



Dompé

Il futuro è già presente



WHO WE ARE

Dompé at a glance


Established in Milan in 1940s, **Dompé is an Italian biopharmaceutical company**

300 MILLION \$
2018 REVENUES



Production recognized for its quality and efficiency at **international level**

60
MILLION PACKAGES OF DRUGS MARKETED IN ABOUT 40 COUNTRIES



The value of our network

PARTNERSHIP
WITH LEADING GLOBAL **BIOTECH** AND **PHARMA** COMPANIES AT INTERNATIONAL LEVEL



People

800



R&D investments on turnover

15%*



*2018 data

The value of strategic partnership in biotech field

BIOGEN
Dompé



genzyme

AMGEN® **Dompé**

Research is at the centre of Dompé strategy

Production site and Research & Development



250 EMPLOYEES
— of which —
70 RESEARCHERS



Watch the video of our L'Aquila Plant here: <https://youtu.be/IHvnWT5qX9g>

Dompé markets



A business based on two pillars



Leadership in Italy in the *Primary Care market*

A commitment to market *innovative therapeutic solutions* worldwide

Incremental innovation - Primary Care

- Pain and Inflammation
- Respiratory Diseases
- Gastroenterology
- Cardiology
- Pediatric
- Sport and Wellness

Breakthrough innovation - Biotech

- Neurotrophic Keratitis
- Hypertension

oxervate

REMODULIN[®]
(treprostinil) Injection

RESEARCH & DEVELOPMENT

Dompé strategic choices



BREAKTHROUGH INNOVATION

R&D



UNMET MEDICAL NEEDS

FOCUS



COMPLEXITY MANAGEMENT

NETWORK

The pillars of our breakthrough innovation



OPHTHALMOLOGY



TRANSPLANTS



ONCOLOGY



DIABETES

**WORKING TO DISCOVER INNOVATIVE TREATMENTS
FOR PATIENTS WORLDWIDE**

Our clinical trials



4 STUDIES

ONCOLOGY

77 CENTRES

5 STUDIES

DIABETES & TRANPLANTS

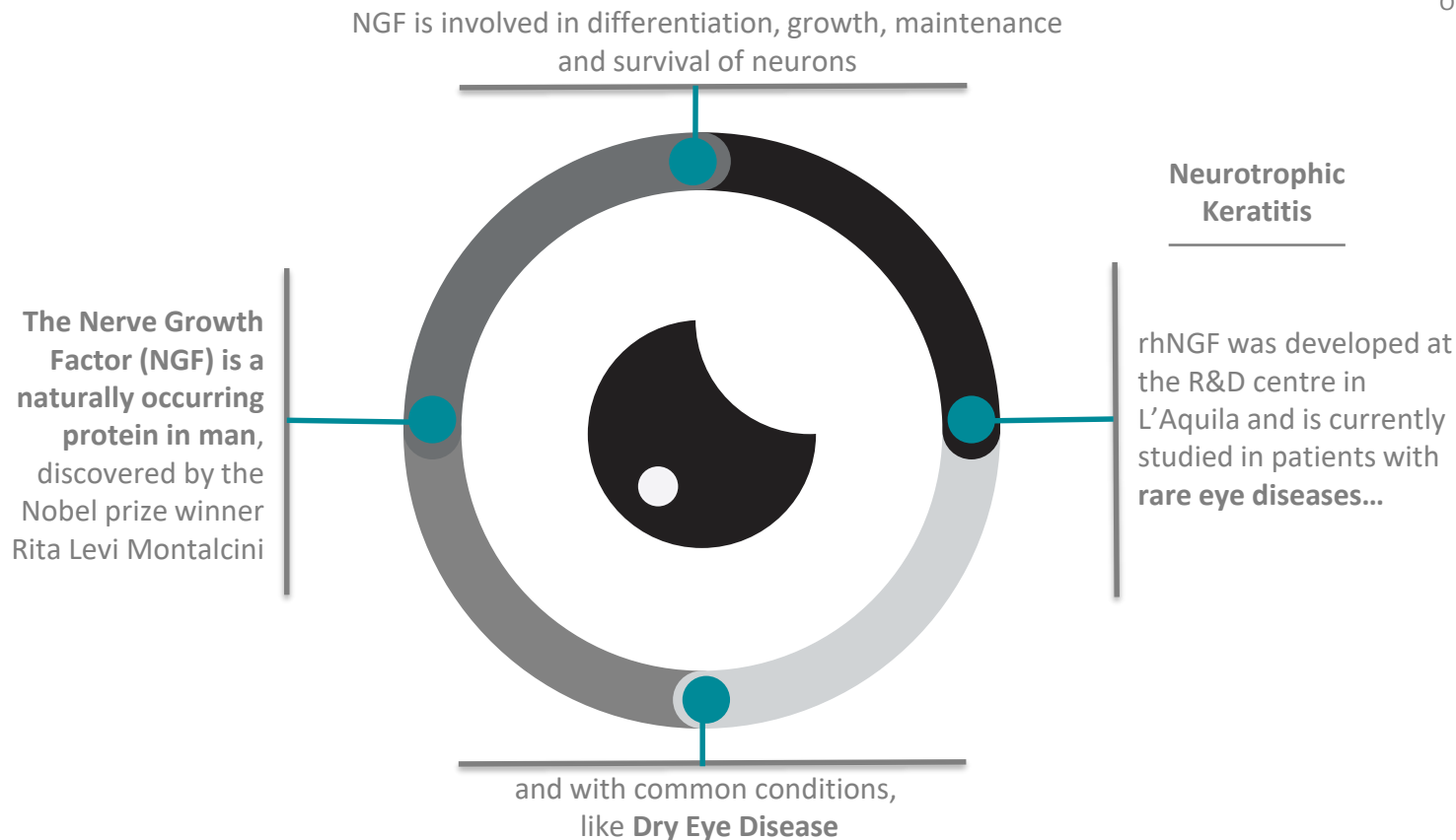
33 CENTRES



Data 2018



rhNGF (cenegermin): an all-round commitment in eye care



Il viaggio del farmaco: il nostro caso... di successo



Breakthrough Innovation: FDA approval

August 2018: FDA approval

oxervate[™] 0.002% (20 mcg/mL)
(cenegermin-bkbj) ophthalmic solution



Dompé receives FDA approval of Oxervate[™] eye drops (cenegermin-bkbj ophthalmic solution), first-in-class recombinant human nerve growth factor with potential to completely heal rare neurotrophic keratitis

- Oxervate is the first-ever application of a human nerve growth factor as drug or treatment, and is the first-ever topical biologic medication approved in ophthalmology.
- The first treatment specifically indicated for neurotrophic keratitis (NK), Oxervate has a mechanism of action that targets the root pathology of the disease.
- Oxervate has the potential to resolve the rare and progressive eye disease with one eight-week cycle of treatment; in clinical trials, approximately 72 percent of patients who used Oxervate achieved complete corneal healing after eight weeks of treatment, and of these patients, approximately 80 percent remained healed after one year.
- Oxervate was authorized by the European Medicines Agency (EMA) in 2017 and represents Dompé's first approved therapy in the United States, where Oxervate received Orphan Drug Designation, Fast Track Status, and Breakthrough Therapy Designation, which led to Priority Review.

Milan, Italy and San Bruno, California, August 22 2018. -- Dompé today announced that the U.S. Food and Drug Administration (FDA) has approved Oxervate[™] (cenegermin-bkbj ophthalmic solution), a breakthrough therapy for neurotrophic keratitis (NK), a rare and progressive eye disease that can lead to corneal scarring and vision loss.¹

"Neurotrophic keratitis can be disabling, hard to treat, and many patients do not respond well to existing therapies," said Reza Dana, Professor of Ophthalmology at Harvard Medical School, Director of the Cornea Service, Senior Scientist at the Massachusetts Eye and Ear, and Dompé medical advisor. "By directly promoting corneal healing, Oxervate has the potential to change the way neurotrophic keratitis is treated, and may eventually result in a new standard of care for patients with this rare condition."

Neurotrophic keratitis is a rare orphan condition that affects fewer than 65,000 persons in the

Learn about NGF & NK

What is Oxervate?

Oxervate[™] (cenegermin-bkbj ophthalmic solution) is the first-ever topical biologic medication approved by FDA. It is a recombinant human nerve growth factor (rhNGF) that promotes corneal healing in patients with neurotrophic keratitis (NK). Oxervate is the first-in-class treatment specifically indicated for NK, a rare and progressive eye disease that can lead to corneal scarring and vision loss. Oxervate was authorized by the European Medicines Agency (EMA) in 2017 and represents Dompé's first approved therapy in the United States, where Oxervate received Orphan Drug Designation, Fast Track Status, and Breakthrough Therapy Designation, which led to Priority Review.

What is Neurotrophic Keratitis?

Neurotrophic keratitis (NK) is a rare and progressive eye disease that can lead to corneal scarring and vision loss.

Symptoms may include:

- Eye irritation
- Corneal clouding
- Increasing eye redness

Over 65,000 people in the U.S. are affected¹

Oxervate & NK Fact Sheet

Baseline	Week 4	Week 8	Week 12

REPARO Study Image

Marketing

In 3 firsts, Dompé's regenerative eye drop Oxervate wins FDA nod for rare disease

The approval is special in that it marks three firsts in the U.S. drug history:

- After winning orphan drug and priority review designations, Oxervate on Wednesday became the first FDA-approved drug for NK
- Oxervate is the first application of a human NGF as drug
- As an eye drop, Oxervate is the first topical biologic approved in ophthalmology

BIOCENTURY

3:06 PM, AUG 22, 2018

BC EXTRA | COMPANY NEWS

FDA APPROVES FIRST DRUG FOR NEUROTROPHIC KERATITIS

BY SANDI WONG

FDA approved Oxervate cenegelein from Dompe Farmaceutici S.p.A. (Milan, Italy) to treat neurotrophic keratitis, a rare eye disease. Oxervate is the first drug approved in the U.S. for the indication, according to the agency.

A spokesperson said Dompe will launch Oxervate in the U.S. by early 2019 and that the price has not yet been determined.

The European Commission approved the drug in July 2017.

The recombinant human nerve growth factor (rhNGF) and has breakthrough therapy, Orphan Drug status and Fast Track designation from FDA for the indication.

Ophthalmology Times

Enter your keywords

Topics

Refractive

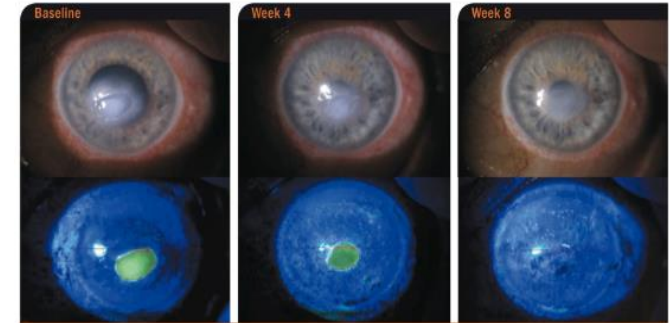
Cataract

Glaucoma

Cornea

Retina

New era for rare corneal disorder



Un altro esempio di network innovation:

Dompé Drug Discovery Platform – EXSCALTE

Il consorzio Antarex



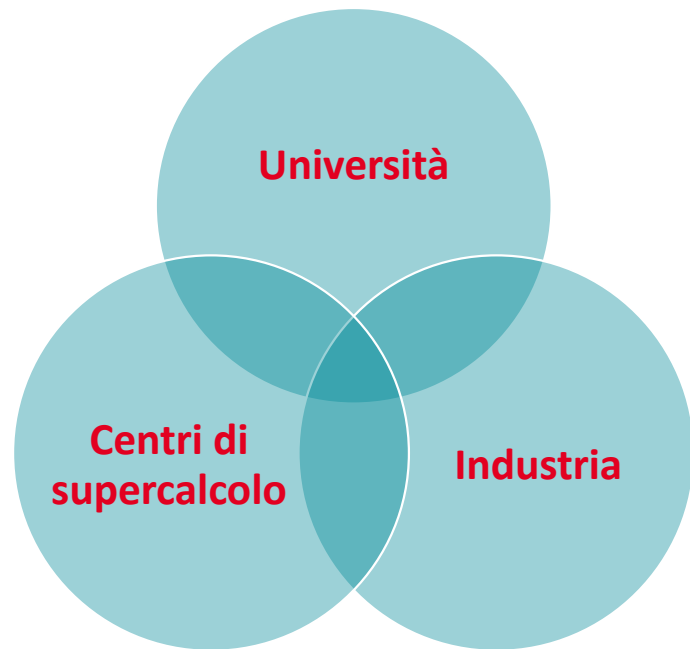
Dompé



IT4Innovations
national
supercomputing
center



ETH zürich



HPC-accelerated Drug Discovery System

Il consorzio Antarex è il frutto del lavoro di una rete di soggetti pubblici e privati per creare una piattaforma di screening virtuale.

Exscalate è una piattaforma di supercalcolo dotata di una “biblioteca chimica” di oltre 500 miliardi di molecole.

Può valutare contemporaneamente più di 3 milioni di molecole al secondo su 30 target biologici.

nature
International journal of science

Article | Published: 06 February 2019

Ultra-large library docking for discovering new chemotypes

Project information

ULTIMATE

Grant agreement ID: 777828

Status

Ongoing project

Start date

1 August 2017

End date

31 July 2019

Funded under:

H2020-EU.2.1.1. , H2020-EU.2.3.1.

Overall budget:

€ 2 011 662,50


EU contribution

€ 1 408 163



Coordinated by:

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