

# Experimental eye drops ease night vision problems for drivers

For the first trial, researchers recruited 145 patients with impaired visual acuity in dim or dark settings and symptoms of glare, halos, and starbursts. They received either the Opus eye drops containing 0.75% phentolamine ophthalmic solution daily or a placebo, for either eight or 15 days.



London: Eye drops developed by Opus Genetics significantly improved night vision in people who had trouble driving in the dark, according to data from two late-stage studies.

For the first trial, researchers recruited 145 patients with impaired visual acuity in dim or dark settings and symptoms of glare, halos, and starbursts. They received either the Opus eye drops containing 0.75% phentolamine ophthalmic solution daily or a placebo, for either eight or 15 days.

After eight days, 13% of study participants who got the phentolamine drops achieved a gain of at least three lines, or 15 letters, on eye charts, compared with 3% of the placebo group. By day 15, 21% who got the drug had seen such an improvement with no change for placebo at 3%.

Patients were also asked to rate their overall night vision problems on a scale of 1-7 with 7 being the most severe. Those treated with phentolamine were at 4.3 by day 8 and 3.3 after 15 days, considered a statistically significant improvement over the placebo group at 4.6 and 4.3, respectively.

By day 15, those who received the Opus Genetics drops also reported significantly less trouble with glare, halos, and starbursts than those treated with placebo.

By acting on a muscle in the iris, the eye drops produce moderate, sustained pupil constriction lasting at least 20 hours, researchers reported in *The American Journal of Ophthalmology*.

Many of the patients were experiencing their symptoms as after-effects of procedures to reshape the cornea, such as LASIK surgery to improve near- or far-sightedness or astigmatism, the researchers noted.

The company also announced encouraging initial results from a second Phase III trial of the eye drops.

In the second trial, "we also saw functional improvements in difficulty of seeing the road because of oncoming headlights; and difficulty seeing due to glare when driving at dawn or dusk, as reported by patients in the trial," Dr. Jay Pepose, Opus Genetics' chief medical adviser, said in a statement.

The U.S. Food and Drug Administration has granted Fast Track designation for the eye drops as a treatment of significant chronic night driving impairment, according to the manufacturer's website. The designation, given to drugs that treat a serious condition or address an unmet medical need, can speed the process of seeking approval.

## US HOSPITALS REPORT NATIONWIDE CANCER DRUG SHORTAGES

A survey of leading U.S. cancer centers released on Thursday illuminates the degree to which they are struggling to obtain medications for their patients, with nearly all identifying some shortages of critical generic therapies.

In late August, the National Comprehensive Cancer Network surveyed pharmacy directors and other clinical and administrative leaders at its 34 member institutions about drug shortages.

Among the 31 centers that responded, all said they are experiencing a shortage of at least one anti-cancer agent, and more than 20% said they currently have shortages of five or more different medications.

A shortage of ifosfamide, a generic chemotherapy used for bladder, ovarian, testicular, uterine, soft tissue sarcoma, osteosarcoma, and blood cancers, was reported by 94% of respondents.

In addition, 71% reported a shortage of carboplatin and 16% were short on cisplatin, which are important chemotherapies used as the backbone of regimens to treat numerous different tumor types, the NCCN said.

The immunotherapy Bacillus Calmette-Guerin for bladder cancer was also in short supply for more than half of the respondents.

When treatment plans had to be modified as a result of these drug shortages, 90% of centers noted a need for repeat prior authorization of the plan by insurance companies, significantly increasing the amount of work per patient and adding in the potential for a delay in care continuity, the NCCN researchers said.

"Nearly every pharmacy director who responded to our survey would like to see economic incentives put in place to encourage high-quality manufacturing for generic cancer medications," Alyssa Schatz, NCCN's vice president of policy & advocacy, said in a statement.

"That is something that advocates have been requesting for years," she said. "As one respondent noted: 'many oncology generics are clinically indispensable but economically unattractive. Without correcting that economic imbalance, shortages are likely to recur.'"

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