

## **Safety and Efficacy of a New Fixed-Combination of Timolol-Brimonidine-Dorzolamide Versus Timolol and Dorzolamide Fixed Combination**

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### **PURPOSE:**

To evaluate the safety, and efficacy of a new fixed combination of 0.5% timolol, 0.2% brimonidine and 2% dorzolamide in the treatment of patients with Open Angle Primary Glaucoma and/or ocular hypertension.

### **METHOD:**

Multicenter, double masked, randomized clinical trial. Patients with Primary Open-Angle Glaucoma and/or Ocular Hypertension were included. Patients were randomized to 2 groups - one group was treated with a new fixed dose formulation of timolol-brimonidine-dorzolamide (KrytanteK Ofteno<sup>®</sup>, Laboratorios Sophia, Mexico) and the second group was treated with timolol-dorzolamide fixed combination (Cosopt<sup>®</sup>, MSD Laboratories, USA). Patients received 1 drop twice a day of either formulations and were examined on days 2, 7, 15, 30, 60, 90, 120, 150 and 180 post-treatment. The primary objective was to compare the efficacy of both formulations, estimated as a decrease in IOP from baseline pre-treatment levels. Safety and tolerance parameters were evaluated.

### **RESULTS:**

112 patients were enrolled— 56 patients in each of the two groups. The mean baseline IOP was  $24.1 \pm 2.6$  mmHg in the KrytanteK Ofteno<sup>®</sup> treatment group, and  $23.6 \pm 2.2$  mmHg in Cosopt<sup>®</sup> group ( $p=0.28$ ). The mean IOP change from baseline at 180 day follow-up visit, was  $9.90 \pm 2.95$  mmHg in the KrytanteK Ofteno<sup>®</sup> group, and  $6.8 \pm 3.42$  mmHg in the Cosopt<sup>®</sup> group. The drop in IOP from baseline was significantly greater in the KrytanteK Ofteno<sup>®</sup> group compared to the Cosopt<sup>®</sup> group ( $p < 0.001$ ). No differences in the safety and tolerance parameters were noted between the two groups.

### **CONCLUSION:**

KrytanteK Ofteno<sup>®</sup> was clearly more effective in reducing the IOP. This new fixed combination allows for the simplification of a multidrug regimen by reducing the total number of drops and preservative instilled per day, avoids washout effect from rapid sequence instillation of individual drops, and may improve adherence to chronic therapy.