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The New England Journal of Medicine Publishes Landmark Study Using 22nd Century's Proprietary Very Low Nicotine Cigarettes

CLARENCE, N.Y.--(BUSINESS WIRE)-- 22nd Century Group, Inc. (NYSE MKT:[XXII](#)), a leader in tobacco harm reduction, announced that *The New England Journal of Medicine* has published a special article describing a milestone study that used the Company's proprietary SPECTRUM research cigarettes ([N Engl J Med 2015; 373:1340-1349](#)). The Center for the Evaluation of Nicotine in Cigarettes led the double-blind, parallel, randomized clinical trial involving 840 smokers at ten locations. The authors concluded that data from the study suggests, as compared with cigarettes of conventional nicotine content, 22nd Century's proprietary low nicotine SPECTRUM cigarettes were "associated with reductions in smoking, nicotine exposure, and nicotine dependence, with minimal evidence of nicotine withdrawal, compensatory smoking, or serious adverse events."

The study, which was funded by the National Institute on Drug Abuse (NIDA) and the U.S. Food and Drug Administration (FDA) Center for Tobacco Products, included six styles of 22nd Century's SPECTRUM research cigarettes. The SPECTRUM cigarettes had nicotine contents ranging from 15.8 mg per gram of tobacco (similar to commercial brands) to 0.4 mg per gram ("very low nicotine"). The very low nicotine SPECTRUM cigarettes contain 95% less nicotine than conventional cigarettes. 22nd Century is the only company in the world capable of growing tobacco with such low nicotine content.

Researchers found that during the 6th and final week of the trial, participants who were assigned 22nd Century SPECTRUM cigarettes with 0.4 mg/g nicotine smoked fewer cigarettes per day (14.9) than those assigned to their usual brand (22.2). In fact, very low nicotine cigarettes were found to reduce exposure to, and dependence on, nicotine and to reduce cravings while adverse events were generally mild and similar among groups. Moreover, in the 30 days following the trial, smokers of very low nicotine cigarettes reported they attempted to quit smoking at a rate double that of participants who smoked cigarettes with 15.8 mg/gram nicotine (34.7% vs. 17%).

The study's lead author, Dr. Eric Donny, explained in an article posted on [usatoday.com](#), "The evidence is getting stronger that reducing nicotine reduces smoking and makes people less addicted to cigarettes and, in doing so, might make them more likely to quit." To further test this theory, 22nd Century's proprietary SPECTRUM cigarettes are being used in a Phase III clinical study that follows 1,250 smokers for five months ([ClinicalTrials.gov NCT02139930](#)).

The results of [previous studies](#) using very low nicotine cigarettes have demonstrated a host of desirable outcomes including reduced smoking, reduced nicotine exposure, reduced nicotine dependence, increased abstinence, reduced exposure to toxicants and few adverse events with little evidence of withdrawal-related discomfort or safety concerns. Unlike "light" cigarettes (as previously labeled and marketed by conventional tobacco companies) which reduce machine-smoking nicotine yields by diluting the smoke rather than by reducing the nicotine content of the tobacco itself, very low nicotine cigarettes do not result in compensatory smoking.

In the past 8 years, the prospect of reducing the addictiveness of cigarettes has received renewed attention from numerous health organizations, including the Institute of Medicine, the World Health Organization (WHO) and the Office of the U.S. Surgeon General. The Tobacco Control Act, enacted in 2009, granted the FDA authority to set standards that reduce the nicotine content of all cigarettes sold in the United States.

"The current study by Donny and colleagues adds to a growing literature supporting the feasibility and potential benefits of a national nicotine reduction policy..." explained public health policy reform advocates, Drs. Michael Fiore and Timothy Baker in a companion article in the same issue of the NEJM. "Reducing the nicotine content of combustible tobacco to levels that will not sustain dependence seems to us to be the most promising regulatory policy option for preventing [at least] 20 million premature deaths."

About 22nd Century Group, Inc.

22nd Century Group is a plant biotechnology company focused on technology which allows it to increase or decrease the level of nicotine in tobacco plants through genetic engineering and plant breeding. The Company's mission is to reduce the harm caused by smoking. 22nd Century currently owns or exclusively controls more than 185 issued patents and more than 50 pending patent applications around the world. The Company's strong IP position led to a licensing agreement with British American Tobacco ("BAT"), the world's second largest tobacco company. Visit www.xxiiicentury.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. 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 year ended December 31, 2014, filed on February 6, 2015, 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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