22nd Century Group, Inc.

July 21, 2011

FDA Clears X-22 IND For Phase II-B Smoking Cessation Clinical Trial

WILLIAMSVILLE, N.Y.--(BUSINESS WIRE)-- 22nd Century Group, Inc. (OTCBB: XXII), a company focused on smoking cessation and tobacco harm reduction products, today announced that the U.S. Food & Drug Administration (FDA) has cleared an Investigational New Drug (IND) Application to conduct a Phase II-B clinical trial using X-22, a prescription smoking cessation aid in development.

X-22 consists of a kit of very low nicotine (VLN) cigarettes made from 22nd Century's proprietary tobacco. X-22 cigarettes for 22nd Century's Phase II-B clinical trial contain 97% less nicotine than Marlboro(R) Gold, the U.S. cigarette market leader, formerly known as Marlboro Lights(R). The X-22 therapy protocol allows patients to smoke X-22 cigarettes without restriction over the 6-week treatment period to facilitate the goal of quitting by the end of 6 weeks.

Independent studies, including successful Phase II clinical trials not sponsored by 22nd Century, have demonstrated that VLN cigarettes made from 22nd Century's proprietary tobacco facilitate quitting by satisfying smokers' cravings for cigarettes while (i) greatly reducing nicotine exposure and nicotine dependence and (ii) separating the act of smoking from the rapid delivery of nicotine.

This August smokers will be enrolled in a multicenter Phase II-B clinical trial. Primary endpoint results of the study, four weeks of continuous abstinence from smoking, are expected to be available in late November. Quit rates of patients using X-22 cigarettes will be compared to those using active control cigarettes with conventional nicotine content. "In addition to looking at the effect of X-22 cigarettes on initial quitting success, the study will also look at the effect on subjects' attitude toward cigarettes and smoking behavior," said Dr. Michael R. Moynihan, 22nd Century's Vice President of Research and Development. "Shorter-term independent studies with VLN cigarettes have shown reductions in craving for cigarettes even after quitting; we are very interested in looking at the persistence of the effect."

The FDA has advised 22nd Century that the Agency will decide by September whether to grant "Fast Track" designation to X-22. The FDA's Fast Track Development Program provides for expedited regulatory review of drugs undergoing clinical trials that treat serious or life threatening diseases and that demonstrate the potential to address unmet medical needs.

According to the Centers for Disease Control and Prevention (CDC), cigarette smoking is the leading cause of preventable morbidity and mortality in the United States, 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 quit previously using nicotine replacement therapy (NRT): gums, patches, nasal sprays, inhalers and lozenges. The other two FDA-approved smoking cessation products, Chantix(R) (known as Champix(R) outside the U.S.) and Zyban(R) were required by the FDA on July 1, 2009 to add Boxed Warnings to their package inserts.

Joseph Pandolfino, 22nd Century's founder and CEO explained, "X-22 has the lowest nicotine content of any cigarette in the world and falls below the drastically reduced nicotine levels recommended by both Dr. David A. Kessler, former FDA Commissioner, and Professor Gregory N. Connolly of the Harvard School of Public Health." Mr. Pandolfino added, "X-22 cigarettes smoke, taste and smell like typical cigarettes and have the potential to significantly increase smoking cessation by encouraging more smokers to attempt quitting with an acceptable and familiar product."

About 22nd Century Group, Inc.

Founded in 1998, 22nd Century Limited, LLC (22nd Century) 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. The company owns or exclusively controls 98 issued patents in 79 countries where at least 75% of the world's smokers reside. 22nd Century 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. Through a merger on January 25, 2011, 22nd Century became a wholly-owned subsidiary of 22nd Century Group, Inc. On June 22, 2011, the company announced that 22nd Century Limited, LLC submitted an IND to the FDA and requested that the FDA grant "Fast Track" designation to X-22.

For additional information, please visit: www.xxiicentury.com

Safe-Harbor Statement under the Private Securities Litigation Reform Act of 1995: This press release may contain forward-looking information within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), 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. Investors are cautioned that any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties, many of which are beyond the company's ability to control, and that actual results may differ materially from those projected in the forward-looking statements as a result of various factors including the "Risk Factors" disclosed in the company's reports filed with the SEC under the Exchange Act, including the company's Form S-1/A filed with the SEC on June 20, 2011 and potential uncertainties regarding the timing of results of the X-22 Phase II-B clinical trial, FDA-designation of X-22 for Fast Track status and FDA-approval of X-22 in general.

Source: 22nd Century Group, Inc.