Comparison of the clinical efficacy and tolerability of latanoprost 0.005% eye drops test formulation, for the treatment of ocular hypertension (OH) and primary open angle glaucoma (POAG), with Xalatan® 0.005% eye drops

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Purpose: This study was designed to evaluate the efficacy and tolerability of Latanoprost 0.005% eye drops versus Xalatan 0.005% eye drops.

Methods: 266 adult patients with OH or POAG were enrolled in a 6-week, multicenter, investigator-blind, parallel group study. Patients were randomized to receive either Latanoprost 0.005% eye drops (Bausch + Lomb, Berlin) QD or Xalatan 0.005% eye drops (Pfizer, New York) QD. The primary endpoint was the mean change in 8 a.m. intra-ocular pressure (IOP) from baseline to the end of the trial. Other evaluations included IOP measurements at 12 noon and 4 p.m., global assessments of efficacy and tolerance, subjective tolerance assessments, standard ophthalmic examinations, vital signs, and adverse events (AEs).

Results: 265 patients were treated. The mean decrease from baseline in 8 a.m. IOP for Latanoprost-treated patients (-7.29 ± 2.61 mmHg) was significantly non-inferior to Xalatan-treated patients (-7.54 ± 2.80 mmHg) (p = 0.0001), for the full analysis set (n = 261). Similar results were obtained in the per-protocol set. A larger proportion of Latanoprost-treated patients (93.9%) had decreased 8 a.m. IOP of at least 15% compared to Xalatan-treated patients (88.5%). In addition, the mean decreases from baseline in IOP at 12 noon and 4 p.m. for the Latanoprost-treated patients were significantly non-inferior to Xalatan-treated patients. There were no differences between the treatment groups with respect to the global assessment of efficacy by the investigators. The overall frequency of discomfort upon instillation was comparable for the Latanoprost (43.9%) and Xalatan (38.2%) treatment groups. A majority of symptoms were of mild intensity. The incidences of burning, itching, and stinging were lower for the Latanoprost-treated patients. For the global assessment of tolerance by the investigators, there was a higher proportion of very good judgements in the Latanoprost group (69.7%) than in the Xalatan group (60.2%). The proportion of patients with AEs was not significantly different between the Latanoprost (14.4%) and Xalatan (14.3%) treatment groups (p = 0.9799). The AEs were mostly mild in severity and there were few treatment-related AEs in both treatment groups. No serious adverse events were observed.

Conclusions: Under the conditions of this study, Latanoprost 0.005% eye drops QD were non-inferior and similarly tolerated compared to Xalatan 0.005% eye drops QD in the treatment of OH and POAG.