FDA Authorizes Clinical Trial for 22nd Century’s BRAND B Low Tar-to-Nicotine Ratio Cigarettes

22nd Century’s Proprietary Brand B Cigarettes Will be a Modified-Risk-Tobacco-Product Candidate

CLARENCE, N.Y.—(BUSINESS WIRE)—22nd Century Group, Inc. (NYSE MKT: XXII), announced today that the U.S. Food and Drug Administration (FDA) has granted 22nd Century authorization to conduct a clinical trial studying the Company’s BRAND B, low tar-to-nicotine ratio cigarettes. This trial is designed to confirm that as smokers make the adjustment to a higher nicotine cigarette, they take in less smoke because the nicotine is more readily available. 22nd Century has engaged a Contract Research Organization with extensive experience in combustible cigarette exposure studies to conduct the BRAND B trial this summer.

According to the Centers for Disease Control and Prevention (CDC), 32% of smokers (nearly 12 million) do not wish to quit smoking. For these smokers, 22nd Century is developing its BRAND B Low Tar-to-Nicotine ratio cigarettes as a reduced exposure product candidate. The Company intends to submit a Modified Risk Tobacco Product (MRTP) application to the FDA for Brand B. Independent surveys have shown that even though 30-50% of American smokers are not committed to quitting, 90% of these smokers would be willing to try a potentially reduced exposure tobacco product. For this reason, 22nd Century believes the Company’s proprietary BRAND B product has enormous market potential.

“Our initial clinical trial investigating the effects of BRAND B’s design-objective — the reduced delivery of smoke components, other than nicotine — is a measurable step forward in the development of our Company’s mission,” explained Dr. Michael Moynihan, Vice President of Research & Development at 22nd Century Group.

About 22nd Century Group, Inc.

22nd Century is a plant biotechnology company focused on technology which allows it to increase or decrease the level of nicotine in tobacco plants and the level of cannabinoids in cannabis plants through genetic engineering and plant breeding. The Company’s primary mission in tobacco is to reduce the harm caused by smoking. The Company’s primary mission in cannabis is to develop proprietary cannabis strains for important new medicines and agricultural crops. Visit www.xxiiicentury.com and www.botanicalgenetics.com for more information.

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, 2016, filed on March 8, 2017, 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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Source: 22nd Century Group, Inc.