ODAK
Project ID: 305661
Funded under: FP7-HEALTH

Orphan Drug for Acanthamoeba Keratitis

From 2012-12-01 to 2017-11-30, closed project

Project details

<table>
<thead>
<tr>
<th>Total cost:</th>
<th>Topic(s):</th>
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<tr>
<td>EUR 5 779 906,80</td>
<td>HEALTH.2012.2.4.4-1 - Preclinical and/or clinical development of substances with a clear potential as orphan drugs</td>
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<tr>
<td>EU contribution:</td>
<td>Funding scheme:</td>
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<tr>
<td>EUR 4 050 255</td>
<td>CP-FP - Small or medium-scale focused research project</td>
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<th>Coordinated in:</th>
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<tr>
<td>France</td>
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Objective

This project will undertake preclinical and clinical research of the Orphan Drug Polihexanide (PHMB). The main objective is to provide a safe and effective drug for the treatment of the rare ocular disease Acanthamoeba keratitis (AK) tested according to international regulatory standards. This debilitating infectious disease is caused by a free living protozoan which, in the absence of treatment, can have catastrophic consequences such as severe pain, visual loss and eye enucleation. There are no approved drugs to treat this disease. After Orphan Drug Designation Protocol Assistance was requested from the European Medicines Agency on our drug development research plan. The proposed protocol incorporates the EMA advice and will include a non-clinical phase, a double-blind placebo controlled Phase I trial and a randomised double-blind, active controlled, parallel groups Phase 3 study (efficacy and safety therapeutic confirmatory study). The primary deliverables will be: 1) experimental scientific evidence on the quality, safety and efficacy of PHMB to provide the basis for a Marketing Authorisation within 5 years; 2) recommendations aiming to improve clinical practices in the management of AK based on the efficacy and safety evidence. ODAK is an industry led project mobilising the critical mass of industrial, pharmaceutical and academic expertise needed to develop and optimise therapeutic approaches to alleviate the severe negative impacts of AK on the health and quality of life of patients. In particular, through identifying optimal PHMB formulations and recommending the best dose-benefit treatment regimes. ODAK directly contributes to the International Rare Diseases Research Consortium goal towards 200 new therapies. An estimated 95% of the total estimated EU contribution to the project will go to industrial partners (of this 32% goes to SMEs). The industrial strength assures a rapid translation of research to market application.

Related information

| Report Summaries | Final Report Summary - ODAK (Orphan Drug for Acanthamoeba Keratitis) |
Coordinator

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EU contribution: EUR 273 800

See on map

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