



Next Generation Topical Ophthalmics

Oculis Announces Successful End-of-Phase 2 Meeting with the FDA for OCS-01 in Two Ophthalmology Indications

Dr. David P. Bingaman Appointed as Vice President, Global Clinical Development

LAUSANNE, Switzerland, July 27, 2020 – Oculis S.A., a biopharmaceutical company focused on developing transformative topical (eye drop) ophthalmic treatments using its innovative formulation technologies to improve the sight and lives of patients, today announced that it has successfully completed an End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA) for OCS-01 in two indications: for the treatment of inflammation and pain following cataract surgery and for the treatment of diabetic macular edema (DME). As a result, the Company is currently planning the Phase 3 trials for both indications, which are expected to begin in the first half of 2021.

“We are very pleased with the guidance received from FDA on key elements of the Phase 3 programs that will support the submission of a New Drug Application (NDA) in both of our targeted indications,” **said Riad Sherif, M.D., Chief Executive Officer of Oculis.** “We look forward to further demonstrating, in our Phase 3 programs, the potential of OCS-01 as a transformative topical treatment for DME and as potentially the first once a day steroid for the treatment of inflammation and pain following cataract surgery.”

Oculis is also pleased to announce the appointment of David P. Bingaman, D.V.M., Ph.D., D. ACVO, as Vice President, Global Clinical Development to further strengthen the Company’s development capabilities. Dr. Bingaman brings more than 20 years of pharmaceutical experience in discovery research and clinical development in the ophthalmology area.

In this new position at Oculis, he will play a key leadership role in all clinical development programs to advance the Company’s pipeline of novel therapeutic candidates, including OCS-01 and OCS-02. A priority for Dr. Bingaman and Oculis in the coming months will be the planning and implementation of the Phase 3 trials. The design of the Phase 3 programs in both indications will be based on the positive Phase 2 trials with OCS-01 in each indication reported earlier in 2020 and feedback recently received from the FDA at End-of-Phase 2 meeting and scientific advice from the European Medicines Agency.

“I am delighted to welcome David to the Oculis team,” **commented Dr. Sherif.** “David brings therapeutic expertise as well as in-depth clinical development experience that will be very valuable to the Company as we advance our novel topical anti-inflammatory treatments OCS-01 and OCS-02 through late-stage clinical development. David will be based in the U.S., where we are currently establishing our operations.”

David Bingaman added: “The potential of Oculis’ pipeline candidates is very exciting. I am convinced that if the advanced product candidates, as well as the topical formulation technologies, come to market, they will have a positive impact on the vision and quality of life of millions of people worldwide. Results from two Phase 2 clinical trials reported earlier this year highlighted OCS-01’s ability to provide anti-inflammatory activity following topical ocular dosing in both front- and back-of-the-eye diseases. Not only could OCS-01 be a once-daily steroid for front-of-the-eye inflammation following cataract surgery, it also may be transformational for patients with sight-threatening DME for whom current approved treatments are invasive intra-ocular injections or implants. OCS-02 is another exciting prospect, as it could become the world’s first topical ocular biologic to address other common inflammatory eye conditions, such as uveitis or offer a personalized treatment for severe dry eye patients. Oculis is at a pivotal time in its development and I am very much looking forward to joining the team to advance these innovative candidates towards patients in need.”

Dr. Bingaman joins Oculis from Panoptica where he was Senior Director and Head of Retina Development since 2011, overseeing all development functions and the execution of multiple trials in neovascular age-related macular degeneration (AMD) and diabetic retinopathy using a topical ocular anti-VEGF candidate. Prior to Panoptica, he held several leadership roles with Alcon Research, the former eye-care division of Novartis, moving from Discovery to Development as his teams' programs were elevated into first-in-man trials.

About Oculis

Oculis S.A. is a biopharmaceutical company focused on developing transformative topical ophthalmic treatments using its innovative formulation technologies to improve the sight and lives of patients.

Oculis' novel topical (eye drop) treatments are non-invasive and represent an unprecedented technical advance for patients with retinal and front-of-the-eye diseases.

The Company's leading clinical candidates include OCS-01 and OCS-02:

- OCS-01 is a novel, high concentration, preservative free, topical formulation of dexamethasone using Oculis' proprietary Solubilizing Nanoparticle (SNP) technology. It has successfully completed two Phase 2 clinical trials: in Diabetic Macular Edema (DME) and for treating inflammation and pain following cataract surgery. OCS-01 has the potential to provide the first non-invasive topical treatment option for DME patients and the first once a day, preservative free steroid for inflammation and pain following ocular surgery.
- OCS-02 is a novel topical anti-TNF alpha antibody and was in-licensed from Novartis. It has successfully completed two Phase 2 clinical trials in Acute Anterior Uveitis and in Dry Eye Disease.

In addition, Oculis' formulation discovery focus and capabilities are enabling the development of a pipeline of topical drugs targeting sight-threatening eye diseases that affect both the anterior and posterior segments of the eye.

Oculis has an experienced management team from global ophthalmic companies and is supported by leading international life science investors. Oculis is headquartered in Lausanne, Switzerland, with research operations in Iceland and France.

To learn more, visit www.oculis.com

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