

Weekly New Drug Approvals

Sep. 2nd 2024

1. Polihexanide

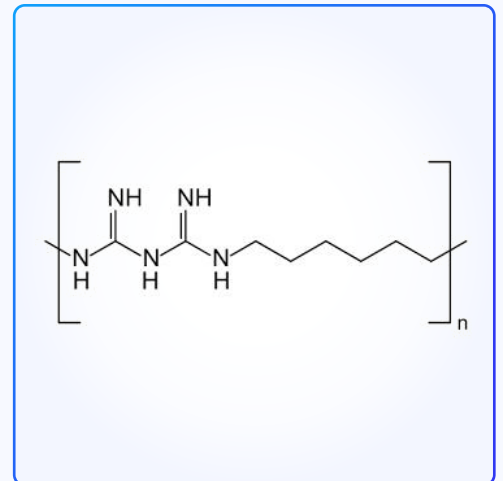
EMA Approval Date: Aug 26th, 2024

Brand name: Akantior

Indication: Acanthamoeba Keratitis

Dosage form: Eye Drops

Company: SIFI



AKANTIOR[®] is an investigational anti-amoebic polymer that has been granted Orphan Drug Designation by both the European Medicines Agency (“EMA”) and Food and Drug Administration (“FDA”) for AK. It acts on both the trophozoites and cysts of the protozoan Acanthamoeba. It is formulated at a unique 0.8mg/ml high dose strength which makes it possible to administer as monotherapy eye drops in single-dose containers. Polihexanide is also being developed by SIFI for the treatment of fungal keratitis for which indication it also has FDA Orphan Drug Designation.



2. Odronextamab

EMA Approval Date: Aug 26th, 2024

Brand name: Ordspono

Indication: Relapsed or refractory (R/R) follicular lymphoma or R/R diffuse large B-cell lymphoma

Mechanism: CD20 inhibitors/CD3 stimulants /ADCC/CD20-directed cytolytic effects

Company: Regeneron

Odronextamab is an investigational CD20xCD3 bispecific antibody designed to bridge CD20 on cancer cells with CD3-expressing T cells to facilitate local T-cell activation and cancer-cell killing. The EMA had previously granted orphan drug status to odronextamab for the treatment of FL and DLBCL. This approval was primarily based on the positive results from the phase I ELM-1 study and the phase II ELM-2 study, which confirmed the robust and durable remission effects of odronextamab in adult patients with R/R FL and R/R DLBCL.