



January 19, 2016

## **22nd Century Meets with FDA on Historic Modified Risk Tobacco Product Application for World's Lowest Nicotine Tobacco Cigarettes**

**"The most promising regulatory policy option for preventing 20 million premature deaths"**

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 last week the Company met with administrators and assigned scientific reviewers at the U.S. Food and Drug Administration (FDA) to review the Company's Modified Risk Tobacco Product (MRTP) application for BRAND A Very Low Nicotine (VLN) cigarettes.

The FDA contacted 22nd Century immediately upon receiving the Company's MRTP application and facilitated – less than 14 days after the Company's submission – a meeting at FDA headquarters to discuss the application and the review process. In attendance were nine members of 22nd Century's team, including executive management, consultants and attorneys, along with 22 FDA staff members; more than 20 additional FDA staff members attended telephonically.

Conclusive independent laboratory testing proves that 22nd Century's 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 Natural American Spirit®. The Company's Modified Risk Tobacco Product application to the FDA requests that BRAND A packaging and marketing be allowed to disclose to consumers that the product contains 95% less nicotine than conventional brands and drastically reduces smokers' exposure to nicotine.

"I am very pleased with the FDA's prompt attention to our MRTP application," stated Henry Sicignano, III, President and Chief Executive Officer of 22nd Century Group. "For U.S. smokers who wish to reduce their exposure to nicotine, 22nd Century's Very Low Nicotine cigarettes are an incredibly important product. Consumers deserve a Very Low Nicotine product choice."

Under the 2009 Tobacco Control Act, the FDA cannot ban conventional tobacco products, such as cigarettes and smokeless tobacco, or require the total elimination of nicotine in tobacco products. However, the FDA has the authority to order the reduction of nicotine to non-addictive levels in some or all cigarettes sold in the United States.

Mr. Sicignano explained, "Besides paving the way for the world's first reduced exposure cigarette, 22nd Century's proprietary technology gives the FDA an invaluable tool if the FDA desires to require *all* U.S. cigarette brands to offer consumers a Very Low Nicotine brand style at non-addictive levels... a very exciting prospect for public health, to say the least."

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. The finished cigarettes containing 22nd Century's proprietary Very Low Nicotine tobacco have the taste and sensory characteristics of conventional cigarettes, but contain only trace amounts of nicotine. The Company looks forward to continuing to work closely with the FDA in the MRTP application process in order to secure a marketing order that will facilitate reduced exposure labelling for BRAND A Very Low Nicotine cigarettes.

In the October 1, 2015 edition of *The New England Journal of Medicine*, Drs. Michael Fiore and Timothy Baker (see [Fiore](#)) wrote: "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." 22nd Century believes that, beginning with the Company's BRAND A Modified Risk Tobacco Product application, the FDA has the option to begin a process of reducing the nicotine content of U.S. cigarettes. In the words of former FDA Commissioner Dr. David Kessler, reducing the nicotine levels in cigarettes to non-addictive levels is "*the ultimate harm reduction strategy.*"

## 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.xxiiicentury.com](http://www.xxiiicentury.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.*

View source version on businesswire.com: <http://www.businesswire.com/news/home/20160119006264/en/>

Investor Relations:

IRTH Communications

Andrew Haag, 866-976-4784

[xxii@irthcommunications.com](mailto:xxii@irthcommunications.com)

or

Redington, Inc.

Tom Redington, 203-222-7399

Source: 22nd Century Group, Inc.