Project Information

Oralis

Grant agreement ID: 887907

DOI
10.3030/887907

Closed project

Funded under
INDUSTRIAL LEADERSHIP - Innovation In SMEs

Total cost
€ 71 429

EU contribution
€ 50 000

Coordinated by
ORAMED LTD
Israel

Start date
1 December 2019

End date
31 March 2020

Project description

First oral insulin for the treatment of type 2 diabetes

Type 2 diabetes affects more than 400 million people worldwide. Almost 50 million of them are European citizens. Efficient control of blood glucose level is critical for the prevention of the disease as well as longer lifespan and higher quality of life for patients. Despite significant progress over recent decades in the treatment of type 2 diabetes, many patients depend on multiple daily insulin injections associated with social stigma, pain and high cost in case of non-adherence to the treatment. Oramed Pharmaceuticals aims to transform the treatment using proprietary technology to protect insulin in the gastrointestinal tract, opening the way to oral insulin treatment. Oramed has produced oral insulin and demonstrated its efficacy in a Phase II clinical
trial with >300 patients. The EU-funded Oralis project provides additional support for a Phase III clinical trial to confirm oral drug efficacy for glycaemic control in type 2 diabetes patients.

**Objective**

Type 2 Diabetes Mellitus (T2DM) affects 415M people globally, 49M of them within Europe. Caring for these individuals costs Europe €181M billion annually. However, more needs to be done as T2DM and its related co-morbidities claim hundreds of thousands of lives each year in the region. The early control of blood glucose levels (BGL) is the key to the prevention of the disease, and longer lifespans with better prognosis and higher quality of life for T2DM patients.

The last century has seen considerable development in T2DM treatment, but the eventual solution to control BGL for many patients are multiple daily insulin injections. This has created a huge global market to be worth €49 billion (est. 2020). The pain, social stigma, and burden associated with injecting insulin contribute to a non-adherence to treatment that has been estimated to be as high as 61%, at a cost 9,649€ per patient per year.

Oramed Pharmaceuticals (Oramed) will transform this paradigm with its POD™ technology. It protects protein therapies like insulin from the harsh conditions in the gastrointestinal tract, allowing then to be taken orally. This opens a way into oral insulin treatment to overcome many of the issues contributing to non-adherence of injected insulin treatment in T2DM patients. Using POD™ technology Oramed has produced the first oral insulin and demonstrated its efficacy in Phase II clinical trials with >300 patients and >5000 doses. We have proven oralis capability to deliver to the liver bioavailable insulin at sufficient concentration to produce significant glucose control in all glycaemic parameters in T2DM patients. Through the SME instrument Oramed will finalise the Phase III clinical trial to confirm the efficacy of oralis for glycaemic control in T2DM patients.

We have already reach commercial agreements to commercialise oralis. Our estimation is to generate a similar revenue creation and market share as the newest injectable insulin options of €1.7 bn in 5 years.

**Fields of science**

- basic medicine
- pharmacology and pharmacy
- pharmaceutical drugs
- biological sciences
- biochemistry
- biomolecules
- proteins
- clinical medicine
- endocrinology
- diabetes
- medical biotechnology
- tissue engineering
- artificial pancreas
- continuous glucose monitors
Programme(s)

H2020-EU.2.3. - INDUSTRIAL LEADERSHIP - Innovation In SMEs
H2020-EU.3. - PRIORITY 'Societal challenges
H2020-EU.2.1. - INDUSTRIAL LEADERSHIP - Leadership in enabling and industrial technologies

Topic(s)

EIC-SMEInst-2018-2020 - SME instrument

Call for proposal

H2020-EIC-SMEInst-2018-2020

See other projects for this call

Sub call

H2020-SMEInst-2018-2020-1

Funding Scheme

SME-1 - SME instrument phase 1

Coordinator

ORAMED LTD
Net EU contribution
€ 50 000,00

Address
Elza St 2
9370648 Jerusalem
Israel

Activity type
Private for-profit entities (excluding Higher or Secondary Education Establishments)

Links
Contact the organisation
Participation in EU R&I programmes

3 of 4
Non-EU contribution

€ 21 429,00

EC signature date: 4 November 2019
Last update: 17 August 2022
Record number: 225701

Permalink: https://cordis.europa.eu/project/id/887907

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