

Star Scientific Files Application with FDA for Ariva-BDL(TM) Approval as First Modified Risk Tobacco Product



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GLEN ALLEN, Va., Feb. 22 /PRNewswire-FirstCall/ -- Star Scientific, Inc. (Nasdaq: [CIGX](#)) announced that on Friday, February 19 the company filed an application with the Food & Drug Administration for approval to market Ariva-BDL™ as a "modified risk" tobacco product under the Family Smoking Prevention and Tobacco Control Act of 2009. This submission is the first such application to be filed with the Tobacco Products Center of the FDA, which has been established to oversee all aspects of tobacco regulation outlined in the 2009 Act. (Logo: <http://www.newscom.com/cgi-bin/prnh/20090317/STARSCIENTIFICLOGO>)

Ariva-BDL™, a dissolvable tobacco lozenge with wintergreen flavoring, is made with flue-cured tobacco that contains levels of tobacco-specific nitrosamines (TSNAs) that are below detectable limits ("BDL") by most current standards of measure. TSNAs have been identified in scientific literature since the early 1950s as one of the most deadly and abundant groups of carcinogens in tobacco and its smoke. Achieving this reduction, known within Star as "ZNT" (zero-nitrosamine tobacco) was accomplished by new work on the StarCured® tobacco curing technology that originally was developed in the 1990s. This innovation is the subject of a patent application filed in December 2008. A recent article by Rickert et al. (*Regulatory Toxicology and Pharmacology* 2009;53(2):121-33) reported total TSNA levels in currently marketed popular moist snuff and "pouch" tobacco products that ranged from 8,814 - 14,557 parts per billion. This range is 1000 times greater than the levels measured in Ariva-BDL™, as outlined in the company's submission.

Star Scientific believes these developments are of great significance in light of the reality that 43 million Americans -- roughly half of them women -- smoke each day. More than half of this population is looking for an acceptable alternative to cigarettes. Cigarette revenues in the United States currently total \$75 - \$80 billion, according to the *Wall Street Journal*. While a number of male smokers in the US now use traditional smokeless tobacco as an alternative to smoking, female smokers do not accept the unpleasant aesthetics of using moist snuff. As a completely dissolvable lozenge, Ariva-BDL™ would offer a useful alternative -- with greatly reduced toxin levels -- to adult smokers of both genders.

Star Scientific originally introduced dissolvable smokeless tobacco to the marketplace almost ten years ago when it launched Ariva® in 2001, and Stonewall Hard Snuff® in 2003. Both products are pieces of powdered and compressed StarCured® tobacco that dissolve completely in the mouth and leave no residue. Ariva®, launched in 2001, was developed for adult dependent smokers who cannot or choose not to smoke. Stonewall Hard Snuff®, launched in mid-2003, is an alternative for adults who use traditional smokeless tobacco products or who identify themselves as "heavy smokers". Over the past nine years the company has learned that Ariva® customers range in age from 30 - 70, and more than half of whom are women. Stonewall Hard Snuff® purchasers range in age from 25 - 65. Customers who are looking for an alternative to moist snuff are largely male, while roughly 30 - 40% of those who purchase the products as an alternative to "heavy" daily cigarette smoking are female. According to callers to the product consumer call center, the majority of purchasers are concerned about continued smoking. Both Ariva and Stonewall are available with wintergreen flavoring, which have been the blend most often purchased by Star's customers.

Ariva® and Stonewall® were the subjects of a federally funded pilot study published last month in *Nicotine & Tobacco Research* that was conducted at the Medical Center of South Carolina. The two-week study involved recruiting smokers uninterested in quitting cigarettes who randomly were either given Ariva® or Stonewall®, or continued smoking cigarettes. The data analysis revealed that among the Ariva/Stonewall group there was a 40% reduction in cigarettes smoked per day, and "significant increases in two measures of readiness to quit, either in the next month or within the next six months. No such changes were found among smokers maintained on conventional cigarettes".

When Star had the opportunity to read the published study, the company's management team was gratified by this new information but did not consider the authors' conclusions unexpected. The independent Scientific Advisory Board that provided input on tobacco-related research to Star directed the company's attention to a body of research indicating that smoking rates among Swedish men (17.9%) were probably among the lowest in the developed world, a dramatic reduction from much higher smoking rates (36%) twenty years before. During the intervening two decades a transition in tobacco use occurred: 20% of Swedish men were now users of snus, Swedish smokeless tobacco that contained reductions in TSNA's. Epidemiological studies concluded in the period 1998 - 2001 found no increase in head or neck cancers, while lung cancer deaths had fallen, among Swedish men.

The company believes that Ariva-BDL™, if approved, will be highly attractive to other companies. For this reason, Star has committed to exploring opportunities for sublicensing agreements with both domestic and international entities, so that Ariva-BDL™ can be made available as broadly as possible to adult dependent smokers.

This press release contains certain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Star Scientific, Inc. and its consolidated subsidiaries (collectively, the "Company") has tried, whenever possible, to identify these forward-looking statements using words such as "anticipates", "believes", "estimates", "expects", "plans", "intends" and similar expressions. These statements reflect the Company's current beliefs and are based upon information currently available to it. Accordingly, such forward-looking statements involve known and unknown risks, uncertainties and other factors which could cause the Company's actual results, performance or achievements to differ materially from those expressed in, or implied by, such statements. These risks, uncertainties and contingencies include, without limitation, the challenges inherent in new product development initiatives, the uncertainties inherent in the progress of scientific research, the Company's ability to raise additional capital in the future necessary to maintain its business, potential disputes concerning the Company's intellectual property, risks associated with litigation regarding such intellectual property, potential delays in obtaining any necessary government approvals of the Company's low-TSNA tobacco products, market acceptance of the Company's new smokeless tobacco products, competition from companies with greater resources than the Company, the Company's decision not to join the Master Settlement Agreement ("MSA"), and the Company's dependence on key employees and on its strategic relationships with Brown & Williamson Tobacco Corporation in light of its combination with RJ Reynolds Tobacco Company, Inc. Although the Company believes the expectations reflected in such forward-looking statements are based on reasonable assumptions, it can give no assurance that the expectations will be attained or that any deviation will not be material. See additional discussion under "Risk Factors" in the Company's Quarterly Report on Form 10-K as filed with the SEC on March 16, 2009, and other factors detailed from time to time in the Company's other filings with the SEC, available at www.sec.gov. All information in this release is current as of this date, and the Company undertakes no obligation to update or advise upon any such forward-looking statements to reflect events or circumstances after the date of this press release or to reflect the occurrence of unanticipated events.

About Star Scientific

Star Scientific is a technology-oriented company with a mission to reduce the harm associated with tobacco at every level. It is engaged in the development of dissolvable smokeless tobacco products that deliver fewer carcinogenic toxins, principally through the utilization of the innovative StarCured® tobacco curing technology. Through its Rock Creek Pharmaceuticals subsidiary it is also involved in the development of nutraceuticals as well as products to address neurological and mood disorders. Star Scientific has a Corporate and Sales Office in Glen Allen, VA, an Executive, Scientific & Regulatory Affairs office in Bethesda, MD, and a manufacturing facility in Chase City, VA. Rock Creek has scientific and research offices in Gloucester, MA, and a regulatory office in Washington, D.C.

See Star's website at: <http://www.starscientific.com>

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