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## **22nd Century Group Announces Initial Results of Smoking Cessation Trial**

*Results will help determine the optimal nicotine content for X-22*

CLARENCE, N.Y. -(BUSINESS WIRE)- 22nd Century Group, Inc. (OTCBB: [XXII](#)), a company focused on smoking cessation and tobacco harm reduction products, today announced X-22, a prescription smoking cessation aid in development consisting of very low nicotine (VLN) cigarettes, showed a reduction of smoking from baseline over the 6-week treatment period in the company's Phase II-B clinical trial. Also, the median number of cigarettes smoked was significantly reduced to 11% of baseline (89% reduction) during the 4-week abstinence period.

However, there was no statistically significant difference compared to the active control, a cigarette containing conventional nicotine levels. A preliminary assessment of the Phase II-B trial data also showed that X-22 did not meet its primary endpoint; there was no statistical difference in quitting during the 4-week abstinence period between X-22 and the active control. The two and three-month follow-up periods of the trial are ongoing. As with other clinical trials utilizing VLN cigarettes, there were no serious adverse events attributable to X-22 and the product was well-tolerated.

“These preliminary quitting results are puzzling when compared to results of other independent studies using our VLN product,” stated Joseph Pandolfino, 22nd Century's CEO. “We are in the process of evaluating the reasons for the unexpected data from our trial, including the real possibility that we may have gone slightly too far in reducing the nicotine content of X-22.”

Previous independent smoking cessation trials, all of which increased cessation, utilized VLN cigarettes containing 22nd Century's proprietary VLN tobacco with a 95% nicotine reduction as compared to conventional cigarettes; the version of X-22 used in 22nd Century's Phase II-B clinical trial contained 97% less nicotine. “Although this appears to be an insignificant difference, it equates to the X-22 version having approximately half of the nicotine of VLN cigarettes utilized in these previous studies,” Mr. Pandolfino explained.

A separate and independent smoking cessation Phase II trial that utilized VLN cigarettes that 22nd Century supplied (containing approximately 95% less nicotine as compared to conventional cigarettes) has recently concluded, and the results are expected to be available in 2012. Over a 6-week treatment period, this 3-arm study evaluated smokers using just VLN cigarettes, just the 21-mg patch and both products concurrently. The results of this Phase II trial will be compared to 22nd Century's Phase II-B trial to determine the variables that optimize cessation, including nicotine content. 22nd Century's management is confident that its VLN cigarettes are a useful tool for smoking cessation and that the results of its Phase II-B trial will be crucial in determining the optimal nicotine content of the company's VLN cigarettes for cessation going forward.

Another independent smoking cessation trial utilizing VLN cigarettes recently concluded, however, subjects in this Phase III trial did not just use VLN cigarettes. Dr. Michael Moynihan, 22nd Century's Vice President of Research and Development, noted, “The *New Zealand Herald* [reported](#) last week that a ‘groundbreaking’ study by Auckland University found that smokers offered VLN

cigarettes in conjunction with nicotine replacement therapy (NRT) had a higher quit rate than those given just NRT patches, gums or lozenges.”

The reduction in cigarette usage in 22nd Century’s own Phase II-B clinical trial and in other independent studies suggests a significant opportunity for 22nd Century’s VLN cigarettes to potentially obtain a “modified risk” claim under the Tobacco Control Act. The company expects the final regulations for modified risk tobacco products to be issued April 2012 by the U.S. Food and Drug Administration (FDA).

22nd Century is committed to the X-22 development program and continuing to assist the public health community, including the FDA, in determining how different nicotine levels in cigarettes affect cessation and smoking behavior, including whether there is a threshold level of nicotine in which cigarettes do not produce dependence. *The New York Times* recently [reported](#) that 22nd Century is supplying SPECTRUM<sup>®</sup> cigarettes to the U.S. government. SPECTRUM<sup>®</sup> contains various levels of nicotine and is solely for research purposes. 22nd Century believes the findings from studies conducted with SPECTRUM<sup>®</sup> will be an important factor in determining tobacco public policy.

About 22nd Century Group, Inc.

Founded in 1998, 22nd Century Limited, LLC (22nd Century), a wholly-owned subsidiary of 22nd Century Group, Inc., is a plant biotechnology company whose proprietary technology allows for the level of nicotine (and other nicotinic alkaloids) in the tobacco plant to be decreased or increased through genetic engineering and breeding. 22nd Century owns or is the exclusive worldwide licensee of 99 issued patents in 79 countries where at least 75% of the world’s smokers reside. The company is committed to developing and commercializing (i) the world’s most effective and acceptable smoking cessation aid and (ii) for those smokers who refuse to quit smoking, consumer-acceptable modified risk tobacco products that reduce exposure to smoke toxins, as compared to conventional cigarettes.

For additional information, please visit: [www.xxiiicentury.com](http://www.xxiiicentury.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 the company, 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 prospectus dated September 20, 2011, including the section entitled “Risk Factors,” and our reports filed with the 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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