SEVENTH FRAMEWORK PROGRAMME

ODAK

Orphan Drug for Acanthamoeba Keratitis

Acanthamoeba keratitis (AK) is a rare infectious eye disease

⇒ Severe symptoms: eye pain and irritation, light sensitivity, redness, tearing and blindness

⇒ Correct diagnosis and early treatment are essential – contact lens wearers are at most risk

⇒ The amoeba resist conventional antimicrobial drugs

FP7 supported the development of Polihexanide (*AKANTIOR®*) as a safe and effective treatment

AKANTIOR® is set to become the first approved treatment for AK

SIFI have announced an early access programme for AK patients

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AK is a rare but severe and seriously debilitating, complex corneal infectious disease caused by Acanthamoeba spp. a ubiquitous free living protozoan. Although incidence is low, 1 in 100,000 in the EU, for patients it is a potentially devastating eye infection causing their vision to deteriorate and can lead to blindness. In countries with a high prevalence of contact lens wearing AK accounts for over 85% of cases, but AK can also occur after corneal trauma, particularly in rural environments. AK is on the rise in developing economies and there is no approved drug to treat this infectious rare disease.

AK is considered to be a challenging disease to treat because the pathogen has resistance to antimicrobial therapies and the poorly under-stood role of the host's inflammatory response that complicates therapy of severe cases. Currently, there are no agents approved for the treatment of AK. AKANTIOR® is set to become the first approved orphan drug for this rare disease offering effective treatment and a cure for the disease.

ODAK was an industry led FP7 collaborative project under-taking the pharmaceutical development of the Orphan Drug PHMB (Polihexanide). Its aim was to provide a safe and effective drug for the treatment of AK. the FP7 project successfully completed the early stage clinical trials and initiated the pivotal Phase 3 study. The study was successfully completed by SIF and the clinical team.

Early clinical development received funding from the European Union Seventh Framework Programme [FP7/2007-2013] for under the grant agreement n° 305661

SIFI

Moorfields Eye Hospital NHS Foundation Trust

CERATIUM HELPING RESEARCH HAPPEN

RTC Research Toxicology Centre

PSR theorphanEXPERTS

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