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22nd Century Receives Order for 3.6 Million New SPECTRUM® Variable Nicotine Cigarettes for U.S. Government-Supported Research

The Company's Research Cigarettes Continue to Fuel Studies Adding to the Vast Body of Research Supporting a National Nicotine Standard for Combustible Cigarettes

WILLIAMSVILLE, N.Y., Dec. 08, 2020 (GLOBE NEWSWIRE) -- 22nd Century Group, Inc. (NYSE American: [XXII](#)), a leading plant-based, biotechnology company that is focused on tobacco harm reduction, announced today that the U.S. Food and Drug Administration (FDA) in coordination with the National Institute on Drug Abuse (NIDA) and others, has submitted an order to 22nd Century for 3.6 million variable nicotine research cigarettes. The Company's research cigarettes will continue to fuel numerous independent, scientific studies to validate the enormous public health benefits identified by the FDA and others of implementing [a national standard](#) requiring all cigarettes to contain minimally or non-addictive levels of nicotine.

The selection of SPECTRUM® cigarettes for use in ongoing research is not connected to 22nd Century's Modified Risk Tobacco (MRTP) application for the Company's reduced nicotine content VLN® cigarettes. 22nd Century believes that authorization of the Company's MRTP application is imminent, and it plans to launch VLN® cigarettes within just 90 days of authorization. 22nd Century continues to maintain a dialogue with the FDA, and the Company believes the agency is in the final stage of review. At this time, the Company has no outstanding requests for information from the FDA, and the Company is confident it has satisfied every FDA requirement for the agency to make a final decision about our application.

"Mitch Zeller, director of the CTP at the FDA recently presented at the Food and Drug Law Institute's Tobacco and Nicotine Products Conference and was asked whether the FDA is still considering moving ahead with the agency's plan to reduce nicotine content in cigarettes to non-addictive levels," said James A. Mish, chief executive officer of 22nd Century Group. "Zeller confirmed that the FDA remains 'absolutely committed to everything that was in that plan.' The continuation of studies to validate the role of reduced nicotine content cigarettes in public health and their potential to reduce and even eliminate tobacco-related diseases and death demonstrate the FDA's continued commitment to tobacco harm reduction."

Mish added, "We are proud to partner with public health researchers and look forward to the next step in the FDA's plan to reduce the nicotine content of all cigarettes sold in the U.S. to minimally or non-addictive levels. 22nd Century remains the leader in reduced nicotine content tobacco products. We believe when the FDA mandate ultimately goes into effect, we will be well-positioned to capitalize on this tremendous opportunity, and we are committed to licensing our technology to make it possible for every cigarette manufacturer in the U.S. to comply with the standard."

Published in 2017, the FDA's ground-breaking [Comprehensive Plan for Tobacco and Nicotine Regulation](#) aims to set a product standard for cigarettes that achieves "minimally or non-addictive" levels of nicotine. Featuring 95 percent less nicotine, the Company's VLN® cigarettes, once authorized, would serve as a vanguard for the FDA's proposed plan. Importantly, the FDA projects that reducing nicotine levels in all combustible cigarettes to just 0.5 milligrams of nicotine per gram of tobacco, a level already achieved by VLN®, would help five million adult smokers quit one year after implementation, save over eight million American lives by the end of the century, and protect future generations from becoming addicted to cigarettes in the first place.

The FDA authorization of VLN® will make 22nd Century the first, and likely the only, company in the world to ever

achieve a MRTP designation for a combustible cigarette. Once authorized, the company will rollout VLN® to convenience stores, pharmacies, and other retail tobacco outlets in the U.S. paired with a compelling marketing campaign to introduce adult smokers to the world's lowest nicotine content cigarette. 22nd Century plans to position VLN® in the premium price segment of the cigarette market and expects it to deliver corresponding margins.

With more than 34 million smokers in the U.S. and more than 1 billion smokers worldwide, the FDA's authorization of 22nd Century's MRTP application has the potential to create significant demand for the Company's VLN® cigarettes. 22nd Century believes that achieving just one-quarter of one percent (0.25 percent) market share with this disruptive product could over time drive the Company's market capitalization more than 10 times higher. In addition, the Company believes that the FDA's authorization of 22nd Century's MRTP will open multiple licensing opportunities for 22nd Century's proprietary reduced nicotine technology in the U.S. and globally.

About SPECTRUM®

SPECTRUM® research cigarettes were developed in collaboration with FDA, NIDA (a division of the National Institutes of Health (NIH)), the Centers for Disease Control and Prevention (CDC), and the National Cancer Institute (NCI). To date, 22nd Century has provided more than 28 million proprietary SPECTRUM® research cigarettes for numerous independent scientific studies, funded largely by the FDA, the National Institutes of Health (NIH), and other U.S. federal government agencies. The studies, using 22nd Century's reduced nicotine content tobacco cigarettes, show that smokers who use the Company's products: (i) reduce their nicotine exposure and dependence, (ii) smoke fewer cigarettes per day, (iii) increase their number of smoke-free days, and (iv) double their quit attempts – all with minimal or no evidence of nicotine withdrawal or compensatory smoking.

About 22nd Century Group, Inc.

22nd Century Group, Inc. (NYSE American: [XXII](#)) is a leading plant biotechnology company focused on technologies that alter the level of nicotine in tobacco plants and the level of cannabinoids in hemp/cannabis plants through genetic engineering, gene-editing, and modern plant breeding. 22nd Century's primary mission in tobacco is to reduce the harm caused by smoking through the Company's proprietary reduced nicotine content tobacco cigarettes – containing 95% less nicotine than conventional cigarettes. The Company's primary mission in hemp/cannabis is to develop and commercialize proprietary hemp/cannabis plants with valuable cannabinoid profiles and desirable agronomic traits.

Learn more at xxiicentury.com, on Twitter [@_xxiicentury](#) and on [LinkedIn](#).

Cautionary Note Regarding Forward-Looking Statements

Except for historical information, all of the statements, expectations, and assumptions contained in this press release are forward-looking statements. Forward-looking statements typically contain terms such as "anticipate," "believe," "consider," "continue," "could," "estimate," "expect," "explore," "foresee," "goal," "guidance," "intend," "likely," "may," "plan," "potential," "predict," "preliminary," "probable," "project," "promising," "seek," "should," "will," "would," and similar expressions. Actual results may differ materially from those explicit or implicit in forward-looking statements. Important factors that could cause actual results to differ materially are set forth in "Risk Factors" in the Company's Annual Report on Form 10-K filed on March 11, 2020 and on Quarterly Reports on Form 10-Q. All information provided in this release is as of the date hereof, and the Company assumes no obligation to publicly update or revise any forward-looking statements as a result of new information, future events, or otherwise, except as required by law.

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