Oculis Provides Updates at R&D Day on Late-Stage Clinical Trials and Announces Key Leadership Appointments

Feb 28, 2024

- Completed enrollment in Phase 2b RELIEF trial of Licaminlimab (OCS-02), anti-TNF (tumor necrosis factor) alpha eye drops in Dry Eye Disease (DED); topline results expected in Q2 2024
- Second Phase 3 trial (DIAMOND-2) of OCS-01 eye drops in Diabetic Macular Edema (DME) initiated as planned, in addition to the ongoing DIAMOND-1 Phase 3 trial initiated in late 2023
- World-renowned retina specialists, Professor Ramin Tadayoni, M.D., Ph.D. appointed as Chief Scientific Officer and Arshad M. Khanani, M.D., M.A., FASRS appointed as Chair of Oculis' Retina Scientific Advisory Board (SAB)
- Seasoned HR executive, Virginia R. Dean, appointed as Chief Human Resources Officer in Boston

ZUG, Switzerland, and BOSTON, Feb. 28, 2024 (GLOBE NEWSWIRE) -- Oculis Holding AG (Nasdaq: OCS) ("Oculis" or the "Company"), a global biopharmaceutical company purposefully driven to save sight and improve eye care, today provides updates at its in-person and virtual R&D Day on continued progress in advancing its late-stage clinical trials and strengthening the organization with additional senior appointments to its management and advisory teams.

In-person and virtual R&D Day today from 9:00 AM to 11:00 AM EST at the InterContinental New York Barclay. For registration, click here.

"2024 promises to be another exciting year for Oculis as we advance our late-stage clinical development programs. We have met two important clinical milestones with the rapid completion of enrollment in the Phase 2b RELIEF trial of OCS-02 in Dry Eye Disease (DED) and the initiation of the second Phase 3 trial of OCS-01 in Diabetic Macular Edema (DME). Additionally, I am very pleased to welcome Ramin and Virginia to the executive team and to continue to work with Arshad, new Chair of the Oculis' Retina SAB, as we continue to advance our clinical programs and start to prepare for our first potential launch in the U.S. I am certain that the extensive experience each of them brings will be invaluable to Oculis," **said Riad Sherif, M.D., Chief Executive Officer of Oculis.** "We look forward to driving this positive momentum in clinical execution of both DIAMOND Phase 3 trials, and in the delivery of clinical milestones this year, including topline results for the Phase 2b RELIEF trial of OCS-02 in DED in Q2 2024."

Completion of Enrollment in Phase 2b RELIEF trial with Licaminlimab (OCS-02) in DED

The Phase 2b RELIEF study evaluating topical anti-TNFα Licaminlimab (OCS-02) in DED was initiated in late 2023 and enrollment of 120 patients was rapidly completed. DED is a common condition estimated to impact nearly 40 million people in 2023 in the U.S. alone.

Elizabeth Yeu, M.D., Eastern Virginia Medical School, Virginia Eye Consultants, and President of ASCRS commented: "With its dual anti-inflammatory and anti-necrotic mechanisms of action, Licaminlimab eye drops have shown promising results in previous trials including: a significant reduction of ocular discomfort in DED, a rapid onset of action, and a good tolerability profile. Based on how the broader class of systemic TNFα inhibitors have dramatically improved the management of multiple inflammatory diseases in other therapeutic areas, I am eagerly awaiting the completion of the RELIEF trial to learn more about the potential of Licaminlimab eye drops to address the unmet needs of the millions of patients living with DED."

Initiation of OCS-01 Phase 3 DIAMOND-2 Trial in DME

The first patient first visit was completed in the second 52-week Phase 3 DIAMOND-2 trial evaluating OCS-01 eye drops for the treatment of DME, a leading cause of vision impairment in working-age adults. In Stage 1 of the DIAMOND program, OCS-01 demonstrated robust statistically significant improvement in vision and reduction in retinal edema vs. vehicle, and was well-tolerated with no unexpected safety findings. The visual acuity improvement observed with OCS-01 at 12-week was similar to approved injectables at the same time point. More information about the Stage 1 results can be found here.

Oculis Strengthens its Executive and Scientific Advisory Teams

Oculis also announced today key executive appointments to bolster its leadership and scientific advisory teams. World-renowned retina specialists, Professor Ramin Tadayoni, M.D., Ph.D. was appointed to the role of Chief Scientific Officer (CSO), and Arshad M. Khanani, M.D., M.A., FASRS, was appointed as Chair of Oculis' Retina Scientific Advisory Board. In addition, Virginia R. Dean, a seasoned human resources executive with significant experience in growing life science companies, was appointed to the role of Chief Human Resources Officer. Dr. Tadayoni, Dr. Khanani and Ms. Dean will play key strategic roles as the Company continues to advance its diversified late-stage pipeline and expands its footprint in the U.S. while it prepares for the potential first commercial launch. Joanne Chang, M.D., Ph.D., has decided to leave the organization for personal reasons and will continue to collaborate with Oculis on special projects.

Ramin Tadayoni, M.D., Ph.D., is a highly distinguished and accomplished retina specialist. He is the current President of EURETINA, the European Society of Retina Specialists and the Retina Department Chairman of Rothschild Foundation Hospital, including the French Myopia Institute. Dr. Tadayoni has been a Principal Investigator in numerous trials and served as an advisor for companies in the ophthalmology space for over two decades on topics spanning across medical, regulatory and market access, including his role as Co-Chair of the Oculis Scientific Advisory Board. Prior to joining Oculis as Chief Scientific Officer, Dr. Tadayoni was a Professor of Ophthalmology at Université Paris Cité, and the Department Chairman at Lariboisière and Saint Louis hospitals in Paris, France. As a passionate physician and researcher, he has authored more than 140 medical and scientific articles and has made numerous contributions to ophthalmology textbooks and is part of several international diseases' classifications groups. He has also received numerous awards of distinction including the American Academy of Ophthalmology Achievement Award and the prestigious Jules Gonin Award from the Retina Research Foundation. Dr. Tadayoni received his medical degree and completed his internship at Paris V University. His retina fellowship was completed at Lariboisière University Hospital while simultaneously pursuing his Ph.D. in Science at Paris VII University and the Paris Vision Institute. He received his undergraduate training in medicine at the University of Marseille.

"After being part of Oculis' journey for the past few years, as Co-Chair of the Scientific Advisory Board, I am thrilled to join the Oculis executive team. As a member of the DIAMOND program Steering Committee and a practicing retina specialist, it has been very exciting to see the positive results in DME with OCS-01 and progress made to date with the initiation of two 52-week Phase 3 trials in DME," **said Ramin Tadayoni, M.D., Ph.D., Chief**

Scientific Officer of Oculis. "I look forward to contributing to the efforts of this outstanding team to further drive Oculis' innovative and diversified pipeline, which has the potential to change the treatment paradigm in ophthalmology across multiple indications."

Arshad M. Khanani, M.D., M.A., FASRS is a world-renowned retina specialist and clinical scientist. He founded the clinical research section at Sierra Eye Associates, and currently serves as its Managing Partner, Director of Clinical Research, and Director of Fellowship. He has been a principal investigator for more than 120 clinical trials and has authored over 100 scientific publications. Additionally, he is a Clinical Associate Professor at the University of Nevada, Reno School of Medicine. Dr. Khanani is an elected member of the Retina Society, Macula Society and has received numerous awards of distinction. He has received the Senior Honor Award from the American Society of Retina Specialists (ASRS) and was also awarded the prestigious ASRS Presidents' Young Investigator Award in 2021.

Virginia R. Dean is a seasoned human resources (HR) leader with over 25 years of experience as a senior HR executive in both start-ups and well-established biopharmaceutical companies. She brings a breadth of experience in scaling up life science companies at various stages of growth, from pre-clinical to fully commercialized. Prior to joining Oculis, she was the Chief People Officer and Senior Vice President at Axcella Therapeutics where she led a rapid transformation of the organization. Over the course of her career, she has scaled five organizations, private and public, and participated in four acquisitions. Ms. Dean received her M.B.A. from Simmons University and holds a B.A. in anthropology from the University of Vermont. She will be based in Oculis' office in Boston, Massachusetts.

About Phase 2b RELIEF Trial of OCS-02 In Dry Eye Disease

The Phase 2b RELIEF trial is a multi-center, randomized, double-masked, vehicle-controlled trial evaluating the safety and efficacy of Licaminlimab for the treatment of moderate-to-severe DED (NCT05896670). The trial was designed based upon the positive findings from multiple previous studies in DED demonstrating significantly reduced ocular discomfort with a greater percentage of high responders vs. vehicle and was well tolerated with no unexpected adverse events reported. The 120 enrolled patients have been randomized to either Licaminlimab or vehicle for a 6-week treatment period and a 2-week follow up. The trial also contains an analysis for a subset of patients with a genetic variant that demonstrated an improved treatment response in the previous Phase 2a trial. RELIEF topline results are anticipated in Q2 2024.

About Phase 3 DIAMOND Program of OCS-01 in Diabetic Macular Edema

The DIAMOND-1 (DIAbetic Macular edema patients ON a Drop) and DIAMOND-2 trials are Phase 3, double-masked, randomized, multi-center trials which will evaluate the efficacy and safety of OCS-01 eye drops in patients with DME. Oculis aims to enroll 350-400 patients in each of these pivotal trials that will be randomized 1:1 to receive OCS-01 or vehicle six times daily for the 6-week induction phase and then three times daily through week 52 for the maintenance phase. The primary endpoint is change in best corrected visual acuity early treatment diabetic retinopathy study (BCVA ETDRS) letter score at Week 52. Secondary endpoints include percentage of patients with ≥15-letter gain in BCVA and change in central subfield thickness (CST), both at Week 52. Both trials were initiated upon the positive findings from stage 1 of the DIAMOND program, which was announced in the second quarter of 2023.

About Oculis

Oculis is a global biopharmaceutical company (Nasdaq: OCS) purposefully driven to save sight and improve eye care. Oculis' highly differentiated pipeline comprises multiple innovative product candidates in development. It includes OCS-01, a topical eye drop candidate for diabetic macular edema (DME) and for the treatment of inflammation and pain following cataract surgery; OCS-02, a topical biologic anti-TNFα eye drop candidate for dry eye disease (DED) and for non-infectious anterior uveitis; and OCS-05, a disease modifying candidate for acute optic neuritis (AON) and other neuro-ophthalmic disorders such as glaucoma, diabetic retinopathy, geographic atrophy, and neurotrophic keratitis. Headquartered in Switzerland and with operations in the U.S., Oculis' goal is to deliver life-changing treatments to patients worldwide. The company is led by an experienced management team with a successful track record and is supported by leading international healthcare investors.

For more information, please visit: www.oculis.com

Oculis Contacts

Ms. Sylvia Cheung, CFO
sylvia.cheung@oculis.com

Investor & Media Relations

LifeSci Advisors

Corey Davis, Ph.D.

cdavis@lifesciadvisors.com

1-212-915-2577

Cautionary Statement Regarding Forward Looking Statements

This press release contains forward-looking statements and information. For example, statements regarding the potential of Oculis' innovative and diversified pipeline to change the treatment paradigm in ophthalmology across multiple indications; the potential benefits of OCS-01 and OCS-02, including patient impact and market opportunity; the potential of OCS-01 for the treatment of DME; the potential of Licaminlimab or OCS-02 eye drops to address the unmet needs of the millions of patients living with DED; expected future milestones and catalysts; the initiation, timing, progress and results of Oculis' clinical trials, including the timing of topline results for the Phase 2b RELIEF trial; Oculis' research and development programs, regulatory, commercial and business strategy, future development plans, and management; and Oculis' ability to advance product candidates into, and successfully complete, clinical trials; the potential benefits of Oculis' senior management and advisory additions; and Oculis' potential first commercial launch in the U.S., are forward-looking. All forward-looking statements are based on estimates and assumptions that, while considered reasonable by Oculis and its management, are inherently uncertain and are inherently subject to risks, variability and contingencies, many of which are beyond Oculis' control. These forward-looking statements are provided for illustrative purposes only and are not intended to serve as, and must not be relied on by an investor as, a guarantee, assurance, prediction or definitive statement of a fact or probability. Actual events and circumstances are difficult or impossible to predict and will differ from assumptions. All forward-looking statements are subject to risks, uncertainties and other factors that may cause actual results to differ materially from those that we expected and/or those expressed or implied by such forward-looking statements. Forward-looking statements are subject to numerous conditions, many of which are beyond the control of Oculis, including those set forth in the Risk Factors section of Oculis' annual report on Form 20-F and any other documents filed with the U.S. Securities and Exchange Commission (the "SEC"). Copies of these documents are available on the SEC's website, www.sec.gov. Oculis undertakes no obligation to update these statements for revisions or changes after the date of this release, except as required by law.



Source: Oculis Holding AG