

# Ocular Therapeutix<sup>™</sup> Strengthens Clinical Team with Appointment of Key Retinal Leaders

April 16, 2024

Nadia K. Waheed, MD, MPH, Appointed Chief Medical Officer; Peter K. Kaiser, MD, to Become Chief Development Officer; Andrea Gibson, PhD, Named Vice President, Medical Collaborations; and Namrata Saroj, OD, to Become Development Strategy Consultant

Dr. Waheed's strong industry track record as a CMO and broad expertise in wet AMD and diabetic retinopathy support advancing the Phase 3 AXPAXLI<sup>TM</sup> program

Dr. Kaiser's vast leadership experience in numerous pivotal trials of approved wet AMD products enhances Ocular's transition to a leading retina care company

Dr. Gibson and Dr. Saroj bring deep experience in clinical trial execution through their joint involvement in the development and commercialization of two landmark retina drugs

BEDFORD, Mass., April 16, 2024 (GLOBE NEWSWIRE) -- Ocular Therapeutix, Inc. (NASDAQ:OCUL) ("Ocular"), a biopharmaceutical company committed to enhancing people's vision and quality of life through the development and commercialization of innovative therapies for wet age-related macular degeneration (wet AMD), diabetic retinopathy, and other diseases and conditions of the eye, today announced that it has **strengthened its clinical development organization** with the appointment of **Nadia K. Waheed, MD, MPH**, as Chief Medical Officer (CMO); **Peter K. Kaiser, MD** as Chief Development Officer (CDO); **Andrea Gibson, Ph.D.**, as Vice President, Medical Collaborations; and **Namrata Saroj, OD**, as Development Strategy Consultant. Dr. Waheed's appointment will be effective as of May 20, 2024. **Jeffrey S. Heier, MD**, will continue in his role as Chief Scientific Officer (CSO).

"I am thrilled to announce the enrichment of Ocular's clinical development organization with the appointment of four recognized retinal disease professionals. Having a strong team of retinal leaders with experience across all aspects of clinical development is essential to Ocular's transformation to becoming a leading retina company," said

Pravin U. Dugel, MD, Executive Chairman, President and Chief Executive Officer of Ocular Therapeutix. "I believe the appointment of Dr. Waheed as CMO, coupled with Dr. Kaiser's deep clinical trial experience, further solidifies the foundation for our successful transition."

"I am confident that Dr. Waheed, as an accomplished CMO, with a robust clinical development track record, experience as a respected retinal surgeon, with post-doctoral training at several world-class institutions and a lengthy publication history, can play an important role in the advancement of our clinical pipeline," continued Dr. Dugel. "In addition, I look forward to continue working closely with **Dr. Kaiser**, a globally recognized retinal specialist, and believe that his deep understanding of the AXPAXLI™ program, combined with his broad experience as a study chairman and lead investigator in numerous pivotal trials for approved products for wet AMD and other indications, significantly enhances the leadership of our program."

Dr. Dugel commented further, "The contributions of Dr. Waheed, Dr. Kaiser and Dr. Heier, combined with the additions of Dr. Gibson, as Vice President, Medical Collaborations, and Dr. Saroj as Development Strategy Consultant, will bolster the effective execution of the AXPAXLI clinical program for retinal disease. In addition, I believe our strengthened clinical team also puts Ocular in an excellent position to accelerate expansion into retinal indications beyond wet AMD, including diabetic retinopathy."

**Dr. Waheed said**, "I am honored to be part of the Ocular Therapeutix team. My experience as a retinal surgeon, combined with my background in scientific and clinical research and direct patient care inspired my desire to bring innovative new therapies to people with retinal diseases. Getting involved in the industry and becoming a CMO has allowed me to take a leadership role in this work. Joining Ocular allows me to build on my prior experiences as a CMO and work on a drug candidate that has the potential to dramatically change the treatment paradigm for retinal diseases and significantly improve patient compliance. I believe AXPAXLI has the potential to provide a durable reduction in disease burden to patients with wet AMD and diabetic retinopathy and I look forward to working with Pravin and my colleagues to advance the clinical development of the product candidate."

**Dr. Kaiser commented**, "Over the course of my career as a retinal surgeon, I have had the privilege of working on several approved products for wet AMD and other ophthalmic indications. I joined Ocular because I believed that AXPAXLI could be a 'game-changer' in the care of retinal disease. I am enthusiastic to apply the breadth of my experience to Ocular in my role as CDO. As we work together to advance the Phase 3 AXPAXLI program, I look forward to welcoming Dr. Waheed and continuing my work with the outstanding team at Ocular."

**Dr. Gibson commented**, "There is an unmet need for clinical trial options available to newly diagnosed wet AMD patients who may be earlier in their disease course. I am excited to work with Ocular to advance the development of AXPAXLI and have the unique opportunity to bring a long-awaited clinical trial option to newly diagnosed patients." **Dr. Saroj noted further**, "Bringing excellence in clinical development to the advancement of novel, FDA-approved products for ophthalmic diseases has been a highlight of my career. I look forward to working with this accomplished team towards the development of AXPAXLI."

# About Nadia K. Waheed, MD, MPH, Chief Medical Officer

Dr. Waheed brings almost 20 years of experience in ophthalmology and leadership to Ocular through her work as a retinal surgeon, scientist, clinical researcher and Board Member in academic and research settings. She has a proven track record in clinical development and as a CMO, with experience in all phases of development including clinical trial design and analysis and regulatory interactions.

Most recently, Dr Waheed served as Chief Medical and Development Officer at Beacon Therapeutics, focused on serious diseases of the eye that cause vision loss and blindness. Prior to her time at Beacon, Dr. Waheed served as Chief Medical Officer, Head of Clinical Development at Gyroscope Therapeutics and played an instrumental role in the company's acquisition by Novartis AG. Previously, Dr. Waheed was Director of the Boston Image

Reading Center and Consultant at the New England Eye Center, Tufts University School of Medicine in Boston. Dr. Waheed is currently Professor of Ophthalmology at Tufts University Medical School and is maintaining her appointment at the New England Eye Center, one day per week.

Dr. Waheed serves as a member of the Board of Directors for the Boston Image Reading Center, including work on two board committees, as well as the boards of iOlyx Pharmaceuticals and Bionic Sight LLC. Before joining industry, Dr. Waheed held academic appointments in Ophthalmology at leading institutions including the Cole Eye Institute, Cleveland Clinic Foundation; Shifa College of Medicine and Tufts University Medical School and New England Eye Center at Tufts Medical Center.

Dr. Waheed has authored over 200 peer-reviewed publications, co-authored and edited three books in Ophthalmology and contributed to several more. She has participated as a principal investigator or co-investigator in many clinical trials and laboratory investigations. Her research interests include diseases of the retina, including wet AMD and diabetic retinopathy, ocular imaging, as well as clinical trial design and analysis.

Dr. Waheed received her medical degree from the Aga Khan University Medical School, Pakistan, *summa cum Laude*, a Master of Public Health degree from the Harvard School of Public Health and is certified by the American Board of Ophthalmology. She trained at the Harvard Medical School/Massachusetts Eye and Ear Infirmary Program in Ophthalmology and completed a fellowship in retina at the Harvard Medical School/Massachusetts Eye and Ear Infirmary in Boston. Over the course of her academic career, Dr. Waheed also established the Retina Unit at the Shifa Hospital. She has received numerous awards including the Young Investigator Award from the Macula Society in 2020, the Achievement Award from the American Academy of Ophthalmology in 2016, and the Teaching Fellow of the Year Award from Massachusetts Eye and Ear Infirmary in 2006.

## About Peter K. Kaiser, MD, Chief Development Officer

Peter K. Kaiser, MD, was appointed as a staff member of the vitreoretinal faculty of the Cole Eye Institute at Cleveland Clinic in 1997, where he now holds the Chaney Family Endowed Chair in Ophthalmology Research and continues to serve as Professor of Ophthalmology at the Case Western Reserve University School of Medicine.

As a National Eye Institute and National Institute of Health RO1-funded principal investigator, Dr. Kaiser leads a team involved in the evaluation of vascular biology in age-related macular degeneration and diabetic retinopathy. In addition, Dr Kaiser is actively involved in clinical research having served as study chairman for numerous major, multi-center, international clinical trials and principal investigator in over 60 trials evaluating new treatments for AMD, diabetic retinopathy, and other retinal disorders. Complementing his research endeavors, Dr. Kaiser serves as the Chair of numerous scientific advisory boards and study steering committees and addresses his research interests as an invited speaker at national and international conferences. Dr. Kaiser is also the Founding Director of the Cole Eye Reading Center, which is involved as a reading center in numerous retinal clinical studies.

Dr. Kaiser is a major contributor to medical literature, having authored several ophthalmology texts and more than 400 peer-reviewed original reports. He is Editor-in-Chief of *Retinal Physician* and Associate Editor of *International Ophthalmology Clinics* and serves on the editorial boards of *American Journal of Ophthalmology, Retina, Retina Today,* and *Ocular Surgery News*. He has been elected and previously served as the Retina Subspecialty Day Board Chairman for the American Academy of Ophthalmology Annual Meeting, as a member of the Board of Directors of the American Society of Retina Specialists (ASRS), and is a member of the Retina Society, Macula Society, EURETINA, and American Ophthalmological Society.

Dr. Kaiser has been recognized by the American Society of Retina Specialists with Honor and Senior Honor Awards, by the American Academy of Ophthalmology with Achievement, Senior Achievement, and Lifetime Achievement Awards. He has been listed as one of the "Best Doctors in America" every year since 2002 and named one of the "150 Top Innovators in Retina" by *Ocular Surgery News*, selected as a charter inductee of the Retina Hall of Fame in 2017, and appeared on the biannual *Ophthalmologist's* "Power List" in 2016, 2018, and 2020 as one of the top 100 most influential people in the world of ophthalmology. He is the team ophthalmologist for the Cleveland Cavaliers of the National Basketball Association.

Dr. Kaiser graduated *magna cum laude with Highest Honors* from Harvard College and received his medical degree *magna cum laude* from Harvard Medical School. He completed an internship in internal medicine at Massachusetts General Hospital, an ophthalmology residency at the Massachusetts Eye and Ear Infirmary and a surgical retinal fellowship at Bascom Palmer Eye Institute where he received the Heed Foundation Fellowship Award.

# About Andrea A. Gibson, PhD, Vice President, Medical Collaborations

Dr. Gibson brings more than 25 years of experience as an ophthalmology clinical development leader and Medical Affairs professional with versatile experience within large top biopharma organizations and start-up/smaller organizations. Dr. Gibson is a recognized expert in clinical trial design and execution, with significant experience in launch/pipeline product study design experience and strategic enrollment activities. Dr. Gibson has also led, initiated and directed Medical Affairs and Market Access efforts spanning, strategic data generation and communication activities. Dr. Gibson joins Ocular from StrategEYES, LLC. Her career includes roles of increasing responsibility at Regeneron Pharmaceuticals, Inc., Genentech, Inc., Merck & Co., as well as Oyster Point Pharma, Inc., Ocular Therapeutix, Inc. and Eyetech Pharmaceuticals, Inc.

Dr. Gibson has a lengthy publication history from her work in numerous early stage and pivotal studies for development stage and approved products. She earned her PhD, Public Health from Walden University.

# About Namrata Saroj, OD, Development Strategy Consultant

Dr. Saroj brings over 20 years of experience focusing on global development and commercialization of drugs and technologies advancing ophthalmic care. Her extensive understanding of the ophthalmology clinical and commercial landscapes is founded on her diverse experiences working across multiple programs. Currently, she collaborates with companies across various stages from early start-ups to late-stage development and commercialization. In this capacity, she has effectively helped these companies with strategic partnerships, clinical development, trial enrollment, launch preparation and commercialization support.

Dr. Saroj has been a significant contributor towards the commercialization of LUCENTIS<sup>®</sup> and EYLEA<sup>®</sup>, two of the most successful biologic products in this sector. She is established in the retina community for her work in clinical development collaborating with investigators and industry experts on clinical trial designs and execution. She has co-authored several peer-reviewed publications in management of retinal diseases.

Dr. Saroj is also the co-founder and Chief Scientific Lead of Clinical Trials Resource Group, a CRO focused on executing ophthalmology clinical trials. Previously, she led the Ophthalmology Medical Affairs team as an Executive Director at Regeneron Pharmaceuticals, Inc. Dr. Saroj has previously held positions at Genentech, Inc. and Manhattan Eye, Ear & Throat Hospital. Dr. Saroj is the President of Association for Macular Diseases, a non-profit organization offering support to individuals, their families, friends, and the professional community.

Dr. Saroj earned her Doctor of Optometry from the University of California, Berkeley. She received a Bachelor of Science in Optometry from the University of California, Berkeley and Bachelor of Arts in Biochemistry, *magna cum laude* with distinction from Whittier College.

# About Ocular Therapeutix, Inc.

Ocular Therapeutix, Inc. is a biopharmaceutical company committed to enhancing people's vision and quality of life through the development and commercialization of innovative therapies for wet age-related macular degeneration (wet AMD), diabetic retinopathy, and other diseases and conditions of the eye. AXPAXLI<sup>™</sup> (axitinib intravitreal implant, also known as OTX-TKI), Ocular's product candidate for retinal disease, is based on its ELUTYX<sup>™</sup> proprietary bioresorbable hydrogel-based formulation technology. AXPAXLI is currently in the first of two planned pivotal Phase 3 trials for wet AMD, the SOL-1 trial, and a Phase 1 clinical trial for the treatment of non-proliferative diabetic retinopathy. The clinical portfolio also includes PAXTRAVA<sup>™</sup> (travoprost intracameral implant, also known as OTX-TIC), currently in a Phase 2 clinical trial for the treatment of primary open-angle glaucoma or ocular hypertension.

Ocular's expertise in the formulation, development and commercialization of innovative therapies of the eye and the ELUTYX platform supported the development and launch of its first commercial drug product, DEXTENZA<sup>®</sup>, an FDA-approved corticosteroid for the treatment of ocular inflammation and pain following ophthalmic surgery and ocular itching associated with allergic conjunctivitis. ELUTYX is also the foundation for two other clinical-stage assets, OTX-CSI (cyclosporine intracanalicular insert) for the chronic treatment of dry eye disease and OTX-DED (dexamethasone intracanalicular insert) for the short-term treatment of the signs and symptoms of dry eye disease, as well as several preclinical programs.

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LUCENTIS® is a registered trade mark of Genentech, Inc., a member of the Roche Group

EYLEA® is a registered trade mark of Regeneron Pharmaceuticals, Inc.

### **Forward-Looking Statements**

Any statements in this press release about future expectations, plans, and prospects for the Company, including the development and regulatory status of the Company's product candidates, including the timing, design, and enrollment of the Company's pivotal trials of AXPAXLI (also called OTX-TKI) for the treatment of wet AMD; the Company's plans to advance the development of AXPAXLI, PAXTRAVA and its other product candidates; the potential utility of any of the Company's product candidates; the Company's new clinical development personnel; the sufficiency of the Company's cash resources; and other statements containing the words "anticipate", "believe", "estimate", "expect", "intend", "goal", "may", "might", "plan", "predict", "project", "target", "potential", "will", "would", "could", "should", "continue", and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forwardlooking statements as a result of various important factors. Such forward-looking statements involve substantial risks and uncertainties that could cause the Company's preclinical and clinical development programs, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the timing and costs involved in commercializing DEXTENZA or any product or product candidate that receives regulatory approval; the ability to retain regulatory approval of DEXTENZA or any product or product candidate that receives regulatory approval; the initiation, design, timing, conduct and outcomes of clinical trials, including the SOL-1 trial, the planned SOL-2 trial and the Company's other ongoing clinical trials; the risk that the FDA will not agree with the Company's interpretation of the written agreement under Special Protocol Assessment for the SOL-1 trial; the risk that even though the FDA has agreed with the overall design of the SOL-1 trial, the FDA may not agree that the data generated by the SOL-1 trial supports potential marketing approval; uncertainty as to whether the data from earlier clinical trials will be predictive of the data of later clinical trials, particularly later clinical trials that have a different design or utilize a different formulation than the earlier trials; availability of data from clinical trials and expectations for regulatory submissions and approvals; the Company's scientific approach and general development progress; uncertainties inherent in estimating the Company's cash runway, future expenses and other financial results, including its ability to fund future operations, including clinical trials; the Company's existing indebtedness and the ability of the Company's creditors to accelerate the maturity of such indebtedness upon the occurrence of certain events of default; the Company's ability to enter into strategic alliances or generate additional funding on a timely basis, on favorable terms, or at all; and other factors discussed in the "Risk Factors" section contained in the Company's quarterly and annual reports on file with the Securities and Exchange Commission. In addition, the forward-looking statements included in this press release represent the Company's views as of the date of this press release. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so, whether as a result of new information, future events or otherwise, except as required by law. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date of this press release.

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