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FDA Authorizes Marketing of 22nd Century Group's Proprietary Moonlight® and Moonlight® Menthol Cigarettes

FDA determines that sale of product in the U.S. is 'appropriate for the protection of the public health'

Williamsville, NY, Dec. 17, 2019 (GLOBE NEWSWIRE) -- 22nd Century Group, Inc. (NYSE American: [XXII](#)), a plant biotechnology company that is a leader in tobacco harm reduction, Very Low Nicotine Content (VLNC) tobacco, and hemp/cannabis plant research, announced today that the U.S. Food and Drug Administration (FDA) has found that the marketing of 22nd Century Group's proprietary Moonlight® and Moonlight® Menthol brand cigarettes are "appropriate for the protection of the public health," and the FDA has issued marketing orders to permit the sale of these products in the U.S. This FDA authorization follows the FDA's review of the Premarket Tobacco Product Applications (PMTA) previously submitted by 22nd Century Group.

"FDA authorization of 22nd Century's proprietary Moonlight® and Moonlight® Menthol brand cigarettes is a major milestone in our efforts to drive meaningful change in the tobacco industry," said Michael Zercher, President and Chief Operating Officer of 22nd Century Group. "22nd Century joins just two other companies in having marketing orders granted under the FDA's PMTA regulatory pathway. Those other companies, Philip Morris International and Swedish Match, are very large, global tobacco companies with significant financial, scientific and regulatory affairs resources, so we are extremely proud of the world-class work done by our regulatory team to successfully secure this marketing authorization from the FDA."

The FDA also issued a [news release](#) today explaining why Moonlight® and Moonlight® Menthol brand cigarettes received authorization for marketing and sales of the products in the U.S. market. In that news release, Mitch Zeller, J.D., the Director of the FDA's Center for Tobacco Products, stated, "Conventional cigarettes are designed to create and sustain addiction to nicotine. In announcing the FDA's comprehensive plan to regulate tobacco and nicotine in July 2017, we noted our commitment to taking actions that will allow more addicted smokers to reduce their dependence and decrease the likelihood that future generations will become addicted to cigarettes... Today's authorization represents the first product to successfully demonstrate the potential for these types of tobacco products to help reduce nicotine dependence among addicted smokers." The FDA news release further provides that, "The agency determined that non-smokers, including youth, are also unlikely to start using the products, and those who experiment are less likely to become addicted than people who experiment with conventional cigarettes."

"We look forward to continuing to work with the FDA regarding our separate Modified Risk Tobacco Product application and to supporting the FDA's continued work in implementing a reduced nicotine product standard to require all cigarettes sold in the U.S. to be made minimally or non-addictive," commented James W. Cornell, Chairman of the Board of Directors of 22nd Century Group. "We remain focused on our core missions of reducing the harm caused by smoking and building a world-class hemp/cannabis company."

About 22nd Century Group, Inc.

22nd Century is a plant biotechnology company focused on technology which allows it to decrease the level of nicotine in tobacco plants and to modify the level of cannabinoids in hemp/cannabis plants through genetic engineering and modern plant breeding. 22nd Century's growth strategies are focused on meaningful, long-term, shareholder value creation. The Company's first strategic growth objective is to drive change in the tobacco industry by reducing the harm caused by smoking through the commercialization of its proprietary Very Low Nicotine Content tobacco and related intellectual property. The Company's second strategic growth objective is to build a leading, profitable business in the fast-growing, emerging, legal hemp/cannabis space by leveraging the Company's leadership in cannabis plant research, comprehensive expertise in FDA-regulated spaces, leadership

team with deep experience in consumer-packaged goods, and strong and flexible balance sheet. To learn more about, 22nd Century please visit www.xxiicentury.com.

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, 2018, filed on March 6, 2019, 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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