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Cornea Society
Advancing the treatment of corneal disease

News

A Cornea Society publication

# 2020 Cornea Fellows Educational Summit

Planning is in progress for the 2020 Cornea Fellows Educational Summit for cornea, external disease, and refractive surgery fellows.

With the ongoing COVID-19 pandemic, the decision was made for content to be available completely virtually. This will include pre-recordings of didactic presentations and industry spotlight sessions, which will be available for attendees to watch in advance. These pre-recorded sessions will be followed by live discussion and Q&A. The 2-day intensive program is designed to complement and reinforce cornea fellowship training. With the change in format this year, a larger number of attendees will have the opportunity to participate as opposed to only 52 fellows.

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
- Technique pearls for routine and complex cataract surgery and corneal transplantation

This year, co-chairs of the Cornea Fellows Educational Summit include Michael Straiko, MD, Greg Ogawa, MD, and Jennifer Li, MD.

The program will be broken up into six sessions covering: selective keratoplasty; suturing IOL exchange and pediatric keratoplasty; ocular surface basics and beyond; cornea, cataract, and refractive; a Cornea Society University program on career paths; and an industry spotlight session.

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Cornea Fellows Educational Summit

Faculty will present on topics such as DSAEK, DMEK, and DALK; cornea and iris suturing; managing dry eye, blepharitis, and other ocular surface disease problems; and cornea considerations in cataract surgery and refractive surgery. **CN**

Faculty from the 2019 Cornea Fellows Educational Summit

oxervate™
(cenegermin-bkbj ophthalmic solution) 0.002% (20 mcg/mL)

# The first FDA-approved pharmacologic treatment that targets the root pathogenesis of neurotrophic keratitis[1-3]

**With OXERVATE, up to 72% of patients achieved complete corneal healing at 8 weeks*[1,4]**

- Cenegermin-bkbj, the active ingredient in OXERVATE, is structurally identical to the human nerve growth factor (NGF) protein made in ocular tissues.[5]
- 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.[1] 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[3,6,7]

## Explore the breakthrough therapy at 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.**

*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).[4,8]

**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.

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US-OXE-1900072 01/20

oxervate™
(cenegermin-bkbj ophthalmic solution) 0.002% (20 mcg/mL)

## 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).

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# President's message


Kathryn Colby, MD, PhD

Dear Colleagues,

It was the Greek philosopher Heraclitus who opined, around 500 BC, that "the only constant in life is change." This is an apt aphorism for 2020, which has turned out to be a year that none of us could have predicted. COVID-19 has certainly changed many things for all of us, both personally and professionally.

After careful exploration of multiple options, the Cornea Society has decided to postpone the World Cornea Congress until at least 2022, when we hope the world will be back to a more normal state, and travel and in-person meetings will once again be feasible. In the final analysis, we decided that this meeting, which has generally occurred just once every 5 years, would not benefit from being held virtually. I would like to thank my program co-chairs Elmer Tu, MD, and Bennie Jeng, MD, as well as the rest of the planning committee for their efforts. The planning that was done for the 2020 meeting will serve as a building block for the future meeting. Thanks also to Don Bell, Carrie Braden, and Jessica Donohoe from ASCRS who provided outstanding administrative support during the planning process. While we are all disappointed about this turn of events, we must roll with the punches and look to the future.

Everyone knows by now that the 2020 American Academy of Ophthalmology (AAO) Annual Meeting will be held virtually. Cornea Society events normally held at AAO will be virtual as well. Our major event, the Cornea Eye Banking Forum, in collaboration with the Eye Bank Association of America, is planned for November 7, with time for virtual networking from 8:30–10 a.m. EST, followed by the scientific program from 10 a.m.–5 p.m. EST. This year's Forum will feature an invited presentation on "Coronavirus and the Donor Cornea," as well as free paper presentations with live Q&A. The Paton Award lecture and the Troutman Award presentation will occur during the meeting. A virtual modification of the ever-popular Paton luncheon will feature case presentations, moderated by Marian Macsai, MD. Watch your email for registration details.

Planning is ongoing for a virtual meeting for cornea fellowship directors in place of the in-person breakfast that has preceded the Forum in recent years. The Cornea Society symposium at the AAO Annual Meeting will be shortened. We will postpone the 2020 Castroviejo Award presentation by Jayne Weiss, MD, and the dinner in her honor to 2021.

We are also exploring virtual options for our annual Cornea Fellows Educational Summit. We will communicate details to the fellowship directors as they are available. Thanks to program directors, Michael Straiko, MD, Jennifer Li, MD, and Greg Ogawa, MD, and executive committee representative Deepinder Dhaliwal MD, for their innovation in creating a virtual substitute for our fellows.

Finally, the Cornea Society is transitioning our management services to AMS. We are grateful for the support we have received from the ASCRS team, especially Don Bell and Pura Valdez, and look forward to future collaborations with ASCRS. Members should not notice much change in their service, but if there are any issues please reach out to me at kathryn.colby@nyulangone.org, or Tim Losch, our AMS contact, at tlosch@aao.org.

As the pandemic has evolved, I'm reminded of the lyrics from the popular culture song "Truckin'": "Lately it occurs to me what a long, strange trip it's been." Indeed. Stay safe in these unprecedented times, my friends.

Kathryn Colby, MD, PhD
President, Cornea Society

# Maria Woodward, MD, selected to participate in AAO Leadership Development Program

**Describe your interest in the Leadership Development Program, including why you should be selected by the Leadership Development Program Selection Committee to participate.**

**Dr. Woodward:** During my training in medical school and residency, I focused my passions of medicine and patient care on becoming an excellent physician, surgeon, and ophthalmologist. Ophthalmology was a natural fit as I loved seeing patients and improving the quality of their lives. This still serves as the foundation for all that I do professionally. In residency, I was awakened to the possibilities that research holds to extrapolate my knowledge, skills and solving clinical and system-level problems. In my research, I focus on improving access and quality of care for patients with anterior segment eye problems. In the past few years, thanks to mentors like Drs. Paul Lee and George Williams, my passion for system-wide problems has highlighted the importance of legislative advocacy and action. I currently serve as a Cornea Society representative to the Ophthalmology Advocacy Leadership (OALG) group. The OALG provides context to understand larger issues for ophthalmologists and how we protect our patients through policy. I also serve on the AAO's Telemedicine Task Force and Regulatory, Research, and External Relations Committee. The Leadership Development Program is a critical program to foster leadership within the Academy. We must protect our patients from the threats to their health, and we must capitalize on the opportunities to improve their health on individual and system levels. I want to participate in the Leadership Development Program to mature my ability to serve as an advocate for our patients.

**Describe how your participation in the Leadership Development Program might benefit your state, subspecialty or specialized interest society.**

**Dr. Woodward:** The Cornea Society benefits from extremely strong leadership and passion in improving the lives of patients with corneal diseases. However, they recognize a gap exists in the future corneal leadership focused on public policy and system level change. We have greatly benefited from the experience and wisdom of Drs. David Glasser and Alan Sugar, among others, who advocate for our patients with lawmakers and within ophthalmology groups. I hope to help the Cornea Society by gaining unique skills during the Leadership Development Program and thereby enhance our ability to advocate for our patients and our specialty.

Specifically, I would develop a forum for corneal specialists and their patients to share their stories as a powerful means to enhance health policy. Leveraging existing Cornea Society practitioner forums such as the Keranet listserv and Cornea Society University, I would help develop a web-based platform to facilitate direct reporting of eye health needs of patients and physicians to the Cornea Society and AAO leaders. Examples could include issues related to drug shortages, high drug costs, access to care issues, or insurance denials of care. Additionally, given my expertise in telemedicine and in light of the use of telehealth during this COVID-19 pandemic, I could work with Cornea Society to report on the use of telehealth for anterior segment diseases and share knowledge gained during the pandemic to help ophthalmologists worldwide. **CN**

# Corneal transplants in the COVID-19 era

On a recent board call, the Cornea Society Board of Directors discussed the resumption of corneal transplants in the COVID-19 era. In mid-June 2020, 75% of the directors reported corneal transplant volumes of at least 50% of their pre-COVID numbers. Safety—for patients, OR staff, and surgeons—was a major concern. Other concerns included tissue access and OR access for ophthalmology surgeries. Many board members noted patient insurance issues, as well as patient reluctance to come in for the required postoperative visits as factors that influenced their surgical volumes. The Cornea Society board data was presented at the EBAA annual meeting. Additionally, a group of international corneal specialists has published a worldwide update, available at: bjo.bmj.com/content/early/2020/07/29/bjophthalmol-2020-317013.long **CN**

# Members With Thesis

- Esen K. Akpek, MD
- Anthony J. Aldave, MD
- Eduardo Alfonso, MD
- Juan Alvarez de Toledo, MD
- Shiro Amano, MD
- James V. Aquavella, MD
- Dimitri T. Azar, MD
- Kenneth A. Beckman, MD
- Michael W. Belin, MD
- Gregg J. Berdy, MD
- Perry S. Binder, MS
- Vatinee Bunya, MD
- Terry E. Burris, MD
- Massimo Busin, MD
- Harrison Dwight Cavanagh, MD
- Clara C. Chan, MD
- Jessica B. Ciralsky, MD
- Glenn C. Cockerham, MD
- Elisabeth J. Cohen, MD
- Kathryn A. Colby, MD
- Minas T. Coroneo, MD
- Maria S. Cortina, MD
- John W. Cowden, MD
- Christopher R. Croasdale, MD
- William W. Culbertson, MD
- Robert D'Amico, MD
- Sophie Deng, MD
- Deepinder K. Dhaliwal, MD
- Claes H. Dohlman, MD
- Kendall E. Donaldson, MD
- Eric D. Donnenfeld, MD
- Allen O. Eghrari, MD
- Randy J. Epstein, MD
- Marjan Farid, MD
- Robert S. Feder, MD
- Luigi Fontana, MD
- Richard K. Forster, MD
- S. Lance Forstot, MD
- Beatrice Frueh, MD
- Sam F. Fulcher, MD
- Anat Galor, MD
- Ronald N. Gaster, MD
- Harry S. Geggel, MD
- Mark S. Gorovoy, MD
- Debra A. Graham, MD
- Mark A. Greiner, MD
- Lewis R. Groden, MD
- Robert H. Gross, MD
- José Güell, MD
- Sadeer B. Hannush, MD
- David R. Hardten, MD
- Martin Heur, MD
- Koji Hirano, MD
- Alfonso Iovieno, MD
- Deborah S. Jacobs, MD
- Bennie H. Jeng, MD
- Vishal Jhanji, FRCOphth
- Albert S. Jun, MD
- Stephen C. Kaufman, MD
- Kenneth R. Kenyon, MD
- Kyeong Hwan Kim, MD
- Terry Kim, MD
- Shigeru Kinoshinta, MD
- Akira Kobayashi, MD
- Douglas D. Koch, MD
- Jonathan H. Lass, MD
- Douglas R. Lazzaro, MD
- Hyunjoo Lee, MD
- W. Barry Lee, MD
- Jennifer Y. Li, MD
- Richard L. Lindstrom, MD
- Walter Lisch, MD
- David Lockington, FRCOphth
- Lawrence E. Lohman, MD
- Jodi Luchs, MD
- Scott M. MacRae, MD
- Marian Macsai, MD
- Ezra Maguen, MD
- Francis S. Mah, MD
- Parag A. Majmudar, MD
- Mark J. Mannis, MD
- Stephen D. McLeod, MD
- Jodhbir S. Mehta, MD
- David M. Meisler, MD
- Luis F. Mejia, MD
- Shahzad Mian, MD
- Mark S. Milner, MD
- Venkateswara V. Mootha, MD
- Naoyuki Morishige, MD
- Majid Moshirfar, MD
- Wuqaas M. Munir, MD
- Ramón Naranjo-Tackman, MD
- Julio Narvaez, MD
- Philip E. Newman, MD
- Verinder S. Nirankari, MD
- Gregory S. Ogawa, MD
- F. Rick Palmon, MD
- Sanjay V. Patel, MD
- Jay S. Pepose, MD
- Henry Perry, MD
- Paul M. Phillips, MD
- Christina R. Prescott, MD
- Francis W. Price, MD
- Yaron S. Rabinowitz, MD
- Gullapalli Rao, MD
- Christopher Rapuano, MD
- Charles Reilly, MD
- Allison E. Rizzuti, MD
- Jennifer Rose-Nussbaumer, MD
- J. James Rowsey, MD
- Christopher Sales, MD
- John R. Samples, MD
- Vincenzo Sarnicola, MD
- Rony R. Sayegh, MD
- Ivan R. Schwab, MD
- Berthold Seitz, MD
- Naazli Shaikh, MD
- Namrata Sharma, MD
- Christine Shieh, MD
- Jun Shimazaki, MD
- Shigeto Shimmura, MD
- Roni M. Shtein, MD
- Charalambos Siganos, MD
- Allan R. Slomovic, MD
- Divya Srikumaran, MD
- Scott X. Stevens, MD
- Doyle Stulting, MD
- Joel Sugar, MD
- Alan Sugar, MD
- Leejee H. Suh, MD
- Zeba A. Syed, MD
- Christopher N. Ta, MD
- Audrey R. Talley-Rostov, MD
- Jaime Tejedor, MD
- Mark A. Terry, MD
- William B. Trattler, MD
- Kazuo Tsubota, MD
- Elmer Y. Tu, MD
- Sonal Tuli, MD
- Woodford S. Van Meter, MD
- Ming X. Wang, MD
- Robert W. Weisenthal, MD
- Jayne S. Weiss, MD
- Maria Woodward, MD
- Sonia H. Yoo, MD
- Alvin L. Young, FRCSI
- Gerald W. Zaidman, MD
- Siamak Zarei-Ghanavati, MD
- Peter Zloty, MD

### The Cornea Society welcomes the following 2020 Members With Thesis:

- Maria De La Paz, MD
- Ula Jurkunas, MD
- Ellen Koo, MD
- Charles Lin, MD
- Alejandro Navas, MD
- Michelle Rhee, MD
- Kimberly Sippel, MD
- Danielle Trief, MD