



Novalar Announces the Launch of OraVerse™ the First Dental Anesthesia Reversal Agent

CHICAGO, FEBRUARY 27, 2009 – Novalar Pharmaceuticals, Inc., a dental specialty pharmaceutical company today announced the launch of OraVerse™, the company's premier dental pharmaceutical product. OraVerse is the first and only local anesthesia reversal agent that accelerates the return to normal sensation and function for patients who want to avoid the unwanted and unnecessary lingering soft tissue anesthesia following routine dental procedures in which a local anesthetic containing a vasoconstrictor was used. The first-in-class product was officially unveiled at the 144th Chicago Dental Society Midwinter Meeting being held at McCormick Place from February 26 – March 1, 2009.

"How to address soft tissue numbness is one of the most commonly asked questions in dentistry. OraVerse is the first solution of its kind that dentists can use to finally answer this question," stated Dr. Stanley Malamed, Professor of Anesthesia & Medicine at the University of Southern California School of Dentistry. "OraVerse will provide dentists with a convenient alternative for completing routine dental procedures that allows patients to comfortably return to their daily routine."

To support the commercialization of OraVerse, Novalar has hired 24 territory managers and three regional directors to coordinate sales efforts to dental professionals. Novalar will initially focus its sales force in six key regions, supporting all other US regions through internal sales and customer care efforts. The primary market segments for OraVerse will be general dental practitioner and pediatric dentist's offices throughout the U.S.

"As a company, Novalar is committed to developing inventive solutions that will revolutionize the practice of dentistry and support clinicians in their efforts to provide outstanding patient care," stated Donna Janson, President and CEO of Novalar Pharmaceuticals. "The launch of OraVerse represents the culmination of years of effort from conception through commercialization. We look forward to translating the experience gained throughout the development of OraVerse to future innovative products in our portfolio."

OraVerse is approved by the U.S. Food and Drug Administration (FDA) as safe and effective for adults and children six years and older and weighing 33 lbs. or more. In clinical trials, patients that received OraVerse experienced a return to normal sensation and function in approximately half the time. The active ingredient in OraVerse is phentolamine mesylate, a drug used in other medical applications for the past 50 years.

OraVerse studies included three multicenter, double-blinded, randomized, controlled clinical trials. Two adult and adolescent trials were conducted with a total of 484 patients who had restorative or periodontal maintenance procedures and who had received one of four leading anesthetics that contained a vasoconstrictor. OraVerse reduced the median time to recovery of normal sensation in the lower lip by 85 minutes (55%), and in the upper lip by 83 minutes (62%) compared to control. In both maxillary and mandibular procedures, the median time to observed recovery of normal function was significantly reduced for patients receiving OraVerse (43% and 50% reduction respectively). The majority of adverse reactions were mild and resolved within 48 hours. There were no serious adverse reactions and no discontinuations due to adverse reactions.

In a pediatric trial with 152 patients, aged 4-11, OraVerse had no effect on adverse events, pain or post-treatment analgesic use, vital signs or oral mucosa. The median time to normal lip sensation in 115 patients 6 to 11 years of age who were trainable in the lip-palpation procedures, for mandibular and maxillary procedures combined, was reduced by 75 minutes (56%).

Clinical data for OraVerse has also been published in a number of leading peer reviewed scientific journals including the nation's leading dental publication, the Journal of the American Dental Association.

OraVerse comes in a standard dental cartridge and is easily injected utilizing the same injection site and an identical technique as that used for local anesthetic. It is used in a 1:1 ratio to local anesthetic and has been tested in doses of ½, 1 and 2 cartridges. For more information or to download a copy of our full prescribing information, please visit www.OraVerse.com.

About OraVerse

OraVerse (phentolamine mesylate) Injection is the first and only local dental anesthesia 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).

Important Safety Information

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. Following parenteral use of phentolamine at doses between 5 to 15 times higher than the recommended dose of OraVerse, myocardial infarction, and cerebrovascular spasm and occlusion have been reported, usually in association with marked hypotensive episodes producing shock-like states. See full prescribing information.

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.

Contacts:

Company Contact:
Novalar Pharmaceuticals
Derek Kelaita
kelaita@novalar.com
(858) 436-1100

Media and Investors:
Porter Novelli Life Sciences
Holli Kolkey Dickson
hdickson@pnlifesciences.com
(619) 849-5380

or

Porter Novelli Life Sciences
Shirley Chow
schow@pnlifesciences.com
(212) 601-8308

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