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22nd Century Files Modified Risk Tobacco Product (MRTP) Application with the FDA for the Company's Very Low Nicotine Content Cigarettes

VLNTM cigarettes contain at least 95% less nicotine than each of the 100 leading cigarette brands in the United States.

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 Modified Risk Tobacco Product (MRTP) application with the U.S. Food and Drug Administration (FDA) for the Company's Very Low Nicotine Content (VLNC) cigarettes. 22nd Century's proposed VLNTM cigarettes, the subject of the MRTP application, are made with the Company's proprietary VLNTM tobacco and, as a result, contain very low levels of nicotine.

There are almost 38 million smokers in the United States. In a [Special Report](#) published in the May 2018 issue of the *New England Journal of Medicine*, a statistical model funded by the FDA predicted that, if all cigarettes in the United States were required to have very low nicotine content, approximately 5 million smokers would quit smoking within a year and that number would increase to a total of 13.0 million within 5 years. By the year 2100, the model estimates that approximately 33 million people would either quit smoking or not start smoking. The model further predicts that 8.5 million deaths will be averted and 134.4 million life years will be gained by the year 2100.

22nd Century's MRTP application joins the Company's previously filed [Premarket Tobacco Application](#) (PMTA). Together, these important applications seek the FDA's authorization to commercialize the Company's VLNTM cigarettes and to advertise that the VLNTM cigarettes contain 95% less nicotine as compared to the 100 leading cigarette brands in the United States.

22nd Century's proposed VLNTM cigarettes are the same as the lowest nicotine content style of the Company's SPECTRUM® research cigarettes. 22nd Century's SPECTRUM® research cigarettes were developed in collaboration with the FDA and other U.S. federal government agencies to provide independent scientists with the products necessary to investigate the public health benefits of reduced-nicotine content cigarettes. Since 2011, 22nd Century has produced and delivered tens of millions of the Company's Very Low Nicotine Content (VLNC) SPECTRUM® research cigarettes for use in dozens of clinical studies funded by more than \$100 million from agencies of the United States federal government.

22nd Century's MRTP application references more than 50 independent studies that utilized SPECTRUM® research cigarettes. Of particular note, the six-week [840-participant study](#) by Donny, *et al.* published in the *New England Journal of Medicine* in October 2015 found that VLNC cigarettes were: "associated with reductions in smoking, nicotine exposure, and nicotine dependence, with minimal evidence of nicotine withdrawal, compensatory smoking, or serious adverse events." A twenty-week [1,250-participant study](#) by Hatsukami, *et al.* published in the *Journal of the American Medical Association* (JAMA) in September 2018 concluded that an immediate reduction in nicotine to very low levels was associated with:

- Lower toxicant exposure across time;
- Fewer cigarettes smoked per day;
- Greater reduction in nicotine dependence; and

- More days in which participants smoked no cigarettes (cigarette-free days).

Cigarette smoking is the leading cause of preventable disease and death in the United States, accounting for more than 480,000 deaths every year, or about 1 in 5 deaths, and more than \$300 billion in healthcare costs. Based on the actuarial model funded by the FDA, VLNC cigarettes have the potential to change the course of public health history by helping to defeat the global tobacco epidemic.

Reducing the nicotine content of cigarettes to non-addictive levels has long been part of the FDA's vision to reduce the harm caused by smoking. In a June 16, 2010 press release, Dr. David Kessler, the former FDA Commissioner, recommended that "[t]he FDA should quickly move to reduce nicotine levels in cigarettes to non-addictive levels. If we reduce the level of the stimulus, we reduce the craving. *It is the ultimate harm reduction strategy.*" (*emphasis added*)

On July 28, 2017, in introducing the FDA's comprehensive plan for tobacco and nicotine regulation, Dr. Scott Gottlieb, the current FDA Commissioner, declared in a public announcement that "looking at ways to reduce nicotine levels in cigarettes so that they are minimally or non-addictive is a cornerstone of our new and more comprehensive approach to effective tobacco regulation."

And, this Fall, during an [FDA webcast](#), Dr. Lynn Hull, Lead Pharmacologist at the Division of Individual Health Science within the FDA's Center for Tobacco Products, reviewed the science behind the FDA's intention to issue a proposed rule that, when finalized and effective, would limit the amount of nicotine in all cigarettes sold in the United States (and perhaps in all other combusted tobacco products as well) to minimally-addictive or non-addictive levels. In the webcast, Dr. Hull indicated a minimally-addictive or non-addictive level of nicotine in cigarettes could be between approximately 0.2 to 0.7mg nicotine per gram of tobacco.

In contrast to the highly addictive tobacco cigarettes marketed by Big Tobacco companies, Altria Group, Inc. ([MO](#)) and Reynolds American Inc., a subsidiary of British American Tobacco ([BTI](#)), 22nd Century's proprietary Very Low Nicotine Content tobacco and technology make possible tobacco cigarettes with a nicotine content which is more than 95% less than conventional cigarettes.

Unlike any other cigarettes on the U.S. market today, 22nd Century's proposed VLN™ cigarettes – with just 0.5mg nicotine per gram tobacco (~0.3 mg per cigarette) – fall squarely within the nicotine range anticipated by the FDA's Dr. Hull. As investors have begun to realize that the FDA is, in fact, truly committed to a comprehensive nicotine reduction plan for *all* cigarettes sold in the United States, the share prices for Altria Group, Philip Morris International ([PM](#)), and British American Tobacco continue to fall and are substantially lower today than they were before the FDA's nicotine reduction plan was publicly announced in July 2017.

"22nd Century's proprietary VLN™ cigarettes have at least 95% less nicotine than each of the 100 leading cigarette brands in the United States. We concur with former FDA Commissioner Dr. David Kessler: Cigarettes with non-addictive levels of nicotine represent 'the *ultimate* harm reduction strategy'." explained Henry Sicignano III, President and Chief Executive Officer of 22nd Century Group. "We believe that the public health implications of very low nicotine content cigarettes are enormous; 22nd Century is tremendously excited about introducing our proprietary VLN™ cigarettes into the U.S. market."

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). 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 facilitates 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 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, Director of Communications
716-270-1523
jvail@xxiicentury.com

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