



June 22, 2017

22nd Century Receives Guidance from FDA on Phase III Clinical Trials

Company plans to commence Phase III trials for “X-22” smoking cessation product in 2018

CLARENCE, N.Y.--(BUSINESS WIRE)-- 22nd Century Group, Inc. (NYSE MKT: [XXII](#)), a plant biotechnology company that is a leader in tobacco harm reduction, announced today that on June 20, 2017, the Company and its wholly owned subsidiary, Heracles Pharmaceuticals, participated in a meeting with the multi-discipline review team in the Division of Anesthesia, Analgesia, and Addiction Products at the Center for Drug Evaluation and Research (CDER) of the U.S. Food and Drug Administration (FDA) regarding the Company’s Investigational New Drug Application (IND) for 22nd Century’s X-22 prescription-based smoking cessation product in development so that it may become available for doctors to prescribe to help their patients to stop smoking. The meeting with the FDA/CDER was very positive and productive. FDA/CDER and the Company will work to reach agreement on the Company’s design and implementation of two parallel, Phase III clinical trials to be conducted by the Company in various parts of the United States to show that the Company’s X-22 prescription-based smoking cessation product will result in a more robust quit rate in smoking as compared to existing smoking cessation products that are already in the market in the U.S. The Company believes that it will be able to achieve such robust results.

Henry Sicignano, III, President and Chief Executive Officer of 22nd Century Group, stated, “The mission of our Company is to reduce the harm caused by smoking and we believe that we can help smokers to successfully stop smoking through the use of our novel X-22 smoking cessation product in development. We look forward to working collaboratively and closely with the FDA during 2017 regarding the approval of important aspects of the two parallel, Phase III clinical trials on X-22 that we intend to commence in the first half of 2018, subject to our determination of whether we will use funds from a third-party or Company funds to conduct such clinical trials. The public health implications of a smoking cessation product that is more robust in effectiveness than other existing smoking cessation products is enormous. We look forward to continuing to work closely with the FDA on this very important public health matter.”

About 22nd Century Group, Inc.

22nd Century is a plant biotechnology company focused on genetic engineering and plant breeding which allows the increase or decrease of the level of nicotine in tobacco plants and the level of cannabinoids in cannabis plants. 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 hemp/cannabis strains for important new medicines and agricultural crops. Visit www.xxiicentury.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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