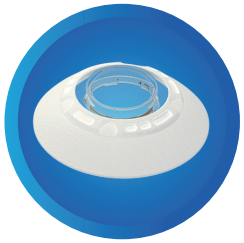
REGULATORY PATH

CorNeat KPro & CorNeat EverPatch

CorNeat Vision designed, manufactured, and extensively tested the CorNeat KPro (synthetic cornea) and the CorNeat EverPatch (synthetic sclera).

Both devices passed the pre-clinical safety-assurance phase, and consequently approved for clinical investigations.



CORNEAT KPRO

Artificial Cornea

In the initial stages, the CorNeat KPro clinical trial will target FDA (510K) clearance (USA) and CE marking (Europe), with limited indications; patients with failed keratoplasty and patients with corneal ailments who are not amenable by keratoplasty.

Given the expected optical superiority over donor tissue, CorNeat Vision plans to conduct a second study with broader indications including first line treatment in selected patients. This will enable CorNeat Vision to expand the device's indications for use. At present, the device is expected to achieve initial regulatory clearance during 2022.

In China, over 5 million patients are in need of donor tissue, with only several thousand transplanted each year. CorNeat Vision is in the process of planning a primary KPro study in China, which will prove the superiority of the CorNeat KPro over other solutions, including keratoplasty, and render it the primary solution for corneal blindness. This study is planned to begin in 2021 and will include 60-70 local patients toward the NMPA (previously CFDA) approval.

The first phase of the study is to be initiated this month, October 2020, at Beilinson Hospital, Israel, with the first-in-human implantation led by Professor Irit Bahar, Director of the Ophthalmology Department at Beilinson Hospital.

REGULATORY PATH

CorNeat KPro & CorNeat EverPatch

Following the implantations in Israel, additional implantations are to be performed at University Health Network (UHN), Toronto, Canada, and at the University of British Columbia (UBC), Vancouver, Canada, by Professor David Rootman and Dr. Alfonso Iovieno, respectively.

Additional clinical trials are planned to commence by the end of 2020. These include in the United States: (i) University of California (UCLA), Los Angeles, led by Dr. Anthony Aldave; (ii) The Cincinnati Eye Institute, Ohio, led by Dr. Edward J. Holland, the Director of Cornea Services at Cincinnati Eye Institute; and Europe: (iii) Fondation Ophtalmologique Adolphe de Rothschild, Paris, France led by Professor Eric Gabison and; (iv) VU University Medical Center (UMC), Amsterdam, Netherlands led by Professor Ruth Lapid-Gortzak. Trials in Europe are planned for early 2021.

The plans above are subject to regulatory approvals and requirements.

For more information: clinicaltrials.gov.

Leading Principal Investigators involved in the CorNeat KPro clinical trials:

Irit Bahar
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Beilinson Hospital

David S. Rootman
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University Health Network

Alfonso Iovnieno
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Anthony J. Aldave
MD
Jules Stein Eye Institute (UCLA)

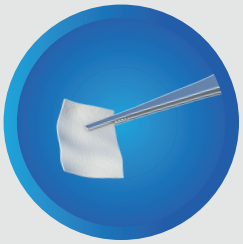
Edward J. Holland
MD
Cincinnati Eye Institute

Eric Gabison
MD PhD
Rothschild/Bichat Hospital

Ruth Lapid-Gortzak
MD PhD
VU University Medical Center Amsterdam

REGULATORY PATH

CorNeat KPro & CorNeat EverPatch



CorNeat EverPatch

Synthetic and Non-Degradable Tissue

The CorNeat EverPatch clinical trial is geared toward obtaining a CE marking by the end of 2021. CorNeat Vision plans to extend the approval for the solution to the American market as a second step and work toward FDA approval after completing the initial trial.

The clinical study toward the CE marking is to be initiated in Q4 2020 at University Health Network (UHN), with first-in-human implantation led by Professor David Rootman. An additional implantation will be performed by Dr. Ike Ahmed at the Prism Eye Institute University, Toronto, Canada.

By the end of 2020, as part of this clinical trial, additional sites are planned to open, which include one site in France, two sites in Israel and three sites in Kenya.

The study in France is planned to be conducted at Fondation Ophtalmologique Adolphe de Rothschild, Paris, led by Professor Eric Gabison. The study in Israel is planned to take place at Meir Medical Center and Beilinson Hospital, led by Professor Ehud Assia and by Dr. Noa Geffen, respectively. The sites in Kenya are planned at Lions SightFirst Eye Hospital, Nairobi, Kenyatta National Hospital, Nairobi, and Kwale Eye Center, Mombasa, and will be led by Dr. Lily Adhiambo Nyamai. The study in Kenya will include glaucoma surgery for study subjects in need, in order to improve the quality of life for such study subjects.

The plans above are subject to regulatory approvals and requirements.

For more information: clinicatrials.gov

Leading Principal Investigators involved in the CorNeat EverPatch clinical trials:

David S. Rootman
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University Health Network

Eric Gabison
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Rothschild/Bichat Hospital

Noa Geffen
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