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Emmecell Receives FDA Regenerative Medicine Advanced Therapy (RMAT) Designation for EO2002 for the Treatment of Corneal Endothelial Disease

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RMAT designation recognizes the potential of EO2002 to address a serious condition with an unmet medical need and provides enhanced opportunities for interaction with the FDA as the EMERALD trial advances.

MENLO PARK, Calif.--(BUSINESS WIRE)--Emmecell, a clinical-stage biotechnology company advancing regenerative ophthalmic therapies through its proprietary Magnetic Cell Delivery™ platform, today announced that the U.S. Food and Drug Administration (FDA) has granted Regenerative Medicine Advanced Therapy (RMAT) designation to EO2002, the Company's lead investigational magnetic human corneal endothelial cell therapy for the treatment of corneal edema secondary to corneal endothelial dysfunction.

RMAT designation is intended to expedite the development and review of regenerative medicine therapies for serious conditions when clinical evidence demonstrates the potential to address an unmet medical need. The designation provides opportunities for early and frequent interactions with the FDA, helping to accelerate clinical development, manufacturing discussions, and regulatory review.

"RMAT designation represents an important regulatory milestone for EO2002 and underscores the potential of our Magnetic Cell Delivery™ platform to address a meaningful unmet need in corneal endothelial disease," said Ramin Valian, Chief Executive Officer of Emmecell. "We are encouraged by the clinical evidence generated to date and look forward to continued collaboration with the FDA as we advance the EMERALD study. Together with our recent financing and clinical progress, this designation further strengthens our development pathway and reinforces our commitment to delivering a minimally invasive treatment option for patients."

EO2002 is an investigational allogeneic cultured human corneal endothelial cell therapy utilizing Emmecell's proprietary Magnetic Cell Delivery™ platform. The technology is designed to enhance the localization and retention of therapeutic cells following administration. The therapy is intended to

restore corneal endothelial function without the need for donor tissue transplantation or invasive endothelial keratoplasty.

About Emmecell

Emmecell is a clinical-stage biotechnology company developing Magnetic Cell Delivery™ technologies designed to improve the precision, localization, and effectiveness of regenerative cell therapies for ophthalmic diseases. By enhancing targeted cell delivery and retention, the Company's proprietary platform has the potential to transform the treatment of corneal endothelial disease and other serious ophthalmic conditions with significant unmet medical need.

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RELEASE SUMMARY

Emmecell receives FDA RMAT designation for EO2002, advancing development of its regenerative cell therapy for corneal endothelial disease.
