



January 4, 2016

22nd Century Files Modified Risk Tobacco Product Application with the FDA for World's Lowest Nicotine Tobacco Cigarettes

Proprietary "Very Low Nicotine" Cigarettes Drastically Reduce Smokers' Exposure to Nicotine

CLARENCE, N.Y.--(BUSINESS WIRE)-- 22nd Century Group, Inc. (NYSE MKT: [XXII](#)), a plant biotechnology company that is a leader in tobacco harm reduction, announced today that on December 31, 2015, the Company's wholly owned subsidiary, Goodrich Tobacco Company, submitted a Modified Risk Tobacco Product (MRTP) application to the U.S. Food and Drug Administration (FDA) seeking a reduced exposure order so that 22nd Century's "BRAND A" Very Low Nicotine (VLN) cigarettes may be introduced into commerce in the United States. The application to the FDA requests that BRAND A packaging and marketing be allowed to disclose to consumers that the Company's proprietary Very Low Nicotine cigarettes reduce smokers' exposure to nicotine.

The World's Lowest Nicotine Tobacco Cigarettes

BRAND A cigarettes contain less than 0.6 mg nicotine per cigarette and less than 0.05 mg nicotine yield per cigarette. In each case, this represents a reduction of at least 95% less nicotine relative to "Big Tobacco" cigarette brands, including Marlboro®, Camel®, Newport®, and American Spirit®. With more than 200 patents relating to the genes in the tobacco plant responsible for nicotine production, 22nd Century is the only company in the world capable of producing virtually nicotine-free tobacco. Without any artificial extraction or chemical processes, 22nd Century's BRAND A cigarettes are made with the Company's proprietary VLN tobacco that is grown on independently-owned farms in the United States. The finished cigarettes have the taste and sensory characteristics of conventional cigarettes, but contain only trace amounts of nicotine so that smokers' exposure to nicotine is drastically reduced.

Under Section 911 of the federal Food, Drug, and Cosmetic Act, a tobacco product may not be introduced for commerce in the United States if the label or advertising represents that the tobacco product contains a reduced level of a substance or a reduced exposure to a substance unless given specific approval to do so by the FDA.

"The scientific testing conducted in support of our submission to the FDA shows conclusively that BRAND A, as compared to conventional tobacco cigarettes, provides smokers with drastically reduced exposure to nicotine," explained Henry Sicignano, III, President and Chief Executive Officer of 22nd Century Group. "We believe that the public health implications of a virtually nicotine-free tobacco cigarette are enormous and 22nd Century is excited about the prospect of introducing BRAND A into the U.S. market."

It has been well established that cigarette smoking is toxic and poses health risks to smokers. Cigarette smoking is a complex behavior that is sustained primarily by the pharmacological properties of nicotine. Accordingly, many public health officials believe it is a critically important health need to provide consumers with a product that reduces exposure to nicotine. This fact echoes former U.S. FDA Commissioner Dr. David Kessler's recommendation that *"the FDA should quickly move to reduce nicotine levels in cigarettes to non-addictive levels... It is the ultimate harm reduction strategy."*

Unlike so-called "light" or "ultra-light" cigarettes (which terms are now banned by the FDA from labeling and marketing in the United States), 22nd Century's proprietary BRAND A cigarettes are designed to deliver greatly reduced ratios of nicotine to other smoke components. The Company's application to the FDA provides a comprehensive overview of the many independent clinical trials that have found that smoking 22nd Century's VLN cigarettes delivers the sensory and behavioral experience associated with conventional cigarettes while providing only minimal exposure to the most addictive component of tobacco.

Most recently, in October 2015, *The New England Journal of Medicine* published a landmark clinical study [N Engl J Med 2015; 373:1340-1349](#) led by the Center for the Evaluation of Nicotine in Cigarettes. The double-blind, parallel, randomized clinical trial by Donny *et al* involved 840 smokers at ten locations who were randomly

assigned to smoke for 6 weeks either their usual brand of cigarettes or one of six types of investigational cigarettes. The researchers concluded that:

As compared with cigarettes of conventional nicotine content, 22nd Century's proprietary Very Low Nicotine cigarettes were "associated with reductions in smoking, nicotine exposure, and nicotine dependence, with minimal evidence of nicotine withdrawal, compensatory smoking, or serious adverse events."

"The current study by Donny and colleagues adds to a growing literature supporting the feasibility and potential benefits of a national nicotine reduction policy..." explained public health policy reform advocates, Drs. Michael Fiore and Timothy Baker in a companion article ([Fiore](#)) in the same issue of *The New England Journal of Medicine*. "Reducing the nicotine content of combustible tobacco to levels that will not sustain dependence seems to us to be the most promising regulatory policy option for preventing [at least] 20 million premature deaths."

The available scientific literature shows that smoking 22nd Century's VLN cigarettes results in reduced nicotine exposure with minimal compensatory smoking behavior and no greater exposure to harmful or potentially harmful toxicants, particularly when exposure is maintained for longer than one week. Similarly the prolonged use of VLN cigarettes seems to result in a decrease in dependence.

"It is the goal of the U.S. Department of Health and Human Services, as outlined in the program Healthy People 2010, to reduce cigarette smoking in the United States to 12% by the year 2020," explained Gregg M. Gellman, 22nd Century's Director of Regulatory Affairs. "Based on the scientific rationale and clinical data referenced in our application to the FDA, we believe 22nd Century's proprietary Very Low Nicotine cigarettes could be an invaluable tool in helping to drastically reduce smokers' exposure to nicotine and thereby greatly reducing cravings for, and consumption of, cigarettes."

With approximately 277 billion cigarettes manufactured in the U.S. in 2014 – representing more than \$80 billion in sales – the cigarette market in the United States remains enormous. At present, however, the United States is completely devoid of any "reduced exposure cigarette" option. If 22nd Century's application to the FDA is successful, the Company's VLN cigarettes will offer millions of American smokers a distinct reduced exposure product choice.

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 cannabis plants through genetic engineering and plant breeding. The Company's primary mission is to reduce the harm caused by smoking. 22nd Century currently owns or exclusively controls more than 200 issued patents and more than 50 pending patent applications around the world. The Company's strong IP position led to a licensing agreement with British American Tobacco ("BAT"), the world's second largest tobacco company. Visit www.xxiicentury.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, 2014, filed on February 5, 2015, 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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Investor Relations:
IRTH Communications

Andrew Haag, 866-976-4784
xxii@irthcommunications.com
or
Redington, Inc.
Tom Redington, 203-222-7399

Source: 22nd Century Group, Inc.