



Journal of the American Dental Association Publishes Key Clinical Data for the Use of OraVerse™ a Local Anesthetic Reversal Agent

San Diego, August 12, 2008 – Novalar Pharmaceuticals, Inc., a dental specialty pharmaceutical company, announced the publication of three clinical trials on the use of OraVerse (phentolamine mesylate) injection as a local dental anesthetic reversal agent in the August 2008 issue of the Journal of the American Dental Association (JADA). The first publication, entitled “Reversal of soft tissue local anesthesia with phentolamine mesylate in adolescents and adults” includes an overview of two pivotal trials while the second publication “Reversal of soft-tissue local anesthesia with phentolamine mesylate in pediatric patients” reviews the pediatric Phase 2 data. Together these key Novalar-sponsored clinical trials were the foundation for the FDA approval of OraVerse in May 2008.

“JADA’s publication of these trials highlights the importance and value of these data to the dental community,” commented Athena Papas, DMD, PhD, Professor at Tufts University School of Dental Medicine, Novalar Scientific Advisor and co-author on both publications. “Many dental patients, including children, could benefit from this clinical research which found that OraVerse helped patients regain sensation to their lips and tongue in approximately half the time following routine dental procedures.”

The first publication details the efficacy and safety of OraVerse in reducing the duration of soft tissue anesthesia in patients receiving standard local anesthetic injections in two Phase 3 clinical trials. Median recovery times in the lower lip and tongue were 70 and 60 minutes compared with 155 and 125 minutes in the control group. Median recovery time in the upper lip was 50 minutes versus 133 minutes in the control. The second publication evaluated the safety of OraVerse in children aged 4 to 11 years following a dental procedure and the efficacy and safety of OraVerse to accelerate the reversal of soft-tissue local anesthesia in children aged 6 to 11 years. No serious adverse events were reported in any of these trials.

“We are very pleased with JADA’s decision to publish these studies,” stated Donna Janson, President and Chief Executive Officer of Novalar. “As the nation’s premier dental journal, publication in JADA further demonstrates the quality of our clinical science and allows Novalar the opportunity to begin educating the dental community on the benefits of OraVerse to both patients and clinicians.”

About OraVerse

OraVerse (phentolamine mesylate) Injection is the only local anesthetic reversal agent that accelerates the return to normal sensation and function following restorative and periodontal maintenance procedures. OraVerse is indicated for the reversal of 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 six years of age or weighing less than 15 kg (33 lbs). Myocardial infarction and cerebrovascular spasm and occlusion have been reported following parenteral use of phentolamine, usually in association with marked hypotensive episodes producing shock-like states. Tachycardia, bradycardia, and cardiac arrhythmias may occur with the use of phentolamine or other alpha-adrenergic blocking agents. Although such effects are uncommon with OraVerse (phentolamine mesylate), clinicians should be alert to the signs and symptoms of these events, particularly in patients with a history of cardiovascular disease.

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.

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