

Press Release

Australia

Major Life Saving Drugs Program funding for rare genetic disease

Sydney, 1 April, 2023 – Australia has joined more than 50 countries around the world in publicly funding an innovative, oral therapy for people with a potentially fatal condition known as Gaucher disease.^{1,2}

Announced by the Federal Health Minister for Health and Aged Care, Cerdelga® (eliglustat) will be added to Australia's Life Saving Drugs Program for the treatment of eligible adults with Gaucher disease type 1.

People with Gaucher disease do not have a sufficient level of an enzyme called beta-glucosidase (glucocerebrosidase) that breaks down a certain type of fat molecule. This causes symptoms such as anaemia (low red blood cell counts), tiredness, easy bruising, an enlarged spleen and liver resulting in a protruding abdomen, bone pain and fractures.¹ The most common form of Gaucher disease, type 1, which affects 90 per cent of people with the condition, generally does not affect the brain.³

The Sanofi clinical development program for Cerdelga is the largest ever conducted in Gaucher disease, with approximately 400 patients treated in 29 countries.

Before starting treatment with Cerdelga, the patient is tested to see how rapidly their bodies break down the medicine. Patients whose bodies break down Cerdelga very rapidly ('ultrarapid metabolisers') and patients who have not been tested, or for whom results of the test are not clear, should not take this medicine.¹

Cerdelga can only be obtained with a prescription and treatment should be started and supervised by a doctor who has experience in the management of Gaucher disease.¹

All medicines have side effects. The most common adverse reactions for Cerdelga (greater than or equal to 10%) are fatigue, headache, nausea, diarrhoea, back pain, pain in extremities, and upper abdominal pain.¹

Professor Stephan Opat

Director of Clinical Haematology, Monash Health

"As a lifelong condition, the goal of treatment is to help people affected by the symptoms of Gaucher disease, which include an enlarged abdomen, bone pain, fractures, fatigue and bruising, enjoy as normal a life as possible.

The availability of an oral therapy suitable for the majority of patients represents a significant shift from intravenous therapy in the management of Gaucher disease type 1."

Gidon Goodman

President, Gaucher Association of Australia & New Zealand

"This is fantastic news for the Gaucher Community. The last 16 years of my life have included a day every fortnight receiving treatment via an intrusive infusion. Today I feel fortunate to join the nine million Australians who take an oral therapy each day to manage chronic conditions."

Dr Kasia Siwek

Country Head of Medical - Speciality Care, Sanofi Australia and New Zealand

"For close to 40 years, Sanofi has been researching and developing life-saving therapies for Gaucher disease. As a partner of the rare disease community in Australia, we are proud to supply seven of the eighteen medicines listed on the Life Saving Drugs Program. Cerdelga® is a testament to our drive to innovate for people with rare diseases"

From April 1, Cerdelga is available on the Life Saving Drugs Program.

The Cerdelga Consumer Medical Information is available at the following link:

<https://www.nps.org.au/medicine-finder/cerdelga-capsules>

For information about Cerdelga, please contact Sanofi Medical Information at 1800 818 806.

Note to Editor:

Prof Stephen Opat has served on advisory boards and been involved in clinical trials sponsored by Sanofi for which compensation was received. For this Sanofi media announcement, no compensation was provided, and the opinions expressed are his own.

Gidon Goodman is the President of the Gaucher Association of Australia and New Zealand and lives with Gaucher disease type 1. In relation to this Sanofi media announcement, no compensation was provided, and the opinions expressed are his own.

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About Sanofi

We are an innovative global healthcare company, driven by one purpose: we chase the miracles of science to improve people's lives. Our team, across some 100 countries, is dedicated to transforming the practice of medicine by working to turn the impossible into the possible. We provide potentially life-changing treatment options and life-saving vaccine protection to millions of people globally while putting sustainability and social responsibility at the centre of our ambitions.

Sanofi is listed on EURONEXT: SAN and NASDAQ: SNY

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Issued by Ethical Strategies on behalf of Sanofi Australia.

References

1. Cerdelga® (eliglustat) Approved Product Information 31 May 2019
2. Sanofi Data on File. July 2022
3. Mayo Clinic. Gaucher Disease. <https://www.mayoclinic.org/diseases-conditions/gauchers-disease/symptoms-causes/syc-20355546> accessed June V2022

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