22nd Century Group, Inc.

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22nd Century Files Investigational New Drug Application and Fast Track Request for X-22; Phase II-B Clinical Trial to Commence Immediately Upon FDA Clearance

WILLIAMSVILLE, N.Y.--(BUSINESS WIRE)--22nd Century Group, Inc. (OTCBB: XXII), a company focused on smoking cessation and tobacco harm reduction, announced today that 22nd Century Limited, LLC submitted an Investigational New Drug Application (IND) to the U.S. Food & Drug Administration (FDA) for 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® Gold, the U.S. cigarette market leader, formally known as Marlboro Lights®. 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.

Immediately upon FDA clearance of the IND, 216 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 this November. Quit rates of patients using X-22 cigarettes will be compared to those using an active control, cigarettes with conventional nicotine content.

22nd Century has requested that the FDA 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. It takes smokers an average of 8 to 11 quit attempts before achieving long-term success. Less than 5% of smokers in the U.S. permanently quit smoking each year.

Joseph Pandolfino, 22nd Century's Chief Executive Officer, stated, "There is clearly a large unmet medical need on a global scale for an effective, non-addictive, user-friendly smoking cessation product—without serious side effects. 22nd Century passionately believes X-22 is that product. The company is confident that the vast majority of smokers desiring to quit smoking would be willing to try X-22." X-22 is patented in the U.S. and internationally—where at least 75% of the world's 1.3 billion smokers reside.

Independent studies, including successful Phase II clinical trials, 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.

An independent Phase II trial of considerable interest to 22nd Century was conducted by Dr. Dorothy Hatsukami, Director of the National Transdisciplinary Tobacco Use Research Center at the

University of Minnesota Masonic Comprehensive Cancer Center and one of the nine voting members of the 12-person Tobacco Products Scientific Advisory Committee (TPSAC) at FDA's Center for Tobacco Products. Dr. Hatsukami's study compared the quitting efficacy of a VLN cigarette (containing 22nd Century's proprietary VLN tobacco), an FDA-approved 4-mg nicotine lozenge, and a low nicotine cigarette (containing 30% of the nicotine of a typical cigarette) in a total of 167 patients treated for 6 weeks (Hatsukami *et al*. 2010).

Point-prevalence abstinence at 6 weeks after the end of treatment was 47% for the group using the VLN cigarette, 37% for the nicotine lozenge group and 23% for the low nicotine cigarette group (p=.0357). Furthermore, the VLN cigarette was associated with greater relief of withdrawal from usual brand cigarettes than the nicotine lozenge. The protocol of 22nd Century's upcoming Phase II-B clinical trial is similar to that of the University of Minnesota trial.

Unlike the low nicotine cigarette, the VLN cigarette was not associated with compensatory smoking behaviors. By the end of the 6-week treatment period, patients in the VLN group (whether they quit or not) on average were smoking 12 VLN cigarettes per day, compared to a baseline of 19 cigarettes per day of their usual brand.

Mr. Pandolfino stated, "Smokers have limited pharmacological choices for quitting: (i) nicotine in different forms, otherwise known as nicotine replacement therapy (NRT), (ii) Chantix® and (iii) Zyban®. Approximately 50% of U.S. smokers have already failed to quit with NRT and some users become addicted to NRT products. Both Chantix® and Zyban® were required by the FDA on July 1, 2009 to add boxed warnings to their package inserts." These warnings highlight that serious neuropsychiatric events, including but not limited to depression, suicidal ideation, suicide attempt and completed suicide, have been reported in patients taking Chantix® and Zyban®. (Chantix® is known as Champix® outside the U.S.)

Since potential quitters are already smokers, X-22 cigarettes do not expose patients to new compounds or new drugs and do not introduce new side effects. As a prescription product, unlike cigarettes sold over-the-counter, X-22 cigarettes would be used for a relatively short period of time (6 weeks) and strictly for smoking cessation.

Mr. Pandolfino added, "X-22 has the potential to significantly increase smoking cessation by encouraging more smokers to attempt quitting with an acceptable and familiar product. X-22 cigarettes smoke, taste and smell like typical cigarettes. X-22 is not an electronic cigarette (e-cigarette). Indeed, e-cigarettes are not cigarettes at all, or even tobacco products, but electronic nicotine delivery devices."

Studies have demonstrated that e-cigarettes have very similar pharmacokinetic properties as the nicotine inhaler, a prescription-only NRT product already approved by the FDA (Bullen *et al.* 2009; Eissenburg 2010). VLN cigarettes made with 22nd Century's proprietary VLN tobacco have been shown to reduce craving for usual brand cigarettes more effectively than the FDA-approved nicotine inhaler (Barrett 2010).

On June 8, 2011, 22nd Century announced that the company's contracted farmers planted substantially more acres of VLN tobacco in 2011 compared to 2010.

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.

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

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