



Novalar Receives FDA Approval for OraVerse™

First approved dental anesthetic reversal agent

San Diego, May 12, 2008 – Novalar Pharmaceuticals, Inc., a dental specialty pharmaceutical company, announced today that the United States Food and Drug Administration (FDA) has granted marketing approval for OraVerse™ (phentolamine mesylate). OraVerse is the first pharmaceutical agent indicated for the reversal of soft-tissue anesthesia and the associated functional deficits resulting from a local dental anesthetic. Novalar is establishing a specialty direct sales force to launch OraVerse in late 2008.

“The approval of OraVerse is the result of the outstanding efforts of our development team, our strong collaboration with the FDA and our focus and commitment to realizing the vision of our founder, Dr. Eckard Weber. This first-in-class therapeutic will provide dental professionals with a novel solution to enhance the overall experience for their patients,” stated Donna Janson, President and Chief Executive Officer of Novalar.

Novalar plans to launch OraVerse at this year’s American Dental Association (ADA) Annual Session being held in San Antonio, Texas from October 16-20, 2008. Novalar’s sales force will focus on general and pediatric dentists for use in patients over six years of age.

Over 300 million cartridges of local dental anesthetic are sold each year in the U.S. alone. Although widely used, it frequently results in unnecessary and lingering soft tissue anesthesia and associated functional deficits. Novalar’s market research with both patients and dentists has indicated strong interest in a product that will reduce the time to normal sensation and function following local dental anesthesia.

OraVerse’s approval for use in adults and children is based on data from several clinical studies, including two Phase 3 studies in adults and adolescents age 12 and older and a Phase 2 pediatric study. The two Phase 3 studies were conducted in 18 centers across the United States, including leading dental schools, clinical research organizations and private clinics. There were 484 dental patients enrolled across the two studies.

In the randomized, double-blinded, controlled Phase 3 studies, following the administration of local anesthetics and completion of the dental procedure, patients were administered either OraVerse or control. OraVerse reduced the median time to recovery of normal sensation in the lower lip (as measured by standardized lip tapping procedures) by 85 minutes compared to control. OraVerse reduced the median time to recovery of normal sensation in the upper lip by 83 minutes. Within one hour after administration of OraVerse, 41% of patients reported normal lower lip sensation as compared to 7% in the control group, and 59% of patients in the OraVerse group reported normal upper lip sensation as compared to 12% in the control group. In both

Phase 3 studies, the primary endpoint showed that OraVerse was statistically different compared to control ($p < 0.0001$).

The multi-center, randomized, double-blinded, controlled Phase 2 pediatric study evaluated the safety and efficacy of OraVerse in the reversal of soft tissue anesthesia in patients undergoing dental procedures after receiving local anesthetic. This study enrolled 152 patients: 96 patients in the OraVerse group and 56 patients in the control group. Of the 152 patients enrolled, 115 were trainable in the assessment method: 72 patients in the OraVerse group and 43 patients in the control group. The study assessed OraVerse's efficacy through the measurement of time to normal lip sensation for those trainable in the assessment. The median time to normal sensation in patients age 6-11 was reduced by 75 minutes for the OraVerse treated group, a 56% acceleration of the time to normal sensation.

In all OraVerse clinical trials, there were no serious adverse events reported and the most common adverse reaction that was greater than control was transient injection site pain. Although tachycardia and cardiac arrhythmia may occur with the parenteral use of alpha-adrenergic blocking agents, such events are uncommon after submucosal administration of OraVerse.

“The Novalar team is extremely excited to bring to market a first-in-class product with such strong interest from both patients and dentists,” added Ms. Janson. “It is seldom that a company is able to conceive, develop and market such an innovative product that has the ability to change the standard of care in dentistry. Novalar is committed to making OraVerse a commercial success and believes we are well positioned to bring additional dental pharmaceuticals to market through our unique development capabilities.”

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).

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.novalarpharm.com.

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