

## **FOR IMMEDIATE RELEASE**

### **NOVALAR announces positive Phase 3 results for novel dental anesthesia reversal agent**

#### **NV-101 results demonstrate safety and efficacy**

**SAN DIEGO, October 3, 2006** - Novalar Pharmaceuticals, Inc. today announced that NV-101, a local dental anesthetic reversal agent, was well tolerated and met its primary endpoints in two pivotal Phase 3 studies. In both trials, NV-101 treated patients reported the return of sensation in less than half the amount of time it normally took after receiving local dental anesthesia.

“We are extremely pleased with the outcome of these studies,” said Donna Janson, President and Chief Executive Officer. “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 2007, and to build the organizational infrastructure necessary to launch NV-101 following FDA approval.” Both pivotal trials were initiated in the first quarter of 2006 after a Special Protocol Assessment (SPA) was completed by the FDA.

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.

NV-101 treated 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 ( $p < 0.0001$ ).

“Further confirmation of the return of sensation following administration of NV-101 came through new, validated assessment tools that evaluated the perception of deficits and functional deficiencies created by local anesthesia such as eating, drinking and speaking” added Janson.

For all patients evaluated, there were no serious adverse events reported and few mild to moderate adverse events in both groups. These events were transient in nature and resolved within the duration of the study.

Additionally, a Phase 2 pediatric double blinded, controlled safety study involving 11 study centers and 152 dental patients (aged 4 – 11) was also recently completed. Results from this trial are expected to be available later this year. Market research studies have indicated strong levels of interest for NV-101. Patients and dentists identified opinions toward local dental anesthesia and expressed interest in decreasing return to normal sensation time.

63 percent of patients surveyed are very, or somewhat, uncomfortable with the sensation of numbness when leaving the dentist;

Patients believe everyday activities are affected by dental anesthesia such as: eating/chewing (64 percent), speaking/talking (46 percent) and drinking (42 percent);

Overall, 86 percent of dentists and 87 percent of patients are very, or somewhat, interested in having NV-101 administered.

“While local dental anesthesia continues to be the most widely used dental anesthetic procedure – with more than 300 million cartridges of local dental anesthetic administered annually in the U.S. – it frequently results in longer-than-necessary soft tissue numbness,” explains Dr. Bruce Rutherford, Novalar’s Vice President, Clinical Development. “The market research, when paired with the Phase 3 studies’ results, demonstrates that both patients and dentists recognize a need for reducing the time to normal sensation following local anesthesia. We believe that Novalar’s novel agent, NV-101, could provide dentists with a useful tool to address this widely identified need.”

#### 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](http://www.novalarpharm.com).

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