

NOVALAR'S NV-101 PRODUCES POSITIVE PHASE II AND III RESULTS

Novalar Pharmaceuticals

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At the 85th Annual Meeting of the International Association of Dental Research, being held from 21st to 24th March, in New Orleans, LA, results are to be presented from two Phase III studies and a paediatric Phase II study of NV-101 (phentolamine mesylate), Novalar Pharmaceuticals' local dental anaesthetic reversal agent.

The two multi-centre, randomised, blinded, controlled, Phase III studies were conducted in 18 centres across the US, including dental schools, clinical research organisations and private clinics. There were 484 dental patients enrolled across the two studies, including adolescents and adults. In the first study, 244 patients received anaesthesia in the mandible and in the second, 240 patients were administered anaesthesia in the maxilla. Following anaesthesia and completion of the dental procedure, patients were administered either NV-101 or a sham control.

Data from the studies show 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 anaesthesia. NV-101 induced a 54.8 and 62.3 per cent decrease in time to normal for those with anaesthesia administered in the mandible and maxilla, respectively. These reductions were statistically different than the control ($p < 0.0001$) and no serious adverse events (SAEs) were reported.

The double-blind, controlled, paediatric safety study involved 11 study centres and 152 dental patients (aged four to 11 years). In this study, the time to normal sensation was reduced by 55.6 per cent, a clinically and statistically significant ($p < 0.0001$) acceleration of the return to normal sensation. As in the Phase III studies, NV-101 continued to be well tolerated, with no SAEs reported, 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 randomised treatment groups and all AEs resolved by the end of the study observation period.

Based on these positive results, Novalar will continue to work closely with the FDA toward a successful submission of its NDA for NV-101 in the second quarter of 2007, and to build the organisational infrastructure necessary to launch the compound following FDA approval. If approved, NV-101 will be the only local anaesthetic reversal agent available for use in paediatric, adolescent and adult patients. Phentolamine mesylate, which is a vasodilator and the active ingredient in NV-101, has been approved and in use in specific medical indications at significantly higher doses for over 50 years.