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22nd Century Continuing Development of its Smoking Cessation Aid; Independent Review of Clinical Trials Involving Very Low Nicotine Cigarettes is Encouraging

WILLIAMSVILLE, N.Y.—([BUSINESS WIRE](#))—22nd Century Limited, LLC (“22nd Century”) is pleased to announce that it is continuing development of a very low nicotine cigarette for use in smoking cessation. Clinical trial results demonstrate that these cigarettes, also referred to as ‘nicotine-free’ and ‘denicotinized,’ may be more effective for quitting than FDA-approved therapies.

22nd Century’s vice-president of research and development, Michael R. Moynihan, Ph.D. recently presented an overview of clinical investigations using very low nicotine (VLN) cigarettes in promoting smoking cessation in a presentation entitled, “Smoking with Reduced Reward as an Aid to Cessation” at the Visiongain 3rd Annual Smoking Cessation Conference in Philadelphia.

Separately, an independent review of using reduced-nicotine cigarettes as a smoking cessation aid will appear in the journal *Nicotine & Tobacco Research*. “Further investigation of RNCs as a cessation aid is warranted,” concludes the authors, Drs. Natalie Walker and Chris Bullen of the Clinical Trials Research Unit, University of Auckland and Dr. Hayden McRobbie, Barts & The London School of Medicine and Dentistry, Queen Mary University of London.

Dr. Moynihan commented, “Although larger clinical trials are needed to validate efficacy, each of the five studies reviewed indicates that VLN cigarettes, used exclusively or in combination with nicotine replacement therapy (NRT), increased quit rates. Of particular interest is the result of the University of Minnesota trial, which suggests that quitting efficacy using VLN cigarettes exclusively may exceed that of NRT.”

The Minnesota trial, led by Dr. Dorothy K. Hatsukami, Director of the Transdisciplinary Tobacco Use Research Center, University of Minnesota Cancer Center, compared quitting efficacy of a VLN cigarette, a low nicotine cigarette, and an FDA-approved 4-mg nicotine lozenge in a total of 167 patients treated for 6 weeks (Hatsukami et al, *Addiction*, in press). Patients exclusively using the VLN cigarette achieved a 43% quit rate (confirmed 4-week continuous abstinence) compared to 28% for the group exclusively using the nicotine lozenge.

Smoking abstinence at 6 weeks after the end of treatment was 47% for the VLN cigarette group versus 32% for the nicotine lozenge group. During the 6-week treatment period, patients smoked less VLN cigarettes per day than they previously had of their usual brand and daily usage of VLN cigarettes continued to decline as they approached the quit date.

22nd Century has exclusive worldwide patent rights to the VLN and reduced-nicotine cigarettes used in the University of Minnesota trial and two other clinical trials reviewed by Dr. Walker and her colleagues, including a 346-patient, phase II trial completed under an FDA-reviewed Investigational New Drug Application (IND). This IND was filed by Vector Tobacco Inc., a subsidiary of Vector Group Ltd. (NYSE: VGR) and former 22nd Century licensee.

22nd Century has rights to use and reference at the FDA all data in this IND, including results from the phase II trial, relating to the patented cigarettes. This phase II trial evaluated patients using reduced-nicotine cigarettes for 6 weeks, including VLN cigarettes for 2 weeks, in combination with NRT. Use of reduced-nicotine cigarettes in combination with NRT was more effective in quitting than use of

NRT alone, and use of reduced-nicotine cigarettes without NRT yielded an abstinence rate similar to that of NRT.

The proprietary tobacco in the VLN cigarette used in the University of Minnesota trial and the phase II trial contains about 1 mg/gm nicotine, equating to only 5% of the nicotine of tobacco in leading 'light' cigarette brands (about 20 mg/gm). The tobacco in the low nicotine cigarette, also used in both trials, contained about 8 mg/gm nicotine. The nicotine content of leading 'light' cigarette brands, therefore, is 20 times that of the VLN cigarette, and in this case, the low nicotine cigarette has 8 times the nicotine of the VLN cigarette. Differences in nicotine content of cigarettes have significant implications for compensatory smoking, dependence, and efficacy in smoking cessation.

Additional studies also demonstrate that VLN cigarettes reduce withdrawal symptoms from and cravings for conventional cigarettes. Dr. Moynihan believes VLN cigarettes are a useful tool in smoking cessation because they alter the perception of cigarettes by extinguishing the association between the act of smoking and rapid nicotine delivery. 22nd Century is planning further clinical trials involving VLN cigarettes and has received guidance from the FDA for a phase II-B optimization trial and phase III trials for its X-22 smoking cessation aid.

Smokers currently have few choices of FDA-approved products for smoking cessation: varenicline (Chantix™), bupropion (Zyban™), and nicotine in several forms (gums, patches, nasal sprays, inhalers and lozenges). Use of these products result in relapse rates that can be as high as 90 percent in the first year after a smoker 'quits.' According to a 2007 Institute of Medicine report, 57 percent of the 44 million adult American smokers do not attempt to quit each year making it imperative that new, effective, and more appealing smoking cessation aids are made available.

VLN cigarettes have potential to significantly increase smoking cessation by encouraging more smokers to attempt quitting with a more acceptable and familiar product. Since potential quitters are already smokers, VLN cigarettes do not expose patients to any new compounds and do not introduce any new side effects. Most smokers continue to smoke their usual brand during other treatments, including 76% of patients in a Chantix™ clinical trial.

For further analysis of smoking cessation therapies, please see: xxiicentury.com/media.html

ABOUT 22nd CENTURY

22nd Century is a biotechnology company focused on the development and commercialization of relevant and well differentiated products created from tobacco plants. The company develops innovative plant lines with combinations of new and/or enhanced traits. 22nd Century's business areas are smoking cessation, modified risk tobacco products, and novel biomass crops for sources of renewable energy, proteins and other products.

See company website at: xxiicentury.com

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