Oculis Announces Positive OCS-01 Phase 2 Data in Patients with Diabetic Macular Edema (DME)

OCS-01 is a proprietary topical nanoparticle formulation of dexamethasone that has the potential to treat retinal diseases

- *The Phase 2 (DX-211) study provides a clinical proof-of-concept of OCS-01 topical drug effect on DME*
- *The study met its pre-defined efficacy endpoints and showed that OCS-01 eye drops were more effective than vehicle in reducing central macular thickness and improving visual acuity in patients with DME*
- *No significant / unexpected ocular adverse events were observed*
- *The results also provide a proof-of-concept of the nanoparticle technology as a potential innovative means to develop topical therapies for retinal diseases*

Data presented at Angiogenesis, Exudation, and Degeneration 2020 Conference, February 8, 2020, in Miami

LAUSANNE, Switzerland, Feb. 09, 2020 (GLOBE NEWSWIRE) -- Oculis S.A., a clinical-stage biopharmaceutical company whose mission is to develop novel topical treatments (eye drops) for ophthalmic diseases, today reports positive data from a phase 2 study of OCS-01, a novel eye drop formulation of dexamethasone, in development for the treatment of diabetic macular edema (DME).

OCS-01 was developed using Oculis' proprietary Soluble NanoParticle technology (SNP), which acts as an ocular drug carrier to enhance bioavailability of drugs in the posterior segment of the eye.

The DX-211 study was a prospective, multi-center, randomized, double-masked, parallel group, vehicle-controlled study. Type 1 or 2 diabetic patients with DME and central macular thickness (CMT) of ≥ 310 µm by SD-OCT and ETDRS best corrected visual acuity (BCVA) letter score ≤ 73 and ≥ 24 in the study eye were randomized to treatment with OCS-01 or matching vehicle eye drops, 1 drop 3 times per day for 12 weeks. Efficacy was evaluated based on the change from baseline to Week 12 of CMT and ETDRS BCVA letter score. Safety was assessed in terms of adverse events and ophthalmology examination.

A total of 144 patients were randomized and 133 patients (92.3%) completed the study. Mean CMT showed a greater decrease from baseline in the OCS-01 group than the vehicle arm at Week 12 (-53.6 µm vs -16.8 µm, p=0.0115). Mean change in ETDRS BCVA letter score from baseline to Week 12 was higher in the OCS-01 group than the vehicle group (+2.62 letters vs +1.04 letters, p= 0.125). P values met the pre-specified conditions in the protocol for statistical superiority of OCS-01 vs vehicle. Local ocular tolerability was not significantly different between the OCS-01 and vehicle groups with the exception of change in intraocular pressure (IOP). IOP increases were more common with OCS-01 than vehicle during the treatment period which was consistent with known dexamethasone effects.

In summary, the study met its pre-defined efficacy endpoints and showed that OCS-01 eye drops were more effective than vehicle in reducing central macular thickness and improving visual acuity in patients with DME. No significant/unexpected ocular adverse events were observed.

Pravin U. Dugel, M.D., Chairman of Oculis' Scientific Advisory Board, Clinical Professor of Ophthalmology, Keck School of Medicine, University of Southern California, and Partner, Retinal Consultants of Arizona at the Retinal Research Institute in Phoenix, said: "DME is a devastating consequence of diabetes and the most common cause of blindness among people of working age in developed countries. The current standard of care involves intravitreal injections, and this has a marked negative impact on patient compliance, accessibility and treatment sustainability. OCS-01 as topical drug presents a truly innovative, non-invasive approach that has the potential to change the treatment paradigm in DME, and one that would be welcomed by physicians and patients alike.

The results of the DX-211 study are very exciting as they clearly show that OCS-01 treatment improves the vision of DME patients as well as demonstrates an objective biological effect on the retina via the OCT measurements. In addition, the safety profile of OCS-01 appears encouraging and manageable, with the lack of local irritation and toxicity. I believe that the OCS-01 data are very promising and that further larger studies are warranted, which, if successful, could highlight an important role for OCS-01 in the routine management of DME patients, and particularly those at the early stages of disease where a watch-and-wait strategy is currently employed."

Riad Sherif, M.D., Chief Executive Officer of Oculis, said: "We are delighted by the results. The DX-211 study validates the potential of OCS-01 to provide patients and their physicians with a potentially transformative topical approach for sight-threatening retinal diseases, such as DME. Furthermore, the study confirms the potential of our unique SNP technology to formulate additional topical therapies to treat back-of-the-eye diseases. The successful completion of this clinical trial, along with the support of the retina community, gives us great confidence for the next development steps ahead for OCS-01."

About Oculis

Oculis is a clinical-stage biopharmaceutical company whose mission is to develop novel topical treatments (eye drops) for ophthalmic diseases for both back- and front-of-the-eye in order to improve the sight and lives of patients worldwide. These topical treatments represent an unprecedented technical advance for patients with back-of-the-eye diseases that are currently managed only by intra-ocular injections or implants; while topical treatments for front-of-the-eye disease are designed to improve patient outcomes by increasing drug bioavailability, reducing dosing frequency and improving patient compliance.

The company's leading clinical candidates include OCS-01 and OCS-02. OCS-01 has shown positive Phase 2 results in DME and is also in Phase 2 for Pain and Inflammation following ocular surgery.

OCS-02 is a novel topical anti-TNF alpha antibody in advanced Phase 2 that has shown efficacy in inflammatory eye diseases and was in-licensed from Novartis.

In addition to its lead clinical candidates, Oculis' proprietary Solubilizing NanoParticle (SNP) technology enables the formulation of drugs as topical treatments and enhances their bioavailability in the relevant eye tissues. The Company is leveraging this proprietary technology to generate a pipeline of topical drugs targeting sight-threatening eye diseases.

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 Reykjavik, Iceland.

To learn more visit www.oculis.com

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