



November 15, 2021

22nd Century Group Applauds Califf Nomination as FDA Commissioner

- *Califf Is a Longtime Proponent of Tobacco Control; Indicated Nicotine Mandate Should Be Key Priority For FDA*
- *M RTP Authorization And Launch of VLN[®] Will Serve as Vanguard for FDA's Proposed Nicotine Cap*

BUFFALO, N.Y., Nov. 15, 2021 (GLOBE NEWSWIRE) -- 22nd Century Group, Inc. (Nasdaq: [XXII](#)), a leading agricultural biotechnology company focused on tobacco harm reduction, reduced nicotine tobacco, and improving health and wellness through plant science, announced today that it strongly supports the nomination of Dr. Robert Califf as the next commissioner of the U.S. Food and Drug Administration (FDA). Califf is known to be a longtime proponent of tobacco control and supporter of the Agency's [Comprehensive Plan for Tobacco and Nicotine Regulation](#).

"We are thrilled to hear that Dr. Califf has been nominated to FDA's top position as Commissioner. This is positive news for 22nd Century Group as he is a longtime proponent of aggressive measures to reduce the harm caused by smoking and is fully supportive of the Agency's plans to render all cigarettes 'minimally or non-addictive,'" said James A. Mish, chief executive officer of 22nd Century Group. "Califf has previously indicated that a nicotine cap should be a key priority for the FDA. We look forward to the implementation of a nicotine mandate – which we believe is the single greatest opportunity to change the trajectory of public health. Our reduced nicotine content cigarette, VLN[®], is the only combustible tobacco product that meets the nicotine levels proposed in FDA's nicotine mandate. We stand ready to support FDA on this critical public health initiative."

Califf was one of the FDA officials at the center of the Agency's plans for Tobacco and Nicotine Regulation under the Obama Administration. In a [2019 blog](#) post for the Association of American Medical Colleges, Califf laid out his plans for regulating tobacco products, including the requirement for the tobacco industry to lower the amount of nicotine in its products to sub-addictive levels using selective breeding, a feat 22nd Century has already achieved in its VLN[®] product.

In recent months, Califf has directly urged the Biden Administration to get tough on tobacco companies. During a March panel discussion hosted by [STAT](#), he stated: "Tobacco use is becoming one of the most important markers of disparities in our economy and our health care system. I hope that this administration will have the courage to fight what will be tough battles."

More than 16 million Americans are currently living with diseases caused by smoking, and with every delay in action, even more people will die from smoking. Introducing a nicotine cap could significantly decrease the chances of youth becoming addicted to cigarettes and could make it easier for currently addicted smokers to quit.

Public health research projects that the enactment of a nicotine cap at 0.5 mg of nicotine per gram of tobacco – a level already achieved by 22nd Century's VLN[®] reduced nicotine content tobacco cigarette – 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 gain more than 134 million life-years by 2100.

In support of the FDA's plan, numerous independent scientific studies, funded largely by the FDA, the National Institutes of Health (NIH), and other U.S. federal government agencies, have demonstrated that using reduced nicotine content tobacco cigarettes helps smokers reduce their nicotine exposure and dependence, smoke fewer cigarettes per day, increase their number of smoke-free days, and double their quit attempts – all with minimal or no evidence of nicotine withdrawal or compensatory smoking.

Securing MRTP designation for VLN[®] remains 22nd Century's highest priority. The Company held a successful meeting with the FDA regarding its MRTP application October 14, 2021. Following the meeting, and in conjunction

with recent Center for Tobacco Products (CTP) activity, the Company's confidence in a positive outcome for its MRTTP application and timing is at its highest level to date. 22nd Century's MRTTP authorization and the launch of VLN[®] will serve as a vanguard for the FDA's proposed mandate to cap the levels of nicotine in combustible cigarettes. The Company's U.S. pilot program and manufacturing capabilities are in place to launch VLN[®] in the U.S. within 90 days of receiving MRTTP designation. Additionally, the Company is advancing its plans to launch VLN[®] in select international markets beginning 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, reduced nicotine tobacco 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 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](#), 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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