



Sanofi-Aventis and Novalar File Marketing Authorization Application for OraVerse® in Five Key European Countries

July 14, 2010 -- Sanofi-Aventis Deutschland GmbH and Novalar Pharmaceuticals, Inc. today announced that the Marketing Authorization Application (MAA) for OraVerse has been accepted for review by the regulatory agencies of the United Kingdom (UK), Germany, Italy, France and Spain. OraVerse is the first and only local anesthesia reversal agent that accelerates the return of normal sensation and function following routine dental procedures. OraVerse is approved for use in the U.S. by the Food and Drug Administration and sold by Novalar direct to U.S. dentists.

“Expansion of OraVerse into Europe represents a significant near-term opportunity for Novalar, and it is our goal to obtain marketing approval by mid-2011,” said Donna Janson, President and Chief Executive Officer of Novalar. “Dentists in the five key countries included in the dossier utilize approximately 270 million cartridges of local dental anesthetic each year, which is about 75% of the total local anesthetic usage in all of Europe. Germany is by far the largest single market for local anesthetic usage and Sanofi-Aventis leads the market with its anesthetic Ultracain®.”

The proposed indication for OraVerse in Europe is comparable to the product’s approved indication in the United States. The application will follow the Decentralized Procedure for obtaining marketing authorization in select European countries, with the UK as the Reference Member State (RMS) and Germany, Italy, France and Spain as Concerned Member States (CMS). The RMS is responsible for interfacing with the applicant, developing the assessment reports, and obtaining comments from the CMS.

In March 2010, Novalar and Sanofi-Aventis announced an exclusive license and distribution agreement for OraVerse. Since that time, the partners have collaborated extensively to successfully submit the MAA and will continue to do so throughout the review process. Under the terms of the agreement, Sanofi-Aventis will be responsible for the launch of OraVerse in Germany upon approval and retains options to extend the license to all European countries. Novalar is eligible for an additional milestone payment upon approval, royalties on product sales in the territory and pre-determined option exercise fees for each additional country added to the license.

About OraVerse®

OraVerse is a breakthrough that reverses unwanted lingering numbness after routine dental procedures where a local anesthetic containing a vasoconstrictor was used. OraVerse is indicated for reversal of the soft-tissue anesthesia, i.e., anesthesia of the lip and tongue, and the associated functional deficits resulting from an intraoral submucosal injection of a local

anesthetic containing a vasoconstrictor. OraVerse is not recommended for use in children less than 6 years of age or weighing less than 15 kg (33 lbs). For more information visit www.oraverse.com.

Important Safety Information

In clinical trials, the most common adverse events with OraVerse (phentolamine mesylate) vs. control were post procedural pain (6% vs. 6%), injection site pain (5% vs. 4%), tachycardia (5% vs. 6%), bradycardia (2% vs. 0.3%) and headache (3% vs. 4%). Following parenteral use of phentolamine in non-dental indications, myocardial infarction and cerebrovascular spasm and occlusion have been reported, usually in association with marked hypotensive episodes producing shock-like states. Although such effects are uncommon with OraVerse, clinicians should be alert to the signs and symptoms of tachycardia and cardiac arrhythmias, particularly in patients with a history of cardiovascular disease, as these symptoms may occur with the use of phentolamine or other alpha-adrenergic blocking agents.

About Novalar®

Novalar is a specialty pharmaceutical company that partners directly with dental professionals to enrich the patient experience. The company is uniquely positioned to develop targeted oral pharmaceutical products and translate the full value of these novel solutions to clinical practice. For more information, please visit www.novalar.com.

About sanofi-aventis®

Sanofi-aventis, a leading global pharmaceutical company, discovers, develops and distributes therapeutic solutions to improve the lives of everyone. Sanofi-aventis is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY). For more information, please visit www.sanofi-aventis.com.

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