



September 25, 2014

22nd Century Group Granted Meeting with FDA to Advance Development of a Potential Modified Risk Cigarette

CLARENCE, N.Y.--(BUSINESS WIRE)-- 22nd Century Group, Inc. (NYSE MKT:[XXII](#)) announced today that the Center for Tobacco Products ("CTP") of the U.S. Food and Drug Administration ("FDA") has granted the Company a meeting on November 12, 2014 to discuss the further development of the Company's potential modified risk tobacco product, code-named BRAND B ("BB-1"), which is a cigarette that is designed to provide an exceptionally low tar-to-nicotine yield ratio. As compared to other commercial low-yield cigarettes, the only differentiating factor of the BB-1 cigarette is that 22nd Century's proprietary high-nicotine tobacco is used, which tobacco is planted, grown, harvested, cured, and processed in exactly the same manner as conventional commercial tobacco.

Pursuant to the Family Smoking Prevention and Tobacco Control Act of 2009 ("Tobacco Control Act"), the Company intends to demonstrate, through BB-1 exposure studies, compelling scientific evidence that 22nd Century's cigarettes (i) reduce exposure to tobacco toxins and (ii) are reasonably likely to result in a measurable and substantial reduction in morbidity or mortality among individual tobacco users. The purpose of the Company's meeting with CTP will be to seek the Agency's concurrence that 22nd Century's proposed BB-1 clinical study is adequate to support the development of BB-1 as a potential modified risk tobacco product.

22nd Century believes that BB-1 will allow smokers to obtain a satisfactory amount of nicotine per cigarette while inhaling less smoke, including "tar" and carbon monoxide. Commercial cigarette brands average a tar-to-nicotine ratio of approximately 13 to 1, meaning that the smoker must inhale 13 parts "tar" for every 1 part nicotine. The tar-to-nicotine ratio of BB-1 is approximately 6 to 1.

By utilizing a combination of 22nd Century's proprietary high-nicotine content tobacco and a special low-yield cigarette design, BB-1 has the nicotine yield of a commercial full flavor cigarette, but the "tar" yield of an "ultra-light" commercial cigarette. Consequently, the Company expects that BB-1 cigarettes will curtail the compensatory smoking behaviors (such as taking bigger puffs and more puffs per cigarette) associated with what were formerly known in the United States as "light" and "ultra-light" cigarettes due to diluted nicotine amounts in the smoke, as compared to their full flavor (high yield) counterparts. The Tobacco Control Act banned the use of "light," "ultra-light" and similar descriptors on the labeling and advertising of cigarettes since these types of cigarettes generally do not reduce smoke exposure.

Joseph Pandolfino, Founder and CEO of 22nd Century Group, explained, "BB-1 is designed to deliver a conventional amount of nicotine to smokers – with substantially less smoke. We look forward to working with the FDA during the development of this exciting product." With FDA concurrence, 22nd Century will conduct an exposure study on BB-1 in the first quarter of 2015.

About 22nd Century Group, Inc.

22nd Century is a plant biotechnology company whose proprietary technology through genetic engineering and plant breeding allows (i) the level of nicotine (and other nicotinic alkaloids) in the tobacco plant to be decreased or increased and (ii) the levels of cannabinoids in the cannabis plant to be decreased or increased, in addition to the cannabinoid profile being tailored. 22nd Century owns or is the exclusive licensee of 129 issued patents in 78 countries plus an additional 51 pending patent applications, and 22nd Century has co-exclusive rights to another 16 patent applications. *Goodrich Tobacco* is focused on commercial tobacco products and potentially less harmful cigarettes. *Botanical Genetics* is focused on natural cannabis-based products for human health, well-being and nutrition, in addition to industrial products refined from cannabis. *Hercules Pharmaceuticals* is focused on X-22, a prescription smoking cessation aid in development.

For additional information, 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. 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, 2013, filed on January 30, 2014, 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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