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Lessening Glaucoma Treatment Burden with Topical Therapies: The Evidence (Part 1)

Announcer:
Welcome to CME on ReachMD. This episode is part of our MinuteCME curriculum.

Prior to beginning the activity, please be sure to review the faculty and commercial support disclosure statements as well as the learning objectives.

Dr. Cui:
This is CME on ReachMD, and I'm Dr. Qi Cui. Omidenepag isopropyl is a novel prostaglandin E2 receptor agonist that increases aqueous outflow through the trabecular and the uveoscleral pathways. Let's dive into the emerging data of this new topical agent.

The AYAME study is a phase 3, randomized, noninferiority trial that evaluated the efficacy and safety of omidenepag isopropyl, abbreviated OMDI, a selective prostaglandin E2 receptor agonist, in Japanese patients with primary open-angle glaucoma or ocular hypertension. The study was completed in 2017, and the results were published in the American Journal of Ophthalmology in 2020. The purpose of the study was to compare the IOP [intraocular pressure]-lowering effects of OMDI ophthalmic solution 0.002% to latanoprost 0.005% at a dose of 1 drop once daily at night for 4 weeks. Eligible patients were age 20 years or older, with a diagnosis of bilateral POAG [primary open-angle glaucoma] or ocular hypertension, with acuity equal to or better than 20/100 on the Snellen chart. Those with advanced visual field loss, recent ocular surgery, a history of ocular inflammation and retinal pathology, or conditions interfering with accurate Goldmann applanation tonometry were excluded. After a washout period of 1-4 weeks, a total of 190 patients were randomized to either OMDI or latanoprost, with 89 completing the study in the OMDI group and 94 completing the study in the latanoprost group. Intraocular pressure was measured at 9:00 AM, 1:00 PM, and 5:00 PM at weeks 1, 2, and 4. The primary endpoint was the change from baseline in mean diurnal IOP at week 4. The noninferiority margin for OMDI compared to latanoprost was determined to be 1.5 mmHg.

Baseline characteristics were comparable between the 2 study groups. At week 4, least squares mean reduction IOP for OMDI, averaging 5.93, plus or minus a standard error of 0.23 mmHg, was found to be noninferior to that of latanoprost, which averaged 6.56, plus or minus a standard error of 0.22 mmHg.

The treatment difference between the 2 groups was statistically, if unlikely to be clinically, significant. No serious adverse events, as determined the by investigators, were observed in either group. The incidence of adverse event was higher in the OMDI group than that in the latanoprost group. The most common ocular adverse events were conjunctival hyperemia, corneal thickening and photophobia, occurring in all cases more frequently in the OMDI group.

In summary, after 4 weeks of treatment, omidenepag isopropyl was shown to be noninferior to latanoprost for intraocular pressure reduction in patients with ocular hypertension or primary open-angle glaucoma, while exhibiting good tolerability.

The RENGE and FUJI studies are two other phase 3 trials conducted in Japan. Results from those trials support the finding of the AYAME study and further suggest that OMDI 0.002% exhibits long-term efficacy whether alone or in combination with timolol 0.5% and may be efficacious in non or poor responders to latanoprost, respectively. Of note, however, a significant percentage of pseudophakic patients in the RENGE study exhibited macular edema after 52 weeks of treatment. Pending long-term efficacy and safety data, omidenepag isopropyl holds promise as a novel IOP-lowering agent for treating glaucoma.

Unfortunately, that's all the time we have today. Thank you for joining me.

Announcer:
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