

## **FOR IMMEDIATE RELEASE**

### **NOVALAR presents results from successful studies of anesthetic reversal agent at International Association of Dental Research Annual Meeting**

**SAN DIEGO, March 20, 2007** - Novalar Pharmaceuticals, Inc. announced that results from two Phase 3 studies and a pediatric Phase 2 study of NV-101, a local dental anesthetic reversal agent, will be presented at the 85 th Annual Meeting of the International Association of Dental Research (IADR) in New Orleans . John Yagiela, D.D.S., Ph.D., Professor and Chair, Diagnostic and Surgical Sciences at UCLA's School of Dentistry will present data from the Phase 3 studies and Sharon Gordon, D.D.S., M.P.H., Ph.D., Associate Professor, Department of Biomedical Sciences and Brotman Facial Pain Center at the University of Maryland , Baltimore , College of Dental Surgery , will present results from the pediatric Phase 2 study.

The IADR is the largest and most prestigious organization for oral, craniofacial and dental research with over 11,000 active individual members worldwide. At the annual meeting, scientists communicate the latest peer reviewed data to facilitate the rapid dissemination and application of dental research findings.

Data from two Phase 3 studies shows that NV-101 was well tolerated, safe, and met its primary and secondary endpoints. In both studies, NV-101 treated patients reported the return of sensation and function in less than half the time it normally took after receiving local dental anesthesia. NV-101 induced a 54.8 percent and a 62.3 percent decrease in time to normal for those with anesthesia administered in the mandible and maxilla respectively. These reductions were statistically different than control ( $p < 0.0001$ ) with no serious adverse events (SAE's) reported.

In the Phase 2 pediatric study for NV-101, the time to normal sensation was reduced by 55.6 percent, a clinically and statistically significant ( $p < 0.0001$ ) acceleration of the return to normal sensation. As in the Phase 3 studies, NV-101 continued to be well tolerated with no SAE's reported in the pediatric population studied.

“We were extremely pleased with the outcome of these studies, and we are delighted that Dr. Yagiela and Dr. Gordon will unveil the results at IADR, the most respected international dental research meeting,” said Donna Janson, President and Chief Executive Officer of Novalar. “Based on these positive results, Novalar will continue to work closely with the U.S. Food and Drug Administration (FDA) toward a successful submission of our New Drug Application for NV-101 in the second quarter of 2007, and to build the organizational infrastructure necessary to launch NV-101 following FDA approval.” If approved, NV-101 will be the only local anesthetic reversal agent available for use in pediatric, adolescent and adult patients.

The two multi-center, randomized, blinded, controlled 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, including adolescents and adults. In the first study, 244 patients received anesthesia in the mandible (lower jaw) and in the second study, 240 patients were administered anesthesia in the maxilla (upper jaw). Following anesthesia and completion of the dental procedure, patients were administered either NV-101 or sham control.

“The fact that NV-101 met its endpoints so clearly, coupled with its excellent safety profile, makes it a potentially very useful treatment option for the reversal of soft tissue anesthesia following routine dental procedures,” said Dr. Yagiela. “Its benefits are meaningful for both dentists and patients.”

Results from the Phase 2 pediatric, double blinded, controlled safety study involving 11 study centers and 152 dental patients (aged 4–11) complemented the Phase 3 results. In this study, the time to normal sensation was reduced by a clinically and statistically significant ( $p < 0.0001$ ) 55.6 percent. There were no SAE’s and no subjects withdrew from the study due to adverse events (AE’s). No differences were apparent in the frequencies or types of AE’s reported by the two randomized treatment groups. All AE’s resolved by the end of the study observation period.

“Children are especially at risk from biting and chewing their cheeks, tongues and lips when numb. The pediatric results for NV-101 provide further evidence that this product could be safe and beneficial in this patient population,” added Dr. Gordon.

#### About NV-101

If approved by the FDA, NV-101 will be the only local anesthetic reversal agent that accelerates the return to normal sensation and function following restorative and periodontal maintenance procedures. The product has been tested in pediatric, adolescent and adult patients. Phentolamine mesylate (a vasodilator), the active ingredient in the investigational agent NV-101, has been approved and in use in specific medical indications at significantly higher doses for over 50 years.

#### About Novalar Pharmaceuticals, Inc.

San Diego-based Novalar Pharmaceuticals, Inc. is a privately held specialty pharmaceutical company. The company’s initial product offering, NV-101, is being evaluated as a local anesthetic reversal agent and was developed to rapidly reverse the lingering and debilitating lip and tongue numbness associated with local dental anesthesia. For more information, visit [www.novalarpharm.com](http://www.novalarpharm.com).

#### Presentation details:

Presentation of Phase 3 data by Dr. Yagiela (Dental Anesthesia Research Section)

Time: 2:30 PM – 4:00 PM , Wednesday, March 21, 2007

Ernest M. Memorial Convention Center , Room 285

Presentation of Pediatric Phase 2 data by Dr. Gordon (Late Breaking News Section)

Time: 9:00 AM , Thursday, March 22, 2007

Ernest M. Memorial Convention Center , Room 287

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