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Aurion Biotech, which specializes in advanced therapies to treat eye diseases, recently appointed Tim Largen as VP of manufacturing to manage the company's cell manufacturing efforts. In addition to managing Aurion's internal team, Largen will coordinate efforts with external teams at Cognate BioServices and S-RACMO, a joint venture of Sumitomo Chemical and Sumitomo Pharma, to support cell production in the U.S. and Japan, respectively.

Aurion's lead clinical candidate is a cell therapy for treating corneal endothelial dysfunction. The treatment was invented by ophthalmic surgeon and researcher Shigeru Kinoshita, PhD, at Kyoto Prefecture University of Medicine, and acquired by Aurion Biotech's parent company CorneaGen in 2020. Aurion Biotech is preparing an NDA for market approval in Japan, and an IND for clinical trials in the U.S.

Corneal endothelial disease is a serious, sight-threatening condition affecting approximately 4% of individuals in developed countries. The current standard of care involves surgical transplant of corneal tissue, but the procedure is complex and demand for donor corneas far exceeds supply. Aurion Biotech's therapy aims to resolve supply issues, as it enables treatment of up to 100 eyes from cells harvested from a single donor.

Aurion's lead cell therapy candidate consists of fully differentiated human corneal endothelial cells which are injected into the anterior chamber of the eye. Once in place, the cells self-align along the corneal stroma. Following the procedure, the patient lies face down for three hours to promote adhesion. Then, in a matter of days, vision is restored.

"Aurion Biotech is continually innovating on production, process methods, know-how, storage media and methods, and packaging of corneal endothelial cells," says Judith McGarry, VP of marketing at Aurion. "Cognate and S-RACMO add high-quality production capability to this effort in the U.S. and Japan, respectively."

Allogeneic transplantation has had its issues. "Other forms of cell therapies have to contend with unchecked cell propagation," McGarry says. "An important differentiator of our cell production process is our ability to control or "turn on" and "turn off" cell replication.
In addition, we are working to expand the scale of our cell production. We are now able to use cells from a single donor to treat 100 eyes, but our goal is to increase that production tenfold, to 1,000 treatments."

Aurion Biotech is also working on novel storage methods to extend the cells' shelf life and to facilitate shipment and delivery of cells globally, and has applied for patents on these methods.

"We are evaluating several different packaging solutions, which are also related to storage, that will extend the cells' shelf life and make these therapies more 'turnkey' for ophthalmologists," McGarry tells *GEN*.
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