



January 5, 2017

## **FDA Provides Positive and Encouraging Feedback for 22nd Century's Very Low Nicotine MRTPA Filings**

### **22nd Century Seeking Approval to Market the World's Lowest Nicotine Tobacco Cigarettes**

CLARENCE, N.Y.--(BUSINESS WIRE)-- 22nd Century Group, Inc. (NYSE MKT:[XXII](#)), a plant biotechnology company that is focused on reducing the harm caused by smoking, today announced that the U.S. Food and Drug Administration (FDA) has provided the Company with helpful and positive feedback on the Company's combined Modified Risk Tobacco Product Applications (MRTPAs) and Premarket Tobacco Product Applications (PMTAs) for 22nd Century's "BRAND A" Very Low Nicotine tobacco cigarettes.

On December 31, 2015, the Company's wholly owned subsidiary, Goodrich Tobacco Company, submitted MRTPAs and PMTAs to the FDA seeking a reduced exposure order for 22nd Century's "BRAND A" Very Low Nicotine cigarettes. More specifically, the Company requested in its MRTPAs permission from the FDA to be able to state, as truthful and accurate in BRAND A packaging and marketing, that the Company's proprietary Very Low Nicotine cigarettes reduce smokers' exposure to nicotine.

With less than 0.6 mg nicotine per cigarette and less than 0.05 mg nicotine yield per cigarette, BRAND A cigarettes are the world's lowest nicotine tobacco cigarettes. Relative to "Big Tobacco" cigarette brands, including Marlboro®, Camel®, Newport®, and American Spirit®, BRAND A contains 95% less nicotine. 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 is very pleased with the productive and encouraging communication it received from the FDA. Though the Company is only requesting an MRTP marketing order that will allow 22nd Century to disclose that BRAND A reduces smokers' exposure to nicotine, the FDA has requested more information related to the independent clinical studies on the Company's Very Low Nicotine tobacco that *focused on smoking cessation and harm reduction objectives*.

Further, though the Company's MRTPAs and PMTAs for BRAND A included a comprehensive overview of many independent clinical trials that have found that smoking 22nd Century's Very Low Nicotine cigarettes delivers the sensory and behavioral experience associated with conventional cigarettes while providing only minimal exposure to the most addictive component of tobacco, the FDA expressed interest in receiving additional documents pertaining to research findings and statistical analyses related to the focus group studies that were conducted in support of the Company's BRAND A applications.

In response to the FDA's requests, and in conjunction with additional clarifying guidance, the Company has withdrawn its existing filings in order to file even more expansive and robust MRTPAs and PMTAs for BRAND A that will include additional scientific data and information from already completed clinical studies on the Company's Very Low Nicotine tobacco cigarettes, in addition to smoking cessation research. In order to help further expedite the FDA review process, the Company also intends to bifurcate its application into separate PMTAs and MRTPAs for BRAND A to enjoy the benefit of the FDA's shorter review timing for PMTAs as compared to MRTPAs.

As 22nd Century expands upon its discussion and interactions with the FDA's Center for Tobacco Products (CTP) on the Company's MRTPAs and PMTAs for its BRAND A Very Low Nicotine over-the-counter product, the Company is also continuing to separately work with the FDA's Center for Drug Evaluation and Research (CDER) with respect to the Company's previously-filed New Drug Application (NDA) for 22nd Century's proposed "X-22" prescription-based smoking cessation product. Thus, 22nd Century is advancing two distinct products – one a proposed reduced exposure combustible cigarette, the other a proposed pharmaceutical smoking cessation aid – with different parts of the FDA.

"The World Health Organization has recommended 'mandated reductions in nicotine to minimally addictive levels.' Unfortunately, at present, smokers in the United States do not have a Very Low Nicotine cigarette option," explained Henry Sicignano, III, President and Chief Executive Officer of 22nd Century Group. "To address this critically important issue, we look forward to collaborating with the FDA in 2017 on both BRAND A and on X-22 in order to provide consumers access to 22nd Century's remarkable Very Low Nicotine products."

#### **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. 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, 2015, filed on February 18, 2016, 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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