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22nd Century Group VP of Regulatory Science to Participate in FDLI Panel in Response to Recent FDA Action on Comprehensive Plan and Reduced Nicotine Mandate

- *Company Supports This Week's Positive FDA Action on E-Cigarettes, Demonstrating the Agency's Commitment to Providing Adult Smokers with Alternatives to Highly Addictive Cigarettes*
- *Applauds FDA's Active Push Forward on Plan to Reduce Amount of Nicotine in All Combustible Cigarettes to Non-Addictive Levels*

BUFFALO, N.Y., Oct. 13, 2021 (GLOBE NEWSWIRE) -- 22nd Century Group, Inc. (Nasdaq: [XXII](#)), a leading agricultural biotechnology company focused on tobacco harm reduction, reduced nicotine tobacco, and health and wellness through plant science, announced today that the Company's Vice President of Regulatory Science, John Pritchard, was invited and will participate as a panelist at the Food and Drug Law Institute (FDLI) [Tobacco and Nicotine Products Regulation and Policy Conference](#) as part of the event's session, "Reactor Panel: Assessing the Past, Present, and Future of the Comprehensive Plan," on Wednesday, **October 27, 2021**, at 11:55 a.m. ET. The session will consider key points of the U.S. Food and Drug Administration's (FDA) Center for Tobacco Products Director, Mitch Zeller's keynote address, and the current state of and future directions for [FDA's Comprehensive Plan](#) for product regulation, in particular the [mandate](#) to make all cigarettes "minimally or non-addictive."

"We are thrilled that John is representing 22nd Century Group on this critically important panel to discuss the FDA's Comprehensive Plan," said James A. Mish, chief executive officer of 22nd Century Group. "Following yesterday's announcement by FDA, there are now authorized products in the vape category, the heated tobacco category, and smokeless tobacco category. The Agency should now authorize 22nd Century's modified risk tobacco product (MRTP) application for our VLN[®] reduced nicotine content cigarettes to give adult smokers another alternative to highly addictive cigarettes." He added, "Such a move would be a significant step towards FDA's proposed standard to reduce the level of nicotine in all combustible cigarettes sold in the U.S. to 'minimally or non-addictive' levels, the health impact of which would be generationally significant, with millions of lives saved. VLN[®] reduced nicotine content cigarettes and non-combustible nicotine products are the two pillars of FDA's harm reduction strategy. VLN[®] cigarettes will help adult smokers reduce their exposure to nicotine, the addictive chemical in tobacco, while those adult smokers who still desire nicotine, less harmful alternatives are now available."

"Set against the backdrop of the pandemic and other challenges, FDA has nonetheless demonstrated its ongoing commitment to advance its Comprehensive Plan. For example, in April of this year, FDA reaffirmed that a product standard for reducing nicotine in cigarettes remained 'on the table,' and the New York Times [reported](#) yesterday that the FDA continues to work on this critical public health initiative," said Pritchard. "I am delighted to have this opportunity to respond to Mitch Zeller's presentation later this month and to share our perspective on FDA's recent and future actions."

Joining Pritchard on the panel will be world-renowned reduced nicotine researcher, Dorothy K. Hatsukami, Professor, Department of Psychiatry and Behavioral Sciences at the University of Minnesota Medical School; Desmond Jenson, Lead Senior Staff Attorney for Federal Regulation, Commercial Tobacco Control Programs, Public Health Law Center at Mitchell Hamline School of Law; and Valerie Briggs Solomon, Assistant General Counsel and Vice President, RAI Service Company.

Public health researchers [project](#) that the enactment of a nicotine cap would help more than five million people to quit smoking within the first year of implementation, save more than eight million American lives by the end of the century, and that more than 134 million life-years would be gained by 2100. More than [16 million Americans](#) are currently living with diseases caused by smoking, and with every delay in action, more people are dying.

Introducing a standard nicotine cap could decrease the chances of future generations becoming addicted to cigarettes and could make it easier for currently addicted smokers to quit.

22nd Century Group's VLN[®] cigarettes, which contain 0.5 milligrams of nicotine per gram of tobacco, are the only combustible tobacco products able to meet the nicotine levels proposed in the FDA's [Advanced Notice of Proposed Rulemaking](#) for a tobacco product standard that requires all combustible cigarettes to contain "minimally or non-addictive" levels of nicotine. The Company's menthol and non-menthol reduced nicotine content cigarettes have already received a Premarket Tobacco Product Application (PMTA) designation indicating FDA's decision that they are "appropriate for the protection of public health." An MRTP designation will allow 22nd Century to communicate the key features of its VLN[®] King and VLN[®] Menthol King cigarettes, including the headline claim of 95% less nicotine. Despite its reduced nicotine content, VLN[®] tastes, smells, and smokes like a conventional cigarette. The Company is fully prepared to launch VLN[®] in the U.S. within 90 days of receiving its MRTP authorization. The Company will continue the launch process for VLN[®] in countries outside of the U.S. that do not require MRTP-type approvals. VLN[®] is expected to be introduced in the first of these international markets in the first quarter of 2022.

About 22nd Century Group, Inc.

22nd Century Group, Inc. (Nasdaq: [XXII](#)) is a leading agricultural biotechnology company focused on tobacco harm reduction and improving health and wellness through plant science. With dozens of patents allowing it to control nicotine biosynthesis in the tobacco plant, the Company has developed its proprietary reduced nicotine content (RNC) tobacco plants and cigarettes, which have become the cornerstone of the [FDA's Comprehensive Plan](#) to address the widespread death and disease caused by smoking. In tobacco, hemp/cannabis, and hop plants, 22nd Century uses modern plant breeding technologies, including genetic engineering, gene-editing, and molecular breeding to deliver solutions for the life science and consumer products industries by creating new, proprietary plants with optimized alkaloid and flavonoid profiles as well as improved yields and valuable agronomic traits.

Learn more at xxiicentury.com, on Twitter [@_xxiicentury](https://twitter.com/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 might 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, 2021. All information provided in this release is as of the date hereof, and the Company assumes no obligation to and does not intend to update these forward-looking statements, except as required by law.

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