

Breakthrough Therapy Designation for Silver Diamine Fluoride granted by FDA

- **Advantage Arrest™ Silver Diamine Fluoride 38% is the first drug to receive Breakthrough Therapy Designation for the arrest of tooth decay**
- **It is the only Breakthrough Therapy Designation ever received for an oral care medicine**

Redmond, OR and West Palm Beach, FL – October 30, 2016 -- Advantage Silver Dental Arrest, LLC and Elevate Oral Care, LLC announced today that the U.S. Food and Drug Administration (FDA) has granted “*Breakthrough Therapy Designation*” to *Advantage Arrest™ Silver Diamine Fluoride 38%* for the arrest of tooth decay in children and adults.

Breakthrough Therapy Designation represents the FDA’s effort to address an unmet, serious, life-threatening medical need where there is no available therapy. It is a process designed to expedite the development and review of drugs that are intended to treat a serious condition as soon as possible and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapies on a clinically significant endpoint(s).

In use for over 80 years as a caries-arresting drug in Japan and other countries, the Designation was granted based on the FDA review of 10 worldwide randomized clinical trials evaluating silver diamine fluoride for caries arrest in children aged 3-9 or adults aged 60-89, as well as studies conducted by Advantage Silver Dental Arrest, LLC. Collectively these trials involved approximately 1500 subjects who were monitored for 1-3 years.

Currently, Advantage Arrest Silver Diamine Fluoride 38% is cleared by the FDA as a medical device for the treatment of dentinal hypersensitivity. It is well known that since it received FDA clearance in 2014 and became commercially available in April 2015, the material has been used extensively by oral health professionals in the U.S. off-label for the arrest of dental caries.

The American Dental Association added a new Code on Dental Procedures and Nomenclature (CDT Code D1354 – Interim Caries Arresting Medicament Application) to achieve uniformity, consistency and specificity in accurately documenting treatment for the efficient processing of dental claims. Multiple insurers and State Medicaid programs are currently reimbursing for the cost of the therapy for caries arrest.

“The Breakthrough Therapy Designation represents a major milestone in our over eight year effort, spearheaded by Dr. Peter Milgrom of Advantage and the University of

Washington, to improve the treatment of severe early childhood dental caries, a serious and rampant disease,” said Dr. Mike Shirlcliff, President of Advantage Silver Dental Arrest, LLC.

Kevin Thomas, President of Elevate Oral Care, the commercialization organization for Advantage Arrest Silver Diamine Fluoride 38% stated, “We are proud to be a part of this exciting advancement that fills such a huge unmet need.”

About Advantage Silver Dental Arrest, LLC

Advantage Silver Dental Arrest (ASDA) is a limited liability company headquartered in Redmond, Oregon. ASDA develops innovative drug products and medical devices for improving oral health. Its professional staff includes internationally recognized scientists with a long record of research achievements and contributions in oral care. In addition to receiving FDA Breakthrough Therapy Designation for silver diamine fluoride solution, ASDA has received multiple Small Business Innovation Research (SBIR) grants for its work in developing innovative dental care technologies.

About Elevate Oral Care, LLC

Founded six years ago, Elevate Oral Care develops, manufactures and markets oral preventive care products for healthcare professionals and consumers. The Elevate management team consists of the former principal owners of OMNII Oral Pharmaceuticals, which was acquired by 3M Company in 2005, as well as a number of other oral care industry professionals with a combined 100 years plus experience in the oral care industry. The current Elevate product line includes our patented FluoriMax® 2.5% Sodium Fluoride Varnish, patent-pending Allday™ Dry Mouth Spray and our proprietary Just Right® metered-dose children’s toothpaste.

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