

NOVALAR ANNOUNCES ACCEPTANCE OF NV-101 NEW DRUG APPLICATION FOR FILING BY FDA

Novalar Pharmaceuticals

PR Newswire (06-19-2007), June 19, 2007

Novalar Pharmaceuticals, Inc. announced The Company's New Drug Application (NDA) for marketing approval of NV-101, a local dental anesthetic reversal agent, was accepted for filing by the U.S. Food and Drug Administration (FDA). The NDA was submitted to the FDA on April 9, 2007.

"The acceptance for filing of the NV-101 NDA by the FDA represents a major regulatory achievement for Novalar and we will continue to maintain an efficient and collaborative exchange with the agency throughout the review process," said Donna Janson, President and Chief Executive Officer of Novalar.

"This is an exciting milestone for the company as we prepare for the transition of the product from development to commercialization. Assuming a positive review by the FDA, we anticipate launch of NV-101 by the third quarter of 2008."

In two Phase 3 studies and a Phase 2 pediatric study, NV-101 was well tolerated and met its primary and secondary endpoints. In the Phase 3 studies, which included 244 and 240 dental patients, NV-101 induced a 54.8 percent and a 62.3 percent decrease in time to normal sensation for those with anesthesia administered in the mandible and maxilla respectively. In the Phase 2 pediatric study involving 152 children ages 4 to 11, the time to normal sensation was reduced by 55.6 percent. In all three studies, the reductions were statistically different than control ($p < 0.0001$) and no serious adverse events were reported.

While local dental anesthesia continues to be the most widely used dental anesthetic procedure, it frequently results in longer-than-necessary soft tissue numbness. Market research with both patients and dentists has indicated strong interest in a product that will reduce the time to normal sensation following local dental anesthesia. If approved, NV-101's safety and efficacy profile could make it a potentially useful treatment option to satisfy this unmet need.

"With the recent addition of Diana P. Friedman as our Vice President of Marketing, we are now focused on the execution of the commercialization plan for the successful U.S. launch of this novel dental pharmaceutical," added Janson. "We are also continuing our commitment to identify and evaluate new dental product opportunities to add depth to our pipeline."