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22nd Century Group Secures New Contract Manufacturing Agreements, Expands Distribution Network and Manufacturing Capabilities Ahead of VLN® Launch

Company will Increase Investment in Tobacco Production and Testing Equipment and Add New Talent in Preparation for Projected Demand

BUFFALO, N.Y., July 22, 2021 (GLOBE NEWSWIRE) -- 22nd Century Group, Inc. (NYSE American: [XXII](#)), a leading plant-based, biotechnology company focused on tobacco harm reduction, reduced nicotine tobacco, and hemp/cannabis research, announced today that it has secured a substantial new agreement with a prominent tobacco industry partner that specializes in exporting cigarettes to countries outside the United States. As a result, the Company will make investments to optimize margins and improve efficiencies by hiring additional staff at its tobacco manufacturing facility in North Carolina, and by installing new equipment at the site to increase efficiencies. 22nd Century will also leverage this new relationship and others through its contract manufacturing operations (CMO) to establish additional distribution channels in preparation for the launch of its VLN® reduced nicotine content (RNC) cigarettes.

“Last year, we were successful in optimizing our contract manufacturing operations. Our net sales and gross profit margin increased year-over-year and we demonstrated to the industry that we are well positioned as a tobacco manufacturer,” says James A. Mish, chief executive officer of 22nd Century Group. “We continue to invest in efforts to prepare for the FDA’s (U.S. Food and Drug Administration) authorization of our Modified Risk Tobacco Product (MRTP) application for our VLN® reduced nicotine content cigarette. With these new agreements and our expanding investments, we are opportunistically using this time to ramp up our operations ahead of authorization, as we prepare to make VLN® available globally.”

This is the latest win for 22nd Century’s CMO operations. Earlier this year, the Company signed on a new cigar contract manufacturing customer, and it is currently in advanced negotiations with two other significant tobacco industry partners that could further expand 22nd Century’s sales domestically and internationally. 22nd Century is focused on preparing for the launch of its VLN® cigarettes, and the Company will leverage these newly established trade relationships to expand distribution of VLN® after the cigarettes are introduced.

In addition to the planned installation of new equipment to reduce waste at its manufacturing facility, the Company recently completed an expansion of testing capabilities at the site, which will allow for rapid, in-house analysis of its tobacco. This will improve the production cost per VLN® sample by more than 90%, while significantly reducing the lead time to uncover key data. Internal testing of the VLN® leaf is scheduled to begin at the facility in August, using the newly installed testing equipment.

The Company is highly confident that it is in the final stages of the FDA’s application process to obtain MRTP designation for its VLN® cigarettes. The FDA has already authorized 22nd Century’s RNC tobacco technology under the Premarket Tobacco Product Application (PMTA) pathway, saying that it is “appropriate for the protection of public health,” and concluding that it offers, “among several key considerations, the potential to reduce nicotine dependence in addicted adult smokers, who may also benefit from decreasing nicotine exposure and cigarette consumption.” MRTP designation will allow 22nd Century to communicate and market the key features of its RNC cigarettes, including the headline claim of 95% less nicotine. Although VLN® contains just 0.5 milligrams of nicotine per gram of tobacco, the cigarettes taste, smell, and smoke like traditional cigarettes. The Company is fully prepared to launch its VLN® cigarettes within 90 days of receiving authorization.

The FDA has proposed a [plan](#) to require all cigarettes sold in the U.S. to be made minimally and non-addictive. [Projections](#) show that when the FDA implements its nicotine cap, it would help five million adult smokers to quit within one year, help 33 million people to avoid becoming regular smokers, and save more than eight million American lives by the end of the century. The Company is fully prepared to license its patented RNC tobacco technology to every cigarette manufacturer in the industry to enable compliance with the FDA's plan.

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. Adult smokers deserve a choice and 22nd Century is committed to bringing VLN® to market.

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 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 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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