



# Cornea Society

*Advancing the treatment of corneal disease*

# News

A Cornea Society publication

## Cornea Society grows membership

**O**ver the past year, the Cornea Society has added 147 new members. As of March 2020, the Cornea Society membership totaled 845, up from 698 in March 2019. The organization has seen growth in both domestic and international members during this period.

“As a member of the Cornea Society Board of Directors, I am excited to see our membership numbers increase over the last several years, in particular seeing an increase of 147 members in just one year,” said **W. Barry Lee, MD**, secretary of the Cornea Society. “I think this is directly attributable to our increased internet presence through webinars, Cornea Society University, kera-net, and the phenomenal educational meetings we hold throughout the year.”

He added that he thinks the focus on the Cornea Fellows Educational Summit is also paying off to help cornea fellows in training see the importance of the society in the early years of their practice. “It is an exciting time to be a member of the Cornea Society for both young and experienced surgeons alike,” Dr. Lee said.

The Cornea Society is committed to advancing the understanding of diseases of the cornea and external eye and is the single largest subspecialty society representing the fields of

cornea, external disease, and refractive surgery. Some of the many benefits of membership include complimentary subscription to the *Cornea* journal and online access, an online subscription to kera-net, advocacy and representation on funding and regulatory legislation, discounts on meeting registration at various ophthalmic meetings, and access to the CorneaEd database.

Membership category options and descriptions for the Cornea Society are listed below.

### Candidate

This is open to those who are actively enrolled in medical education and/or training (i.e., medical students, residents, and fellows). The term of membership is for 1 year and is complimentary. Applicants must present a current CV and letter from their fellowship director.

### Member

This is open to those who are board-certified ophthalmologists (ABO or foreign equivalent) or PhDs engaged in research in visual science. A current CV must accompany the online application.

### Fellow of the Cornea Society

This is open to those individuals who have graduated from an AUPO-FCC

compliant cornea fellowship program and have been in practice for a minimum of 4 years. Applicants must be endorsed in writing by a Member with Thesis and provide a letter from their fellowship director attesting to the applicant’s successful completion of a cornea fellowship. Applicants must also provide a current CV along with a brief personal statement detailing their interest and activity in cornea since fellowship.

### Member with Thesis

This is open to those who are board-certified ophthalmologists (ABO or foreign equivalent), and who have completed a fellowship in cornea and external disease of at least 1 year’s duration in a program approved by the Membership Committee, or have a minimum of 5 years post-residency experience with a substantial portion in cornea and external disease. Materials to accompany the online application are a current CV, two letters of recommendation from a current Member with Thesis, and a copy of a paper published in a scientific journal where he or she was the first or corresponding author and the work was completed after fellowship. **CN**

## The first FDA-approved pharmacologic treatment that targets the root pathogenesis of neurotrophic keratitis<sup>1-3</sup>

With OXERVATE, up to 72% of patients achieved complete corneal healing at 8 weeks\*<sup>1,4</sup>

- Cenegermin-bkbj, the active ingredient in OXERVATE, is structurally identical to the human nerve growth factor (NGF) protein made in ocular tissues.<sup>5</sup>
- NGF is an endogenous protein involved in the differentiation and maintenance of neurons, and acts through specific high-affinity (ie, TrkA) and low-affinity (ie, p75NTR) NGF receptors in the anterior segment of the eye to support corneal innervation and integrity.<sup>1</sup> Endogenous NGF is believed to support corneal integrity through 3 primary mechanisms (shown in preclinical models): corneal innervation, reflex tear secretion, and corneal epithelial cell proliferation and differentiation<sup>3,6,7</sup>

Explore the breakthrough therapy at [Oxervate.com/HCP](https://www.oxervate.com/HCP)

### Indication

OXERVATE is a recombinant human nerve growth factor indicated for the treatment of neurotrophic keratitis.

### Important Safety Information

#### WARNINGS AND PRECAUTIONS

Patients should remove contact lenses before applying OXERVATE and wait 15 minutes after instillation of the dose before reinsertion.

#### ADVERSE REACTIONS

The most common adverse reaction in clinical trials that occurred more frequently with OXERVATE was eye pain (16% of patients). Other adverse reactions included corneal deposits, foreign body sensation, ocular hyperemia, ocular inflammation, and increase in tears (1%-10% of patients).

For additional safety information, see accompanying Brief Summary of Safety Information on the adjacent page and full Prescribing Information on [Oxervate.com/HCP](https://www.oxervate.com/HCP).

\*Complete corneal healing was defined as the absence of staining of the corneal lesion and no persistent staining in the rest of the cornea after 8 weeks of treatment. Based on results from the REPARO trial (Europe, NGF0212; N=156) and the US trial (NGF0214; N=48).<sup>4,8</sup>

**References:** 1. OXERVATE (cenegermin-bkbj) full prescribing information. Dompé. October 2019. 2. FDA approves first drug for neurotrophic keratitis, a rare eye disease [FDA news release]. August 22, 2018. 3. Mastropasqua L, Massaro-Giordano G, Nubile M, Sacchetti M. Understanding the pathogenesis of neurotrophic keratitis: the role of corneal nerves. *J Cell Physiol.* 2017;232:717-724. 4. Bonini S, Lambiase A, Rama P, et al. Phase II randomized, double-masked, vehicle-controlled trial of recombinant human nerve growth factor for neurotrophic keratitis. *Ophthalmology.* 2018;125:1332-1343. 5. Voelker R. New drug treats rare, debilitating neurotrophic keratitis. *JAMA.* 2018;320:1309. 6. Müller LJ, Marfurt CF, Kruse F, Tervo TMT. Corneal nerves: structure, contents and function. *Exp Eye Res.* 2003;76:521-542. 7. Sacchetti M, Lambiase A. Diagnosis and management of neurotrophic keratitis. *Clin Ophthalmol.* 2014;8:571-579. 8. Center for Drug Evaluation and Research, US Food and Drug Administration. Oxervate (cenegermin-bkbj) BLA 761094. Medical Review(s). July 19, 2018. [https://www.accessdata.fda.gov/drugsatfda\\_docs/nda/2018/761094Orig1s000TOC.cfm](https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/761094Orig1s000TOC.cfm).



## Brief Summary of Safety

Consult the full Prescribing Information for complete product information.

### INDICATIONS AND USAGE

OXERVATE™ (cenegermin-bkbj) ophthalmic solution 0.002% is indicated for the treatment of neurotrophic keratitis.

### DOSAGE AND ADMINISTRATION

Contact lenses should be removed before applying OXERVATE and may be reinserted 15 minutes after administration.

If a dose is missed, treatment should be continued as normal, at the next scheduled administration.

If more than one topical ophthalmic product is being used, administer the eye drops at least 15 minutes apart to avoid diluting products. Administer OXERVATE 15 minutes prior to using any eye ointment, gel or other viscous eye drops.

### Recommended Dosage and Dose Administration

Instill one drop of OXERVATE in the affected eye(s), 6 times a day at 2-hour intervals for eight weeks.

### ADVERSE REACTIONS

Clinical Studies Experience Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in the clinical studies of a drug cannot be directly compared to rates in the clinical studies of another drug and may not reflect the rates observed in practice.

In two clinical trials of patients with neurotrophic keratitis, a total of 101 patients received cenegermin-bkbj eye drops at 20 mcg/mL at a frequency of 6 times daily in the affected eye(s) for a duration of 8 weeks. The mean age of the population was 61 to 65 years of age (18 to 95). The majority of the treated patients were female (61%). The most common adverse reaction was eye pain following instillation which was reported in approximately 16% of patients. Other adverse reactions occurring in 1-10% of OXERVATE patients and more frequently than in the vehicle-treated patients included corneal deposits, foreign body sensation, ocular hyperemia, ocular inflammation and tearing.

### USE IN SPECIFIC POPULATIONS

#### Pregnancy

Risk Summary There are no data from the use of OXERVATE in pregnant women to inform any drug associated risks.

Administration of cenegermin-bkbj to pregnant rats or rabbits during the period of organogenesis did not produce adverse fetal effects at clinically relevant doses. In a pre- and postnatal development study, administration of cenegermin-bkbj to pregnant rats throughout gestation and lactation did not produce adverse effects in offspring at clinically relevant doses.

#### Animal Data

In embryofetal development studies, daily subcutaneous administration of cenegermin-bkbj to pregnant rats and rabbits throughout the period of organogenesis produced a slight increase in post-implantation loss at doses greater than or equal to 42 mcg/kg/day (267 times the MRHOD). A no observed adverse effect level (NOAEL) was not established for post-implantation loss in either species.

In rats, hydrocephaly and ureter anomalies were each observed in one fetus at 267 mcg/kg/day (1709 times the MRHOD). In rabbits, cardiovascular malformations, including ventricular and atrial septal defects, enlarged heart and aortic arch dilation were each observed in one fetus at 83 mcg/kg/day (534 times the MRHOD). No fetal malformations were observed in rats and rabbits at doses of 133 mcg/kg/day and 42 mcg/kg/day, respectively. In a pre- and postnatal development study, daily subcutaneous administration of cenegermin-bkbj to pregnant rats during the period of organogenesis and lactation did not affect parturition and was not associated with adverse toxicity in offspring at doses up to 267 mcg/kg/day. In parental rats and rabbits, an immunogenic response to cenegermin-bkbj was observed. Given that cenegermin-bkbj is a heterologous protein in animals, this response may not be relevant to humans.

#### Lactation

There are no data on the presence of OXERVATE in human milk, the effects on breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered, along with the mother's clinical need for OXERVATE, and any potential adverse effects on the breastfed infant from OXERVATE.

#### Pediatric Use

The safety and effectiveness of OXERVATE have been established in the pediatric population. Use of OXERVATE in this population is supported by evidence from adequate and well-controlled trials of OXERVATE in adults with additional safety data in pediatric patients from 2 years of age and older [see *Clinical Studies* (14)].

#### Geriatric Use

Of the total number of subjects in clinical studies of OXERVATE, 43.5% were 65 years old and over. No overall differences in safety or effectiveness were observed between elderly and younger adult patients.

### NONCLINICAL TOXICOLOGY

Carcinogenesis and Mutagenesis Animal studies have not been conducted to determine the carcinogenic and mutagenic potential of cenegermin-bkbj.

Impairment of fertility Daily subcutaneous administration of cenegermin-bkbj to male and female rats for at least 14 days prior to mating, and at least 18 days post-coitum had no effect on fertility parameters in male or female rats at doses up to 267 mcg/kg/day (1709 times the MRHOD). In general toxicology studies, subcutaneous and ocular administration of cenegermin-bkbj in females was associated with ovarian findings including persistent estrus, ovarian follicular cysts, atrophy/reduction of corpora lutea, and changes in ovarian weight at doses greater than or equal to 19 mcg/kg/day (119 times the MRHOD).





# Cornea Society

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## President's message

Dear Colleagues,

What a difference a few months makes. My last President's message in January focused on World Cornea Congress 2020, which we were all eagerly anticipating. Fast forward 10 weeks and the world is a completely different place. Most of us are sheltering in place, not doing elective surgeries, only providing urgent/emergent eyecare, and spending much of our day on Zoom.

Everyone knows by now that we have postponed World Cornea Congress 2020. While we hated to do this, it was truly unavoidable. Cornea Society leadership is actively working on another option to hold World Cornea Congress in 2020. Stay tuned for more details, but rest assured our focus on collaboration will continue to be a guiding principle. I am grateful for the hard work and camaraderie of my fellow program chairs Elmer Tu, MD, and Bennie Jeng, MD, along with our administrative support team (Don Bell, Carrie Braden, and Pura Valdez) and all the members of the Program Committee.

We have begun planning for the 2020 Cornea Fellows Educational Summit on October 15–18, in Atlanta, Georgia. The program directors are Michael Straiko, MD, Gregory Ogawa, MD, and Jennifer Li, MD. This popular program brings together cornea fellows for a long weekend of didactics, skills transfer wet labs, and networking with cornea leaders. We are making a few changes to improve the program, including the addition of some optional events on Sunday morning, such as a job fair. Fellowship directors, watch your email for details.

I'm pleased to highlight that our journal *Cornea* has a new editor-in-chief, Reza Dana, MD, as well as new additions to the senior editor roster and the Editorial Board. We have already seen an uptick in journal submissions, and we look forward to new journal features, including "Controversies" and "Point/Counterpoint" articles. As a reminder, the journal is a benefit of Cornea Society membership.

In closing, I'd like to offer some philosophical thoughts. This is a challenging, truly unprecedented, anxiety-provoking time. For those of you who have lost loved ones or sustained personal health consequences from COVID-19, our thoughts and deepest sympathies are with you. While it is easy to focus on what the rest of us have lost (graduations, conferences, family celebrations, dinners with friends, going to the gym, handshakes, and hugs), I encourage each of you to remember what we still have and what we will have again in the future. A positive attitude will help us get through this. Humor is a great antidote to sadness. There are some clever song parodies on the internet ("My Corona" by Chris Mann is one of my favorites), and I have especially enjoyed the back and forth between the Cuomo brothers in New York. It's nice to see that other siblings besides my daughters argue about which one is "mom's favorite." I've encouraged the members of my department at the University of Chicago to set some personal goals for this time when we cannot do our regular daily activities as ophthalmologists. These can include getting that R01 or paper written, giving extra lectures, reading a book for pleasure, doing a 90-second plank, or simply appreciating the stillness that has been forced upon us. When we look back on this time, we can remember these goals. Finally, take a moment to notice the beauty of the world around us. It is still there, despite COVID-19. These strategies will help us get through the challenging months ahead.

Stay safe, my friends. I look forward to the time when we can gather again.



Kathryn Colby, MD, PhD

Kathryn Colby, MD, PhD  
Cornea Society President

## World Cornea Congress 2020 postponed

Dear Colleagues,

It is with much sadness that we make the official announcement that we are rescheduling World Cornea Congress 2020: The Future in Focus. As you are all aware, the coronavirus pandemic has made it impossible to have an international conference. While we are disappointed that events have led to this, we want to ensure the safety of all World Cornea Congress participants, which is not possible at present. We are very grateful to all who committed time to planning this meeting, including the World Cornea Congress Planning Committee, the

supra-national cornea societies who planned joint symposia, the national and subspecialty cornea organizations that contributed courses and special topic sessions, the more than 800 participants who submitted free papers and posters, and the 130 invited speakers. We are also grateful for the support of our exhibitors and our sponsors, including Novartis, our platinum sponsor, and Allergan, our gold sponsor. We also thank our outstanding administrative team, Don Bell, Cornea Society executive director, and Carrie Braden, meeting planner extraordinaire. As a result of the efforts of many people, we had planned a comprehensive program that showcased the field of cornea. We look

forward to convening for the World Cornea Congress in the future, once the pandemic is under control. Thank you again for your dedication to our field. We will get through this challenge. In the meantime, stay safe.

With best wishes,  
Kathryn Colby, MD, PhD  
Bennie Jeng, MD  
Elmer Tu, MD  
*World Cornea Congress  
Program Directors*

## Cornea Society awards

The Cornea Society has selected the recipients of this year's Castroviejo Award, given each year to the "most outstanding individual in the field of cornea and anterior segment of the eye," and the Dohlman Award, recognizing teaching excellence.

### Castroviejo Award

This year, the winner of the Castroviejo Award is Jayne Weiss, MD, New Orleans, Louisiana.

Dr. Weiss is known for her extensive work in the cornea subspecialty, including the IC3D classification of corneal dystrophies publications. Her interest in Schnyder corneal dystrophy spans more than 20 years, during which time she has studied the clinical findings, visual prognosis, discovered the causative gene and mutations, animal models, and currently is PI of an R21 grant studying mechanisms of disease. She is also site PI for the multicenter National Eye Institute/National Institutes of Health U10 grant, Zoster Eye Disease Study.

"Dr. Weiss embodies the best of the field of cornea; she is an outstanding clinician and a well-respected researcher

whose work will leave a long-lasting impact on our field," said Kathryn Colby, MD, PhD, Cornea Society president. "She has a long history of service to the field and to the Cornea Society."

Each year the Cornea Society names the most outstanding individual in the field of cornea and the anterior segment of the eye to receive the Castroviejo Medal and to deliver the Castroviejo Lecture at the Cornea Society scientific symposium at the American Academy of Ophthalmology (AAO) annual meeting. This is the Cornea Society's highest award and is given in recognition of exceptional contributions in support of the mission: to promote knowledge, research, and understanding in cornea, external disease, and refractive surgery. The award is named for Ramon Castroviejo, MD, the father of modern corneal transplant surgery and the inspiration for the founding of the Cornea Society.

### Dohlman Award

This year, the winner of the Dohlman Award is Eduardo Alfonso, MD, Miami, Florida.

Dr. Alfonso has taught nearly 300 residents and fellows over a 35-year period, including many influential leaders in the ophthalmology field today.

"Eddie is a leader in the field of corneal infections," said Sonia Yoo, MD. "He was a Dohlman fellow and has spent his career at Bascom Palmer, most recently as the chairman of the department. He is a great mentor and leader."

The Dohlman Award is given each year to recognize a lifetime of teaching excellence in the field of cornea and external disease and for contributions to the profession. Claes Dohlman, MD, PhD, the inaugural recipient of the award and for whom it is named, created the first formal corneal fellowship program in the U.S. at the Massachusetts Eye and Ear Infirmary and the Retina Foundation (now Schepens Eye Research Institute) in Boston, Massachusetts. Dr. Dohlman has trained hundreds of fellows, many of whom went on to become full professors. His commitment to teaching and education has enabled many of his students to leave their mark on the field of ophthalmology. **CN**

When ocular itch gets in the way  
of their day...

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Available by prescription only.

ZERVIAE delivers the proven power of cetirizine—  
a leading oral allergy medication—now targeted  
to the eyes.<sup>1,2,a</sup>

- Clinically meaningful and rapid reduction in ocular itch vs vehicle at 15 minutes and 8 hours ( $P < 0.0001$  at all time points measured)<sup>1,3</sup>
- Designed for comfortable delivery with Hydrella™, a glycerin and HPMC formulation<sup>1,4</sup>
- Administered as a single drop, twice daily approximately 8 hours apart<sup>1</sup>

STUDY DESIGN: The pivotal trials for ZERVIAE included two Phase 3, double-masked, randomized, vehicle-controlled, parallel-group studies involving 201 patients. Study 2 required more severe allergic conjunctivitis symptoms. Patients were screened for an allergen response using the conjunctival allergen challenge (CAC) model and randomized to receive either ZERVIAE or vehicle. Primary efficacy endpoints were ocular itching and conjunctival redness 15 minutes and 8 hours post treatment instillation.<sup>3</sup>

#### INDICATIONS AND USAGE

ZERVIAE™ (cetirizine ophthalmic solution) 0.24% is a histamine-1 (H1) receptor antagonist indicated for treatment of ocular itching associated with allergic conjunctivitis.

#### DOSAGE AND ADMINISTRATION

Instill one drop in each affected eye twice daily (approximately 8 hours apart).

#### IMPORTANT SAFETY INFORMATION

##### WARNINGS AND PRECAUTIONS

**Contamination of Tip and Solution:** As with any eye drop, care should be taken not to touch the eyelids or surrounding areas with the dropper tip of the bottle or tip of the single-use container in order to avoid injury to the eye and to prevent contaminating the tip and solution. Keep the multi-dose bottle closed when not in use. Discard the single-use container after using in each eye.

**Contact Lens Wear:** Patients should be advised not to wear a contact lens if their eye is red. ZERVIAE should not be instilled while wearing contact lenses. Remove contact lenses prior to instillation of ZERVIAE. The preservative in ZERVIAE, benzalkonium chloride, may be absorbed by soft contact lenses. Lenses may be reinserted 10 minutes following administration of ZERVIAE.

#### ADVERSE REACTIONS

The most commonly reported adverse reactions occurred in approximately 1–7% of patients treated with either ZERVIAE or vehicle. These reactions were ocular hyperemia, instillation site pain, and visual acuity reduced.

**Please see brief summary of Full Prescribing Information on the adjacent page.**

HPMC=hydroxypropyl methylcellulose.

<sup>a</sup>Based on a U.S. News report on data from the 2019 Pharmacy Times Survey of Pharmacists' OTC Recommendations.

**References:** 1. ZERVIAE [package insert]. Fort Worth, Texas: Eyeavance Pharmaceuticals LLC; 2020. 2. *U.S. News & World Report*. Antihistamines for allergies. <https://health.usnews.com/health-products/top-rec-antihistamines-oral-8>. Accessed October 7, 2019. 3. Meier EJ, Torkildsen GL, Gomes PJ, et al. Phase III trials examining the efficacy of cetirizine ophthalmic solution 0.24% compared to vehicle for the treatment of allergic conjunctivitis in the conjunctival allergen challenge model. *Clin Ophthalmol*. 2018;12:2617-2628. 4. Malhotra RP, Meier E, Torkildsen G, et al. Safety of cetirizine ophthalmic solution 0.24% for the treatment of allergic conjunctivitis in adult and pediatric subjects. *Clin Ophthalmol*. 2019;13:403-413.



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NEW



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cetirizine ophthalmic solution, 0.24%

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## ZERVIAE™ (cetirizine ophthalmic solution) 0.24%

### Brief Summary

#### INDICATIONS AND USAGE

ZERVIAE (cetirizine ophthalmic solution) 0.24% is a histamine-1 (H1) receptor antagonist indicated for treatment of ocular itching associated with allergic conjunctivitis.

#### DOSAGE AND ADMINISTRATION

**Recommended Dosing:** Instill one drop of ZERVIAE in each affected eye twice daily (approximately 8 hours apart). The single-use containers are to be used immediately after opening and can be used to dose both eyes. Discard the single-use container and any remaining contents after administration. The single-use containers should be stored in the original foil pouch until ready to use.

#### CONTRAINDICATIONS

None.

#### WARNINGS AND PRECAUTIONS

**Contamination of Tip and Solution:** As with any eye drop, care should be taken not to touch the eyelids or surrounding areas with the dropper tip of the bottle or tip of the single-use container to avoid injury to the eye and to prevent contaminating the tip and solution. Keep the multi-dose bottle closed when not in use. Discard the single-use container after using in each eye.

**Contact Lens Wear:** Patients should be advised not to wear a contact lens if their eye is red.

ZERVIAE should not be instilled while wearing contact lenses. Remove contact lenses prior to instillation of ZERVIAE. The preservative in ZERVIAE, benzalkonium chloride, may be absorbed by soft contact lenses. Lenses may be reinserted 10 minutes following administration of ZERVIAE.

#### ADVERSE REACTIONS

**Clinical Trials Experience:** Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trial of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

In 7 clinical trials, patients with allergic conjunctivitis or those at risk of developing allergic conjunctivitis received one drop of either cetirizine (N=511) or vehicle (N=329) in one or both eyes. The most commonly reported adverse reactions occurred in approximately 1%-7% of patients treated with either ZERVIAE or vehicle. These reactions were ocular hyperemia, instillation site pain, and visual acuity reduced.

#### USE IN SPECIFIC POPULATIONS

##### Pregnancy

###### Risk Summary

There were no adequate or well-controlled studies with ZERVIAE in pregnant women. Cetirizine should be used in pregnancy only if the potential benefit justifies the potential risk to the fetus.

###### Data

##### Animal Data

Cetirizine was not teratogenic in mice, rats, or rabbits at oral doses up to 96, 225, and 135 mg/kg, respectively (approximately 1300, 4930, and 7400 times the maximum recommended human ophthalmic dose (MRHOD), on a mg/m<sup>2</sup> basis).

##### Lactation

###### Risk Summary

Cetirizine has been reported to be excreted in human breast milk following oral administration. Multiple doses of oral dose cetirizine (10 mg tablets once daily for 10 days) resulted in systemic levels (Mean C<sub>max</sub> = 311 ng/mL) that were 100 times higher than the observed human exposure (Mean C<sub>max</sub> = 3.1 ng/mL) following twice daily administration of cetirizine ophthalmic solution 0.24% to both eyes for 1 week. Comparable bioavailability has been found between the tablet and syrup dosage forms. However, it is not known whether the systemic absorption resulting from topical ocular administration of ZERVIAE could produce detectable quantities in human breast milk.

There is no adequate information regarding the effects of cetirizine on breastfed infants, or the effects on milk production to inform risk of ZERVIAE to an infant during lactation. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for ZERVIAE and any potential adverse effects on the breastfed child from ZERVIAE.

**Pediatric Use:** The safety and effectiveness of ZERVIAE has been established in pediatric patients two years of age and older. Use of ZERVIAE in these pediatric patients is supported by evidence from adequate and well-controlled studies of ZERVIAE in pediatric and adult patients.

**Geriatric Use:** No overall differences in safety or effectiveness have been observed between elderly and younger patients.

#### NONCLINICAL TOXICOLOGY

##### Carcinogenesis, Mutagenesis, Impairment of Fertility

###### Carcinogenicity

In a 2-year carcinogenicity study in rats, orally administered cetirizine was not carcinogenic at dietary doses up to 20 mg/kg (approximately 550 times the MRHOD, on a mg/m<sup>2</sup> basis). In a 2-year carcinogenicity study in mice, cetirizine caused an increased incidence of benign liver tumors in males at a dietary dose of 16 mg/kg (approximately 220 times the MRHOD, on a mg/m<sup>2</sup> basis). No increase in the incidence of liver tumors was observed in mice at a dietary dose of 4 mg/kg (approximately 55 times the MRHOD, on a mg/m<sup>2</sup> basis). The clinical significance of these findings during long-term use of cetirizine is not known.

###### Mutagenesis

Cetirizine was not mutagenic in the Ames test or in an *in vivo* micronucleus test in rats. Cetirizine was not clastogenic in the human lymphocyte assay or the mouse lymphoma assay.

###### Impairment of Fertility

In a fertility and general reproductive performance study in mice, cetirizine did not impair fertility at an oral dose of 64 mg/kg (approximately 875 times the MRHOD, on a mg/m<sup>2</sup> basis).

#### PATIENT COUNSELING INFORMATION

**Risk of Contamination:** Advise patients not to touch dropper tip to eyelids or surrounding areas, as this may contaminate the dropper tip and ophthalmic solution. Advise patients to keep the bottle closed when not in use. Advise patients to discard single-use containers after each use.

**Concomitant Use of Contact Lenses:** Advise patients not to wear contact lenses if their eyes are red. Advise patients that ZERVIAE should not be used to treat contact lens-related irritation. Advise patients to remove contact lenses prior to instillation of ZERVIAE. The preservative in ZERVIAE solution, benzalkonium chloride, may be absorbed by soft contact lenses. Lenses may be reinserted 10 minutes following administration of ZERVIAE.

**Administration:** Advise patients that the solution from one single-use container is to be used immediately after opening. Advise patients that the single-use container can be used to dose both eyes. Discard the single-use container and remaining contents immediately after administration.

##### Storage of Single-use Containers:

Instruct patients to store single-use containers in the original foil pouch until ready to use.

##### Rx Only

**Manufactured by:** Renaissance Lakewood, LLC. Lakewood, NJ 08701

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# Cornea Fellows Educational Summit planned for October in Atlanta

**T**his year, the Cornea Fellows Educational Summit, for cornea, external disease, and refractive surgery fellows, will take place from October 15–18, in Atlanta, Georgia. This 2-day intensive program features both classroom and skills transfer lab components and is designed to complement and reinforce cornea fellowship training.

The Summit's curriculum has been developed to address specific educational challenges identified by cornea fellowship directors and is designed to provide: training to improve diagnostic and treatment skills within the clinic setting, instruction on patient selection and surgical techniques for refractive surgery, and technique pearls for routine and complex cataract surgery and corneal transplantation. Sessions involving hands-on skills technique training in both refractive and corneal transplant surgery have been included to provide additional experience and to better prepare fellows for their first years in practice.

The meeting will be chaired this year by Michael Straiko, MD, Gregory Ogawa, MD, and Jennifer Li, MD.

"As in prior years, we expect that this will be a highly anticipated meeting for next year's cornea fellows," Dr. Li said. "We have a wonderful group of faculty, many of whom are returning from years past."

Dr. Li added that this is "one of the most unique meetings [the fellows] will ever attend." It is organized by Cornea Society, and all of the content is directed toward the fellows in their exact stage of training/education. "Moreover, they will have the opportunity to meet other young corneal surgeons and build connections that will hopefully last throughout their careers," she said.

Dr. Li shared some of the topics that are expected to appear on this year's program. The program includes talks on corneal transplantation tech-



## Cornea Society

*Advancing the treatment of corneal disease*

### Cornea Fellows Educational Summit

niques from penetrating keratoplasty to newer endothelial keratoplasty techniques and deep anterior lamellar keratoplasty, which will be taught by Dr. Straiko, Christopher Sales, MD, and Deepinder Dhaliwal, MD. New this year will be talks on Descemet stripping only, given by Kathryn Colby, MD, PhD, and pediatric keratoplasty by Christina Prescott, MD, PhD, Dr. Li said. Additionally, Dr. Ogawa will be returning with his highly informative talks on iris suturing and IOL exchange technique, and Bennie Jeng, MD, Sonal Tuli, MD, and Jessica Ciralsky, MD, will discuss the management of ocular surface diseases and corneal infections, while Dr. Dhaliwal will be covering basics of keratorefractive surgery.

Dr. Straiko said there will be several spotlight lunch and dinner programs. The spotlight lunches will be industry-sponsored with industry representatives speaking, while the dinners will be focused on Cornea Society University and highlight topics like choosing a career path or career advice from faculty members.

"One of the highlights of the summit are the skills lab sessions where participants will be able to practice DMEK, DSAEK, and iris suturing techniques," Dr. Li said. "These skills labs are led by our faculty and provide the hands-on practice experience that many fellows

find particularly beneficial as they are beginning their fellowships."

Dr. Straiko added that Dr. Sales will be the wet lab director this year, and an artificial anterior chamber that Dr. Sales developed will be utilized for the labs.

With the slightly adjusted time-frame (the meeting generally takes place in September), the Cornea Fellows Educational Summit will take place after the Written Qualifying Exams this year. "This should take some of the pressure off the fellows, and they will be able to enjoy their packed, educational weekend," Dr. Li said.

It's a great jumpstart for fellows, Dr. Straiko said. "We try to get wide coverage on the whole breadth of cornea medical and surgical training and give them key tips that they can take back to their institutions," he added.

Dr. Straiko said there will be space for 52 fellows to attend this year's event. However, he noted that in an effort to get participation from a variety of programs, each AUPO-certified corneal fellowship program will get an invitation letter with the option to nominate one fellow from their program. He said they hope to expand the event for even more fellows to attend in the future. **CN**