



Cornea Society

Advancing the treatment of corneal disease

News

A Cornea Society publication

World Cornea Congress VIII preview



WORLD CORNEA CONGRESS VIII

World Cornea Congress VIII, to take place May 14–15, 2020, directly preceding the ASCRS Annual Meeting in Boston, Massachusetts, will showcase a wealth of knowledge on a wide range of cornea topics. Featuring a variety of speakers from around the world, the program will include symposia, special sessions, courses, paper sessions, and posters.

Several of the moderators from the meeting weighed in on what they're looking forward to and what to expect from some of the individual sessions.

During the World Cornea Congress, there will be individual sessions cosponsored by the Asia Cornea Society, EuCornea, and PanCornea. **Anthony Aldave, MD**, Los Angeles, California, is involved in the planning of the joint Cornea Society-PanCornea symposium.

As vice president of international relations for the Cornea Society, Dr. Aldave worked with **Juan Carlos Abad, MD**, president of PanCornea, to select a topic for the joint symposium that would be of significant interest to both practicing corneal specialists and vision science researchers from the Americas as well as around the globe.

"Keratoconus, being one of the most common corneal disorders worldwide, was an obvious choice for the focus of the symposium," he said. "We discussed areas of both consensus and

controversy in the field and decided to make these the topics for presentation."

There are differing opinions, even among experts in the field, regarding the classification, pathogenesis, diagnosis, and treatment of keratoconus, Dr. Aldave said. "Despite the publication of the Global Consensus on Keratoconus and Ectatic Diseases in 2015, there remain many unanswered questions and controversial issues in this ever-expanding topic," he said. "This symposium will gather input from experts around the world to stimulate the audience to get a glimpse of what has been solidified over the last 15 years, the still-controversial topics, and the state-of-the-art new diagnostic and therapeutic modalities."

Dr. Aldave said he is looking forward to reconnecting with colleagues from around the globe while at the World Cornea Congress and learning from their experiences through symposia, paper and poster presentations, and informal discussions.

The EuCornea joint symposium will focus on topics in lamellar keratoplasty, while the Asia Cornea Society joint symposium will feature presentations on dry eye and ocular surface disease.

Jessica Ciralsky, MD, New York, New York, is helping to plan a Cornea Society University (CSU)-specific session, which she said will be geared toward young practicing

ophthalmologists. It is important to have a session dedicated to young physician research for several reasons. "There is a lot we can all learn from millennials who think differently and approach problems with a different mindset," she said. "It will also help engage the younger generations by presenting a new group of speakers with a fresh perspective." The focus of the session will be on young cornea specialists who think outside the box and engage in cutting-edge research.

Vance Thompson, MD, Sioux Falls, South Dakota, also commented on the symposium he's involved with. "Terry Kim, MD, and I are excited to moderate the joint Cornea Society-ASCRS Refractive Surgery Symposium at World Cornea Congress," he said. "We had the honor of collaborating with **Bennie Jeng, MD**, and **Kathryn Colby, MD, PhD**, to choose topics that overlap between refractive and cornea." The session will be titled "Refractive Surgery Symposium: Corneal Conditions, Controversies, and Conundrums Encountered in Refractive Surgery" and will cover topics including epithelial thickness mapping, prevention and management of corneal haze after refractive surgery, neuropathic pain, and customized topography-guided ablations.

"These topics represent some of the most important pre- and postoperative issues and surgical techniques happening today in refractive corneal surgery," Dr. Thompson said. "Many of these issues we deal with every day are helped tremendously by a comprehensive approach to refractive surgery that respects corneal biomechanics, anatomy, and physiology, and there is no better place for a program like this than World Cornea Congress."

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The first FDA-approved pharmacologic treatment that targets the root pathogenesis of neurotrophic keratitis¹⁻³

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](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).^{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.



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,

Happy 2020, a year that we ophthalmologists have long been awaiting. I'm excited to be serving as president of the Cornea Society in this historic year.

Elmer Tu, MD, Bennie Jeng, MD, and I, along with Don Bell, Carrie Braden, and the Program Committee, have been hard at work planning World Cornea Congress (WCC) 2020: The Future in Focus. Mark your calendars for this meeting, which will take place at the Boston Convention and Exhibition Center on May 14–15. A guiding principle for WCC 2020 is collaboration, stemming from the understanding that we and the field are stronger when we include diverse perspectives. Our most ambitious meeting to date, WCC 2020 will truly be a world cornea congress, featuring cutting-edge sessions cosponsored by EUCornea, PanCornea, and the Asia Cornea Society, as well as instruction courses organized by colleagues from Italy, Germany, India, and Japan. We've collaborated with Cornea Society University (CSU), our program for younger members, on a symposium featuring talks by up-and-coming young stars. Join us for this special CSU symposium to see what the next generation has to say. We're also proud to feature sessions cosponsored by the ASCRS Glaucoma Clinical Committee and the ASCRS Refractive Surgery Clinical Committee.



Kathryn Colby, MD, PhD

In the initial call for abstracts, we received more than 800 submissions, which will allow for a robust free paper and electronic poster program. We will have one more call for submissions for a "late breakers" session coming soon. Consider submitting your most exciting research for this session. Finally, all delegates are invited to the opening reception, which will take place at the Westin Hotel adjacent to the Boston Convention and Exhibition Center immediately after the close of the meeting on Thursday. Come for food, drinks, and fellowship with the corneal specialists of the world.

As you can see from these few highlights, there is something for everyone at WCC 2020. Watch your email for the preliminary program. Registration opened February 3. Act quickly for the lowest first tier rates.

While much of our effort has been focused on WCC 2020, we are also working to position the Cornea Society for continued future success. To increase involvement from our younger members, we are now accepting applications for our new membership category, Fellow of the Cornea Society. Open to those who have completed an AUPO-FCC compliant corneal fellowship and who have been in practice for at least 4 years, this membership category provides voting rights as well as the ability to serve in society leadership positions. Pura Valdez, membership coordinator, will be reaching out to those of you who are eligible to elevate to this new category, and you can find the application here. Please consider becoming a Fellow of the Cornea Society. We need the voices of our younger members to make our society strong and vibrant.

I'd like to welcome our new board members and thank them in advance for their efforts on behalf of our society over the coming years. I'm very grateful to have such experienced and dedicated corneal specialists as partners. Enjoy the rest of the winter. See you in Boston!

Kathryn Colby, MD, PhD
Cornea Society president



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References: 1. Holly FJ. Lacroiphilic ophthalmic demulcents. *US Ophthalmic Rev.* 2007;3:38-41. 2. FRESHKOTE PF Drug Facts. Eyevance Pharmaceuticals LLC; 2018. 3. Holly FJ. *Colloidal Osmosis — Oncotic Pressure*. Grapevine, TX: Dry Eye Institute; 2006. 4. Fuller DG, Connor CG. Safety and efficacy of FreshKote® used as a rewetting agent in Lotrafilcon-A® contact lens wearers. Poster presented at: American Academy of Optometry Annual Meeting; November 17-20, 2010; San Francisco, CA. 5. Nemer. Novelia®. <https://nemer.net/products/ophthalmic-novelie-eyedropper/>. Accessed March 14, 2019.



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Maria Soledad Cortina, MD, Chicago, Illinois, will help run a keratoplasty session, which she said will focus on high-risk keratoplasty, including keratoprosthesis, and will debate alternatives to the artificial cornea for patients with severe ocular surface disease.

Other topics to be covered include infections, contact lenses, ocular surface lesions, eye banking, Fuchs' dystrophy, and more.

Jodhbir Mehta, MD, Singapore, and **Sophie Deng, MD**, Los Angeles, California, are organizing the free paper sessions for the meeting. "The free paper sessions will cover every important topic in cornea and external eye disease," Dr. Deng said.

The sessions will highlight exciting and new work from all over the world, Dr. Mehta added. "From 800 submissions, 190 have been selected, follow-

ing review by a five-person committee, for presentation as free papers," he said. Many of the others will be invited to be presented among the more than 250 posters.

Dr. Deng also mentioned that two papers sessions will be reserved for late-breaking topics. "Surgery is the hot topic this year," she said. "We have a large number of papers on endothelial keratoplasty, keratoprosthesis, and refractive surgery." To emphasize the quality of clinical studies, there will also be a session on clinical trials.

Dr. Mehta added that there will be presentations on some novel and interesting work done in stromal and endothelial regeneration, keratoconus, and immunological diseases, as well as in corneal biology and imaging.

"The free paper sessions will complement the fixed program at

World Cornea Congress by offering cutting-edge research from around the world," Dr. Mehta said. The organizing committee was careful to ensure worldwide representation in the program so that it will be more inclusive and interesting to the audience, he added. **CN**

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The Cornea Society would like to thank the following companies for their support of World Cornea Congress VIII (as of 1/30/20; list is not final):

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“The Cornea Society is incredibly grateful for the many generous sponsors who have enabled us to make World Cornea Congress VIII our best meeting to date.”

—Kathryn Colby, MD, PhD,
Cornea Society President

“Novartis’ involvement in this year’s World Cornea Congress underscores our commitment to delivering innovative therapies to treat diseases and disorders of all areas of the eye. Our participation provides a key opportunity to share how we are addressing ocular diseases today—and over the long term—with the range of healthcare professionals who are on the front lines with the many patients we are mutually committed to helping.”

—Patrick Mooney, Vice President and
Head, US Ophthalmics, Novartis

“Dompé decided to attend World Cornea Congress because of our commitment to cornea, as we recently launched Oxervate for neurotrophic keratitis in the United States. World Cornea Congress is the perfect arena to touch so many members of the cornea community across the U.S. and world. We are looking forward to connecting with customers and educating the cornea community on neurotrophic keratitis, as well as discussing earlier diagnosis and treatment of this progressive disease.”

—Jill Pake, Associate Director,
Field Marketing, Dompé US

Highlights from Keracon 2019

In December 2019, several representatives from the Cornea Society attended and presented at Keracon 2019, the 7th annual meeting of the Cornea Society of India, in Kumarakom, Kerala. Speakers included **Vishal Jhanji, MD**, Pittsburgh, Pennsylvania, **Christina Prescott, MD**, Bel Air, Maryland, **Christopher Rapuano, MD**, Philadelphia, Pennsylvania, **Elmer Tu, MD**, Chicago, Illinois, **Maria Soledad Cortina, MD**, Chicago, Illinois, **Ronald Gaster, MD**, Orange County, California, and **Rony Sayegh, MD**, Cleveland, Ohio. Several weighed in on their experience at the meeting and the presentations they shared.

Dr. Rapuano called it a “very high-quality meeting.” There were around 500 attendees, and most speakers were from India but certainly there were invited speakers and attendees from all over the world.

The Cornea Society was invited to give a symposium at the meeting in which Dr. Rapuano spoke, but he was also asked to speak at others as well. In all, Dr. Rapuano gave three talks and participated in several panels, speaking about dry eye, repairing a dislocated IOL during DSAEK, and pediatric cornea transplantation.

The meeting featured talks from stalwart speakers from all over the world and covered almost all things cornea, Dr. Jhanji said. “The sessions on corneal ectasia, surgical innovations,

and ocular inflammatory diseases were exceptionally good,” he said. The presentations in the Cornea Society session covered dry eye disease topics, and the speakers in the Asia Cornea Society session shared tips for surgical success for management of infectious keratitis with large grafts, pediatric keratoplasty, and endothelial keratoplasty.

It was Dr. Prescott’s first year attending the Keracon meeting, but she noted that it “will not be the last.” The range of speakers and topics was wonderful, with speakers from throughout India as well as international guests, she said. “My favorite part of the meeting was meeting new people, as well as seeing my friends from LV Prasad and Aravind.”

Dr. Muralidhar, from LV Prasad, gave a great talk on performing DSO/DWEK in infants with Peters anomaly, Dr. Prescott said. “With all the excitement at the recent Cornea Society meeting regarding DSO/DWEK for Fuchs’, it was interesting to see this technique used in a very different patient population,” she said. “This was of particular interest to me given that pediatric corneal surgery is a passion of mine.”

She added that there was a great talk on the etiology of allergic conjunctivitis as well as some future potential therapies by Dr. Sajjad Ahmad from Moorfields Eye Hospital.

This was Dr. Tu’s second Keracon meeting. “I was very much looking forward to returning,” he said. “The first meeting was an eye opener as to the incredible array of knowledge, innovation, and skill that exemplifies cornea expertise in India.”

“The organization was excellent, the food and culture terrific, and the hospitality wonderful,” Dr. Tu said. “Besides speaking in our own symposium, which was well attended, the organizers integrated us into the rest of the meeting, which rounded out the experience.”

Dr. Cortina echoed the sentiment that the meeting was excellent. “It was my first time attending, and I was particularly interested in the ocular surface session, as some of the diseases are more frequent and advanced in India. Their experience is incredible, and there is so much to share and learn from each other,” she said, adding that she’s looking forward to attending in the future. **CN**

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2020 Cornea Fellows Educational Summit

The 2020 Cornea Fellows Educational Summit will be held October 15–18 in Atlanta, Georgia, at the Westin Peachtree Plaza Hotel. The three chairs of the meeting are **Michael**

Straiko, MD, Gregory Ogawa, MD, and Jennifer Li, MD.

This year the Cornea Society will be working with the 53 AUPO Fellowship Compliance Programs on registration. In the past it has been first come, first

served, and that sometimes results in deserving fellows missing out because the slots fill too quickly. The goal in 2020 is to work more closely with the program directors on a fairer approach to registration. **CN**

Cornea Society partners with PAN Foundation

The Patient Access Network (PAN) Foundation is an independent, national 501 (c)(3) organization dedicated to helping federally and commercially insured people living with life-threatening, chronic and rare diseases with the out-of-pocket costs for their prescribed medications. Partnering with generous donors, healthcare providers, and pharmacies, PAN provides the underinsured population access to the healthcare treatments they need to best manage their conditions and focus on improving their quality of life. Since its founding in 2004, PAN has provided nearly 1 million underinsured patients with more than \$3 billion in financial assistance through close to 70 disease-specific programs.

Neurotrophic keratitis

The PAN Foundation offers financial

assistance to individuals with neurotrophic keratitis. To be eligible for assistance, patients must meet the following eligibility criteria:

1. The patient must be getting treatment for neurotrophic keratitis.
2. The patient must have Medicare health insurance that covers his or her qualifying medication or product.
3. The patient's medication or product must be listed on PAN's list of covered medications.
4. The patient's income must fall at or below 500% of the Federal Poverty Level.
5. The patient must reside and receive treatment in the United States or U.S. territories (U.S. citizenship is not a requirement).

If eligible, patients can be approved for a grant of \$4,000 per year. Patients may apply for a second grant during

their eligibility period subject to availability of funding.

For more information about the program, visit panfoundation.org/index.php/en/patients/assistance-programs/neurotrophic-keratitis.

To apply for a neurotrophic keratitis grant from the PAN Foundation, patients can visit the online patient portal or call 866-316-7263.

Providers may also be interested in registering on the PAN portal and applying for grants on behalf of their patients. For more information, visit providerportal.panfoundation.org. **CN**



BOSTON | MAY 14-15, 2020

Immediately preceding the ASCRS ASOA Annual Meeting

World Cornea Congress VIII, Featuring:

Symposia

- Infections
- EUCornea Joint Symposium
- Surgical Innovations
- PanCornea Joint Symposium
- Cornea Society University
- Asia Cornea Joint Symposium
- Future Directions

Spotlight Sessions

- Fuchs' Dystrophy
- Ocular Surface Disease

Special Topics

- Contact Lens Update
- Keratoplasty

- The Interface Between Glaucoma and Cornea
- Refractive Surgery
- Eye Banking
- Complex Keratoplasty/ Anterior Segment Reconstruction

Courses

- Pediatric Cornea
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