

Cortiject Dexamethasone Lipid Emulsion for the Treatment of Diabetic Macular Edema: A Pilot Study

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Background: To evaluate the safety and tolerability of a single intravitreal injection of NOVA63035 dexamethasone lipid emulsion administered at one of four doses in patients with diabetic macular edema (DME) secondary to diabetic retinopathy.

Material and Methods: This phase 1, open-label, dose-escalation study was carried out in 4 cohorts of patients in which each cohort (n = 5 up to 6) of patients receive a single intravitreal injection of NOVA63035 containing 100 µg to 800 µg of Dexamethasone. Patients are to be followed during one year. The main outcome measures include change in foveal thickness measured by OCT, best-corrected visual acuity, incidence of adverse events and incidence of complications related to the IVT.

Results: The results concern the interim data of the first three cohorts. 4 sites have recruited and 15 patients have been injected (mean age 67 years). Mean foveal thickness decreased in all three cohorts following treatment, and remained lower at the last available visits (respectively at Month 9, Month 6 and Day 30 for cohorts 1 through 3) as compared to screening.

Conclusion: A single Intravitreal injection of NOVA63035 provides significant improvement in macular edema secondary to diabetic retinopathy. These promising results need to be confirmed with further and larger studies.