



Emmecell Announces FDA Acceptance of IND Application for EO2002 in Corneal Edema

– First-in-class novel magnetic cell-based therapy has potential to modify disease –

MENLO PARK, Calif., September 22, 2020 – Emmetrope Ophthalmics LLC (“Emmecell”), a clinical-stage biotechnology company pioneering the discovery and development of cell-based therapies for the treatment of eye diseases, today announced that the U.S. Food and Drug Administration (FDA) has accepted the Investigational New Drug application (IND) for EO2002, its lead candidate for the treatment of corneal edema. The active IND enables Emmecell to initiate a Phase 1 clinical trial designed to assess the tolerability, safety, and efficacy of EO2002 in patients with corneal edema. Patients with corneal edema suffer from vision loss and pain, and the disease is the most common indication for corneal transplantation.

Jeffrey L. Goldberg, MD, PhD, professor and chair of ophthalmology at Stanford University, and company co-founder, commented, “The FDA’s acceptance of our IND is an important validation of our novel Magnetic Cell Delivery platform and marks a significant milestone for Emmecell as our lead product candidate, EO2002, advances into the clinic. We look forward to embarking on our next chapter as a clinical-stage company, harnessing the power of our platform to discover and develop new cell-based therapies that have the potential to transform the lives of patients with serious eye diseases by succeeding where current treatments have not.”

EO2002, a first-in-class, non-surgical, magnetic cell-based therapy with the ability to modify disease, was developed by Emmecell through its exclusive Magnetic Cell Delivery (MCD) nanoparticle platform. EO2002 provides easier access to treatment before the disease becomes disabling and painful, and has the potential to prevent or delay the onset of more serious procedures, including corneal transplantation.

“In initial preclinical and early phase human testing, EO2002 has demonstrated a strong safety and efficacy profile,” added Dr. Goldberg. “We have an obligation to patients with corneal edema and look forward to initiating this Phase 1 clinical trial of our lead candidate, which is believed to be the first ever clinical evaluation of a non-surgical, MCD-based therapy to treat this sight-threatening condition.”

Site initiation activities are underway for the Phase 1 clinical trial of EO2002. The Company anticipates that enrollment will begin in the first quarter of 2021.

About Corneal Edema

When the inner-most layer of cells in the cornea – the endothelium – decrease in number, whether from the trauma of cataract surgery or from disease or dystrophy, the cornea swells with fluid (edema), and loses its optical clarity. Patients with corneal edema suffer from vision loss and pain. Currently, there are no non-surgical procedures approved for the treatment of advanced corneal edema; the only options for these patients are corneal transplantation surgery or endothelial keratoplasty, which are technically demanding surgical procedures with many limitations. Corneal edema is the most common indication for corneal transplantation.

Magnetic Cell Delivery: A Revolutionary Cell Therapy Platform

Regenerative medicine using cell therapies to replace or enhance damaged tissue is often limited by the ability to localize these cells to the target tissue. Once delivered, these cells then need to remain at that site to facilitate integration into the host tissue. Through its proprietary Magnetic Cell Delivery (MCD) nanoparticle platform, Emmecell solves the challenges of delivery, retention, and integration of cell therapies by leveraging magnetic nanoparticles to effectively localize and integrate cell therapies to the appropriate target tissue.

Emmecell's exclusive MCD nanoparticle platform addresses the limitations of the current surgical options for corneal edema with a safe, effective, non-surgical approach to transplant its proprietary corneal endothelial cells in the eye. With the availability of an effective and safe therapeutic option for corneal edema, patients with clinically significant but still mild disease will not need to wait until their condition progresses before being offered treatment.

About Emmecell

Emmecell is a privately held, clinical-stage biotechnology company pioneering the discovery and development of cell-based therapies for the treatment of eye diseases via its exclusive Magnetic Cell Delivery (MCD) nanoparticle platform technology. Emmecell solves the challenges of delivery, retention, and integration of cell therapies by leveraging magnetic nanoparticles to effectively localize and integrate cell therapies to the appropriate target tissue. Emmecell has a broad intellectual property (IP) portfolio and is focusing its initial efforts on ophthalmic indications. Headquartered in Menlo Park, CA, Emmecell is also the parent company of CellIMP (www.cellimp.com), which provides current good manufacturing practices (cGMP) manufacturing services. For more information, please visit www.emmecell.com.

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