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NOVALAR's Positive Phase 2 Pediatric Study Results Support Recent Pivotal Data in Adolescents and Adults

Novel dental anesthesia reversal agent demonstrates safety, efficacy in pediatric patients

SAN DIEGO, November 15, 2006 – Novalar Pharmaceuticals, Inc. today announced that NV-101, a local dental anesthetic reversal agent, met its safety and efficacy endpoints in a Phase 2 study for pediatric patients. In this study, 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 serious adverse events reported in the pediatric population studied.

“These pediatric results complement our recently announced Phase 3 efficacy data in adolescents and adults, supporting the broad and safe use of NV-101 for patients as young as 4 years of age,” said Donna Janson, Novalar’s President and Chief Executive Officer. “These positive results will be an important addition to our New Drug Application (NDA) for NV-101 in 2007, and, if approved, will contribute towards the adoption of this novel agent for dental patients.”

The randomized, blinded, controlled study was designed to evaluate the safety and efficacy of NV-101 in the reversal of soft tissue anesthesia (STA) in pediatric subjects (ages 4-11) undergoing dental or periodontal maintenance procedures in the mandible (lower jaw) or maxilla (upper jaw) after receiving local anesthesia. Subjects were randomized with respect to the study treatment, NV-101 or sham control. The study enrolled 152 subjects; 96 patients in the NV-101 group and 56 patients in the sham control group. Of the 152 subjects enrolled, 118 were trainable in the assessment method; 75 patients in the NV-101 group and 43 patients in the sham control group.

The study assessed NV-101’s efficacy through the measurement of time to normal lip sensation for those trainable in the assessment. The median time to normal sensation (as measured by standardized lip tapping procedures) was 60 minutes for the NV-101 treated group and 135 minutes for the sham control group, a clinically and statistically significant 55.6 percent ($p < 0.0001$) acceleration of the time to normal sensation.

There were no serious adverse events (SAEs) and no subjects withdrew from the study due to AEs. No differences were apparent in the frequencies or types of AEs reported by the two randomized treatment groups. All AEs resolved by the end of the study observation period.

“The rate of recovery from local anesthesia for children is important because they may have an increased risk of chewing their lips and tongue while numb,” explained Dr. Bruce Rutherford, Novalar’s Vice President, Clinical Development. “This study

demonstrated significant and safe acceleration of return to normal sensation in children which may therefore reduce the chance of injury.”

Pediatric Study Reinforces Phase 3 Results for NV-101

Two multi-center, randomized, blinded, controlled Phase 3 studies, conducted in 18 centers across the United States, demonstrated similar results. In the first study, 244 adult and adolescent 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.

NV-101 treated adolescent and adult patients experienced return of sensation in less than half the amount of time after receiving local dental anesthesia with a statistically significant 54.8 percent decrease in time for those with anesthesia administered in the mandible compared to the control group ($p < 0.0001$), and a statistically significant 62.3 percent decrease in time for those with anesthesia administered in the maxilla compared to the control group ($p < 0.0001$).

About NV-101

If approved by the FDA, NV-101 will be the only local anesthetic reversal agent available for use in pediatric, adolescent and adult (including geriatric) patients which accelerates the return to normal sensation and function following restorative and periodontal maintenance procedures. 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.

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