

GLAUCOMA TODAY NEWS

RHOPRESSA: FDA APPROVED AT LAST

BY STEPHEN DAILY



After setbacks and years of clinical testing, Aerie Pharmaceuticals in December received FDA approval for netarsudil ophthalmic solution 0.02% (Rhopressa) for the lowering of elevated IOP in patients with open-angle glaucoma or ocular hypertension. The FDA approval decision was made 2 months ahead of the scheduled Prescription Drug User Fee Act (PDUFA) goal date of February 28, 2018.

"It's been a long road, and it's hard to almost fathom the fact that [it goes] all the way back [to] 2005, when Dr. David Epstein, the chair of ophthalmology at Duke at the time, was thinking that we should have a drug that once-a-day treats the trabecular meshwork, which is the underlying cause," Vicente Anido Jr, PhD, Chairman and Chief Executive Officer at Aerie, said in an interview with Eyewiretoday.com.

"After all these years, to actually have the first product come through our pipeline and out, and getting it approved, is a tribute to him, and I think certainly is going to be a

great value to the doctors and the patients that are going to be receiving the drug."

Aerie says that Rhopressa is the only once-daily product available that specifically targets the trabecular meshwork. Preclinical and clinical studies have demonstrated that netarsudil lowers episcleral venous pressure, which contributes to approximately half of IOP in healthy individuals. The approval was based on data from the phase 3 Rocket 1, Rocket 2, and Rocket 4 studies, comparing once-daily netarsudil to twice-daily timolol.

Aerie will hire 100 sales representatives early in the first quarter of 2018 and plans to launch the drug by mid-second quarter of 2018.

Aerie is currently working to gain formulary coverage for commercial plans, which represent approximately half of the US market. The other half of the US market is covered through Medicare Part D, and the company expects its formulary presence for the Medicare market to commence in January 2019.

STUDY IN SECONDS

TITLE

Baerveldt Shunt Surgery Versus Combined Baerveldt Shunt and Phacoemulsification: A Prospective Comparative Study

AUTHORS

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PUBLISHED

British Journal of Ophthalmology
December 15, 2017

OBJECTIVE

To compare the safety and efficacy of phacoemulsification combined with Baerveldt tube (BT) implantation versus BT implantation alone in patients with refractory glaucoma.

GROUPS

Thirty-eight phakic eyes underwent phacoemulsification combined with BT implantation, and 38 pseudophakic eyes underwent BT implantation alone.

RESULTS

The combined group had a higher failure rate (37% vs 15%; $P = .02$) and median IOP (14 vs 12 mm Hg; $P = .04$) at 3 years. Failure was defined as inadequate IOP control (pressure of either 5 mm Hg or less, or > 21 mm Hg); a < 20% reduction in IOP from baseline; reoperation for glaucoma; loss of light perception; or implant removal.

There was no significant difference between the groups in mean number of antiglaucoma medications (1.7 vs 1.3), median visual acuity (0.8 vs 0.7 logMAR), or postoperative complication rate (13% in both groups).

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\$0.23

Additional amount US physicians will receive for an average office visit under Congress's new Medicare fee-for-service rate.

Read more at bit.ly/Medicareraise

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The number of times Bascom Palmer Eye Institute has been named No. 1 in ophthalmology in the *U.S. News & World Report* Best Hospitals list.

See the list at bit.ly/TopOphth



DRINK TEA TO LOWER GLAUCOMA RISK

Researchers found that daily hot-tea drinkers were 74% less likely to be diagnosed with glaucoma than those who drank no tea, according to a study published in the *British Journal of Ophthalmology*.¹

1. Wu CM, Wu AM, Tseng VL, Yu F, Coleman A. Frequency of a diagnosis of glaucoma in individuals who consume coffee, tea and/or soft drinks. *Br J Ophthalmol*. <http://bit.ly/TeaGlaucoma>. Accessed January 15, 2018.



END OF MEDICAL DEBT FOR COLUMBIA STUDENTS?

The Columbia University College of Physicians and Surgeons has received a \$250 million gift from P. Roy Vagelos, MD, that could eliminate the need for student loans for all of its future medical students. Students with the greatest financial need would receive full-tuition scholarships, while others would get only grants, not loans, to make up their need, the school told the *New York Times*.

Get the whole story at bit.ly/Columbiagift

iDOSE TRAVOPROST ACHIEVES SUSTAINED IOP REDUCTION

Glaukos announced that its travoprost intraocular implant with the iDose delivery system continued to provide sustained reduction in IOP in a 12-month interim cohort of patients in its US investigational new drug phase 2 clinical trial, according to a company news release. Implanted during a microinvasive procedure, the iDose Travoprost is filled with a special formulation of travoprost and is designed to continuously elute therapeutic levels of the medication from within the eye for extended periods of time. When depleted, the iDose Travoprost can be removed and replaced in a similar procedure.

The multicenter, randomized, double-masked phase 2 trial included 154 patients. It was designed to evaluate two models of the iDose delivery system with two different travoprost elution rates compared with topical timolol ophthalmic solution 0.5% and had a primary efficacy endpoint of noninferiority to topical timolol.

The latest phase 2 results are from an interim cohort of 74 patients, 49 of whom were implanted with one of the iDose Travoprost implant models, with 25 patients in the timolol comparator group. In the implant patients, iDose Travoprost achieved an approximate 30% reduction in mean IOP versus baseline IOP during the first 12 months. In addition, the mean number of glaucoma medications ranged from 0.54 to 0.56 at 12 months in the fast and slow iDose Travoprost elution implant groups, respectively, compared with a mean 0.72 medications in the timolol group.

The most recent phase 2 data showed a favorable safety profile for iDose Travoprost with no adverse events of hyperemia reported to date in either elution group, the news release said.

CLICKWORTHY

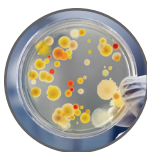
HEALTHY EATING LINKED TO KIDS' HAPPINESS



Healthy eating is associated with better self-esteem and fewer emotional and peer problems in children, regardless of body weight, a study found.

bit.ly/Clickworthy118a

THE WAR ON MICROBES



Antibiotic resistance could lead to 10 million deaths per year by 2050, public health experts warn. Here's what the US government is doing about it.

bit.ly/Clickworthy118f

AN AMERICAN DOCTOR IN CANADA



Doctors who have worked on both sides of the border discuss whether a Canadian system could work in the United States.

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HOOKWORM IS BACK



Thought to be eradicated in the United States by the 1980s, hookworm has been found in rural Alabama.

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US HEALTH SYSTEM FAILS NATIVE AMERICANS, POLL FINDS



The life expectancy of Native Americans in some states is 20 years shorter than the national average, NPR reports.

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OVERHEARD

"AS WE SAY IN SOUTH DAKOTA,

'SAY WHAT YOU MEAN,

MEAN WHAT YOU SAY, AND

DON'T SAY IT MEAN.'"

—John P. Berdahl, MD, on making ethical choices when serving as a key opinion leader, from the January issue of BMC sister publication *CRST*.¹

1. Berdahl JP. Why be a key opinion leader? *CRST*. January 2018. <https://crstoday.com/articles/2018-jan/why-be-an-opinion-leader/>.

LETTER TO THE EDITOR

I recently read with interest the article "First, Do No Harm" by Arkadiy Yadgarov, MD, in the November/December 2017 issue of *Glaucoma Today*.¹ In this piece, Dr. Yadgarov discusses proceeding with nonsurgical treatment options when surgery may not be the best or safest choice for various ocular problems—in this case, advanced glaucoma in a monocular patient.

Indeed, the concept of thoroughly reviewing the risks, benefits, and alternatives of care is a bedrock of medicine and surgery in any specialty—and especially in ophthalmology, where blindness is the feared concern of any ocular surgical procedure.

This type of informative approach is one that medical students—and certainly ophthalmology residents and fellows—are advised of, and this educational skill merits ongoing study. Caution should always be exercised when promoting surgical options that may or may not be the safest and/or most effective for the patient who trusts his or her doctor's thoughtful care.

Dr. Yadgarov's well-written article certainly brings this subject to the attention of all ophthalmologists.

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1. Yadgarov A. First, do no harm. *Glaucoma Today*. November/December 2017.

—Compiled by Stephen Daily, Executive Editor, News; and Carrie Adkins-Ali, Managing Editor. ■