Oculis' Nanoformulation Proved Promising in Treating Diabetic Macular Edema

2020-04-13
Oculis S.A., a clinical-stage biopharmaceutical company specializing in the development of innovative medications for ophthalmic diseases, announced that its novel proprietary topical nanoparticle formulation of dexamethasone, called OCS-01, showed promising results in the phase 2 study for the treatment of visual acuity in patients with diabetic macular edema (DME).

Once a distant idea likened by many to science fiction, new data suggests an eye drop that effectively treats diabetic macular edema (DME) could be a reality sooner than many expected.

Results of a phase 2 study from Oculis S.A. indicate use of OCS-01, a novel proprietary topical nanoparticle formulation of dexamethasone, could reduce central macular thickness and lead to improvements in visual acuity in patients with DME.

"The current standard of care involves intravitreal injections, and this has a marked negative impact on patient compliance, accessibility and treatment sustainability," said Pravin Dugel, MD, chairman of Oculis' Scientific Advisory Board and clinical professor of Ophthalmology at the Keck School of Medicine, University of Southern California, in a statement from Oculis. "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 12-week phase 2 DX-211 study, which was presented at Angiogenesis, Exudation, and Degeneration 2020 Conference in Miami, was designed as a prospective, multicenter, randomized, double-masked, parallel-group, vehicle-controlled study examining the use of OCS-01 eye drops in diabetics patients with DME. The study included a total of 144 patients with type 1 or type 2 diabetes, an ETDRS best corrected visual acuity (BCVA) letters score between 24 and 73, and a CMT greater than 310 µm—as measured by SD-OCT.

The 144 included were randomized to treatment with OCS-01 eye drops at a dosage of 1 drop 3 times per day for 12 weeks or to vehicle eye drops at the same dosage. The primary endpoint of the proof-of-concept trial was change in ETDRS BCVA letters score from baseline to 12 weeks and secondary endpoints included the number of individuals with BCVA improvements of 10 or more and 15 letters in comparison to baseline, CMT thickness on OCT, intraocular pressure (IOP), subject satisfaction.

Of the 144 patients randomized, 133 completed the study. Upon analysis, investigators observed the use of OCS-01 was associated with greater decreases in mean CMT from baseline to 12 weeks than in the vehicle arm (-53.6 µm vs -16.8 µm, P = .0115). Additionally, the mean change in letter score from baseline to week 12 was higher in patients using OCS-01 than in the vehicle arm of the study (+2.62 letters vs +1.04 letters, P = .125).

In regard to other secondary endpoints, observed local ocular tolerability was not significantly different between either arm of the study with the exception of change in intraocular pressure, which was more common in the OCS-01 arm during the treatment period. The statement from Oculis noted this is consistent with known dexamethasone effects and that no significant or unexpected ocular adverse events occurred during the trial.

“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,” said Riad Sherif, MD, chief executive officer of Oculis.

Read the original article on MD Magazine.