

## NITYR (nitisinone) Tablets for tyrosinaemia type 1 will be available with fully subsidised access on the Life Saving Drugs Program across Australia

MELBOURNE, Australia, April 29<sup>th</sup>, 2019 – [Orpharma Pty Ltd.](#) and [Cycle Pharmaceuticals Ltd.](#) are pleased to announce listing of NITYR™ (nitisinone) tablets on the [Life Saving Drugs Program \(LSDP\)](#) as of the 1<sup>st</sup> of May 2019.

NITYR™ was approved in June 2018 by the Australian Therapeutic Goods Administration (TGA) for the treatment of Hereditary Tyrosinaemia type 1 (HT-1) in combination with dietary restriction of tyrosine and phenylalanine. Listing on the LSDP will make the product readily available to all patients diagnosed with the condition. NITYR™ is the first generic nitisinone formulation to be listed on the LSDP.

Listing on the LSDP coincides with New Zealand's Pharmaceutical Management Agency (PHARMAC) Rare Disorders Subcommittee's recent decision to recommend funding of nitisinone with a high priority. A final decision is yet to be made by New Zealand's Pharmacology and Therapeutics Advisory Committee (PTAC). These outcomes will make NITYR™ the first and only generic nitisinone formulation readily available in the southern hemisphere.

NITYR™ is currently approved by a number of competent authorities and has been available in a number of jurisdictions including the United States and Canada.

HT-1 is an ultra-rare genetic disease that can cause hepatic, renal and neurological complications. In most cases, if left untreated, the disease is fatal. The current number of patients with this condition in Australia is estimated at 20 patients.

NITYR™ was developed by [Cycle Pharmaceuticals Ltd.](#) after many years of research and development to find an alternative formulation to ORFADIN\* (nitisinone) capsules. NITYR™ is clinically proven to be bioequivalent to ORFADIN; has an improved formulation allowing it to be stored at room temperature and administered with or without food. NITYR™ tablets are small and tasteless allowing for ease of swallowing and are available in 2, 5 and 10 mg strengths. NITYR™ can be disintegrated in water and administered using an oral syringe, the preparation can be stored for up to 24 hours, allowing NITYR™ to be used by patients of any age.

**Please review the Product Information before prescribing. The Product information can be accessed at: <http://www.orpharma.com/products/orphan>**

NITYR is a registered trademark of Cycle Pharmaceuticals Limited in the United Kingdom, licensed by Orpharma Pty Ltd in Australia and New Zealand. – GL-0014 (April 2019)

\*Orfadin is a registered trademark of Swedish Orphan Biovitrum International AB (publ).

### About Orpharma

Orpharma is an Australian pharmaceutical company focused on the supply of orphan, paediatric and emerging therapeutics. Orpharma is Australia's first and only one stop shop for metabolic products supplying a range of low protein food, medical nutrition and medicines. Orpharma is collaborating with global leaders in biotechnology and pharmaceuticals to deliver therapies to patients in need. The company's current product portfolio includes innovative medicines targeting rare metabolic diseases, cancer and anti-infectives. For more information about Orpharma visit [www.orpharma.com](http://www.orpharma.com)

## **About Cycle Pharmaceuticals**

Cycle is a pioneering pharmaceutical company, reimagining how drugs can benefit patients to make their lives easier and improve their quality of life at every stage. Specifically, Cycle focuses on three areas of pharmaceutical development:

- Improving orphan drugs, which treat the under-served rare disease patient community;
- Repurposing drugs – creating a new indication for an already existing drug; and
- Generics – reinstating generic drugs previously available in the market

With Headquarters in Cambridge (UK) and offices in Boston, Mass. (USA), Cycle has developed unique partnerships with renowned universities around the world. For further information, please visit [www.cyclepharma.com](http://www.cyclepharma.com).

## **FOR FURTHER INFORMATION PLEASE CONTACT**

Hala Raghieb, CEO, Orpharma Pty Ltd.

Phone: +61 3 9863 7411

E-mail: [enquiries@orpharma.com](mailto:enquiries@orpharma.com)