership in creating tobaccos with very low levels of nicotine:

"Commercialization of such products [tobaccos with very low levels of nicotine] is also made difficult by: (1) the fact that genome editing technology (CRISPR-cas9) currently does not appear to be available to tobacco

companies; and (2) the various patent restrictions on the use of certain genetic-engineering techniques (**the patents on nicotine synthesis pathway genes, for example, are held almost exclusively by 22nd Century Group**)." (emphasis added)

Reynolds American is not the first to suggest that it will take multi-national tobacco companies 20-years to develop tobacco with very low levels of nicotine. As reported by Sam Chambers of Bloomberg Business, Rolf Lutz, Director of Product Policy at [Philip Morris International Inc.](#) estimated "it would cost the company \$10 billion to \$12 billion to extract nicotine from all the cigarettes it sells across the European Union." Chambers went on to report: "Lutz said the cost could be minimized by genetically modifying tobacco plants, **but this would take about 20 years.**" (emphasis added)

"Fortunately, 22nd Century's VLN™ technology makes feasible and eminently achievable the FDA's stated goal of rendering cigarettes minimally or non-addictive," explained Henry Sicignano, III, President and Chief Executive Officer of 22nd Century Group.

To make VLNC cigarettes a prompt reality for all smokers, 22nd Century has announced that the Company is willing to license the use of the Company's VLN™ technology and VLN™ tobacco seeds/plants to all interested companies. The availability of this licensing opportunity from 22nd Century negates any argument by other tobacco companies that contend it is somehow not possible to comply with the planned FDA nicotine reduction mandate.

"Big tobacco companies now have a choice: Combat, obfuscate and attempt to delay the most important public health initiative of the last 100 years... or demonstrate a genuine commitment to improving the health of their customers," explained Mr. Sicignano. "Now that 22nd Century's VLN™ technology is proven and readily available for licensing, it will be interesting to see which Big Tobacco companies genuinely care about smokers... and which are determined to keep their customers addicted to the deadliest consumer product available on the market."

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.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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