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Enrollment Completed in 22nd Century's X-22 Phase II-B Clinical Trial

CLARENCE, N.Y.--(BUSINESS WIRE)--22nd Century Group, Inc. (OTCBB: [XXII](#)), a company focused on smoking cessation and tobacco harm reduction products, announced today that enrollment of its X-22 Phase II-B clinical trial has been successfully completed; 234 smokers have been randomized in the double-blind, active-controlled, multi-center smoking cessation study.

X-22, a prescription smoking cessation aid in development, consists of a kit containing very low nicotine (VLN) cigarettes containing 22nd Century's proprietary tobacco. X-22 VLN cigarettes contain 97% less nicotine than Marlboro® Gold, the U.S. cigarette market leader, formerly known as Marlboro Lights®.

"Completed enrollment of our Phase II-B clinical trial for X-22 represents another key milestone for 22nd Century. We were originally targeting 216 subjects and are pleased to have 234 subjects in our study," explained Joseph Pandolfino, founder and CEO of 22nd Century.

22nd Century's Phase II-B trial is the largest study of its type to date. The X-22 therapy protocol allows subjects to exclusively smoke VLN cigarettes, without concurrent use of nicotine replacement therapy (NRT), over a 6-week treatment period to facilitate the goal of quitting by the end of treatment.

Primary endpoint results of the study, four weeks of continuous abstinence from smoking (measured immediately following the 6-week treatment period), will be announced by the company in early December 2011. Quit rates of subjects using X-22 cigarettes will be compared to quit rates of those subjects using active control cigarettes (containing conventional nicotine content). Two and three-month follow-up quit rates (from the end of treatment) will also be evaluated.

22nd Century submitted a request for Fast Track designation for X-22 and on August 18, 2011, the U.S. Food and Drug Administration (FDA) informed the company that designation of X-22 as a Fast Track product could not be granted at that time but, if the company desires further consideration, it should submit a new request for Fast Track designation. 22nd Century will file its subsequent Fast Track request with the FDA at approximately year-end 2011, which will include results of its Phase II-B clinical trial—the first clinical trial sponsored by 22nd Century under its own Investigational New Drug Application (IND). All previous smoking cessation studies with VLN cigarettes containing 22nd Century's proprietary tobacco, including Phase II clinical trials which all indicated efficacy, were independent studies and were not previously sponsored by 22nd Century under its own IND.

Mr. Pandolfino stated, "We believe X-22 will be granted Fast Track status by the FDA after completing our company-sponsored Phase II-B clinical trial because, as in other Phase II trials with VLN cigarettes, we expect X-22 to demonstrate one or more advantages (over currently approved smoking cessation products) in the following areas: efficacy, safety, compliance and convenience."

22nd Century believes hundreds of millions of smokers worldwide are desperate for a novel and effective smoking cessation product without serious side effects. According to the Centers for Disease Control and Prevention (CDC), cigarette smoking is the leading cause of preventable morbidity and mortality in the U.S., causing approximately 440,000 premature deaths annually. Out of 46 million American smokers, approximately 20 million make a serious attempt to quit smoking every year. On average, it takes smokers 8 to 11 quit attempts before achieving long-term success. Less than 5% of smokers in the U.S. permanently quit smoking each year.

Approximately 50% of U.S. smokers have failed to previously quit using NRT products: nicotine gums, patches, nasal sprays, inhalers and lozenges. On July 1 2009, the FDA [announced](#) that (the other two FDA-approved smoking cessation products) Chantix[®] (known as Champix[®] outside the U.S.) and Zyban[®] were required by the FDA to add Boxed Warnings to their package inserts.

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 98 issued patents in 79 countries where at least 75% of the world's smokers reside. We are 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

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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