ANALOG PHARMA AND DIPHARMA ANNOUNCE US FDA APPROVAL OF ABBREVIATED NEW DRUG APPLICATION (ANDA) OF 20 mg GENERIC NITISINONE CAPSULES (TEMPERATURE STABLE)

Princeton, NJ and Chiasso, Switzerland, May 31st, 2023 – Analog Pharma (member of Duchesnay Pharmaceutical Group, hereafter "Analog") and Dipharma S.A. ("Dipharma") are pleased to announce that their 20 mg nitisinone abbreviated new drug application (ANDA) has received final approval from the U.S. Food and Drug Administration. Nitisinone Capsules are a room temperature stable, AB-rated, generic equivalent of Swedish Orphan Biovitrum's Orfadin®, and are now available in 2, 5, 10 and 20 mg capsules. Analog currently distributes the 2, 5, and 10 mg products through specialty pharmacies and now has available the 20 mg capsules for distribution.

Nitisinone capsules are a hydroxy-phenylpyruvate dioxygenase inhibitor indicated for the treatment of adult and pediatric patients with hereditary tyrosinemia type 1 (HT-1) in combination with dietary restriction of tyrosine and phenylalanine. Since its use as the first-line treatment of HT-1, nitisinone has replaced liver transplantation for this rare condition. The most common side effects of nitisinone are elevated tyrosine levels, low platelet count, low white blood cell count, pink eye, white or cloudy cornea from scarring, inflammation of the cornea, light sensitivity, eye pain, inflammation of the eye lid, cataracts, low granulocytes - cells involved with immunity, nose bleeds, itching of the skin, redness and scaling of the skin, dry skin, rash and hair loss.

Tanya Carro, Executive Vice President, Analog Pharma, commented, "*With the approval of the 20 mg capsule, we now have a full complement of room temperature stable strengths for our generic Nitisinone. Considering that the 20 mg is the most commonly prescribed strength of Orfadin®, this will bring American patients with Hereditary Tyrosinemia type-1 (HT-1) a room temperature stable treatment option. The addition of this new dosage form to our portfolio demonstrates our continued commitment to offering high quality cost-effective generic drugs for the treatment of rare diseases.* "

Analog's Nitisinone capsules are available to eligible patients for as little as $0* per prescription.

"*We are pleased to announce that the FDA has now approved our 20 mg Nitisinone capsules:"* - said Marc-Olivier Geinoz, CEO of Dipharma – "*For the first time, American HT-1 patients will have access to 20 mg capsules which are stable at room temperature for 3 years. This is the result of the collaboration between Dipharma and our American partner Analog Pharma, which achieved this milestone ahead of time: our next milestone for this year is to extend – from 2 to 3 years - the stability at room temperature of the lower strength capsules as well. Dipharma is a pioneer in developing improved generic pharmaceutical products for rare diseases: our desire to innovate and our engagement do not stop, but every day we continue to seek new and better solutions for patients around the world*".

*Terms and conditions apply

About HT-1

Hereditary Tyrosinemia type-1 (HT-1) is a rare inborn error of metabolism (IEM) in which the body is unable to completely break down the amino acid tyrosine, and so harmful substances are formed, causing serious liver problems and liver cancer. HT-1 is progressive and can be fatal if untreated. For more information on HT-1, please visit https://www.dipharma.ch/metabolic-diseases/hereditary-tyrosinemia-type-1/.

About Nitisinone

INDICATION

Nitisinone capsules are a hydroxy-phenylpyruvate dioxygenase inhibitor indicated for the treatment of adult and pediatric patients with hereditary tyrosinemia type 1 (HT-1) in combination with dietary restriction of tyrosine and phenylalanine.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Increased levels of plasma tyrosine, eye symptoms, developmental delay and skin changes:

- Inadequate restriction of tyrosine and phenylalanine intake can lead to elevations in plasma tyrosine
- Maintain reduction in dietary tyrosine and phenylalanine while on nitisinone.
- Your healthcare provider should not adjust your dosage of nitisinone in order to lower the plasma tyrosine concentration.
- Plasma tyrosine levels greater than 500 micromol/L may lead to the following:
    - Ocular signs and symptoms including corneal ulcers, corneal opacities (cornea appears white or cloudy due to scarring), keratitis (inflammation of the cornea), conjunctivitis (pink eye - inflammation or infection of the outer membrane of the eye), eye pain, and light sensitivity
        - Your healthcare provider will obtain slit-lamp examination prior to treatment, regularly during treatment and may reexamine you if you develop symptoms or if your tyrosine levels exceed 500 micromol/L.
    - Variable degrees of intellectual disability and developmental delay
    - Painful hyperkeratotic plaques (thickening of the skin) on the soles and palms.
- Maintain plasma tyrosine levels below 500 micromol/L.

Changes in blood profile:

- You may develop leukopenia (low white blood cell count), severe thrombocytopenia (low number platelets, the cells that help the blood to clot), or both.
- Your healthcare provider will monitor white blood cell and platelet counts during treatment with nitisinone.

ADVERSE REACTIONS

The most common side effects (>1%) of nitisinone are elevated tyrosine levels, low platelet count, low white blood cell count, pink eye, white or cloudy cornea from scarring, inflammation of the cornea, light sensitivity, eye pain, inflammation of the eye lid, cataracts, low granulocytes - cells involved with immunity, nose bleeds, itching of the skin, redness and scaling of the skin, dry skin, rash and hair loss.

DRUG INTERACTIONS

Nitisinone can interfere with other medicines.
Tell your healthcare provider about all the medicines you take.

USE IN SPECIFIC POPULATIONS

- **Pregnancy:** Limited available data with nitisinone use in pregnant women are not sufficient to determine a drug-associated risk of adverse development outcomes. Tell your healthcare provider immediately if you are pregnant or plan to get pregnant.
- **Lactation:** There are no data on the presence of nitisinone in human milk, the effects on the breastfed infant, or the effects on milk production. Tell your healthcare provider immediately if you are breastfeeding or plan to breastfeed.
- **Pediatric Use:** The safety and effectiveness of nitisinone have been established in pediatric patients for the treatment of HT-1 in combination with dietary restriction of tyrosine and phenylalanine.
- **Geriatric Use:** Clinical studies of nitisinone did not include any subjects aged 65 and over.

Please read the Full Prescribing Information and Patient Instructions here.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

About Dipharma
Dipharma S.A. is a Swiss specialty pharmaceutical company, developing high quality, improved, medicines for rare diseases. Dipharma S.A. is part of a third-generation group of family-owned companies that have grown to a global presence.
With a portfolio of generic orphan products for the treatment of Phenylketonuria, Gaucher Disease, Hereditary Tyrosinemia Type 1, Urea Cycle Disorders and others, Dipharma S.A. provides improved solutions for patients affected by inborn metabolic diseases at an affordable cost and with a global reach. For more information, please visit www.dipharma.ch

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About Analog Pharma
Analog Pharma, member of Duchesnay Pharmaceutical Group, is headquartered in Princeton, NJ, and is dedicated to producing the highest quality generic medications. Its goal is to ensure the widest possible access to high-quality medications that healthcare professionals and patients have come to rely on by producing generic versions of exceptional quality. Analog Pharma takes great pride in providing the generic medications that patients need, when they need them. For more information, please visit www.analogpharma.com

About Duchesnay Pharmaceutical Group
Duchesnay Pharmaceutical Group, with its affiliated companies, is headquartered in Blainville, Quebec. The group consists of five pharmaceutical companies to meet the needs of patients in Canada, the U.S., and abroad. The companies are Duchesnay and Duchesnay USA, both dedicated to women's health; Médunik Canada and Medunik USA, which provide treatments for rare diseases; and Analog Pharma, an American generic drugs company, specializing in authorized generics and orphan drugs. From its state-of-the-art manufacturing plant, the Group can export its innovative treatments to more than 50 countries.

Duchesnay, Medunik and Analog, through their proprietary research and development, and through partnerships, offer innovative treatments for a variety of medical conditions in women's health, urology, oncology as well as for rare diseases. The group of companies recognizes the dedication and

professionalism of its employees and promotes a positive culture and flexible work environment. It is deeply committed to environmental responsibility and giving back to the community through the support of various charitable organizations. For more information, please visit duchesnaypharceuticalgroup.com or analogpharma.com.

Orfadin® is a registered trademark of Swedish Orphan Biovitrum/SOBI. In the United States of America Orfadin® was first approved in January 2002 for the treatment of HT-1.

DISCLAIMER

This press release may contain certain forward-looking statements. Although the Company believes its expectations are based on reasonable assumptions, these forward-looking statements are subject to numerous risks and uncertainties, including scientific, business, economic and financial factors, which could cause actual results to differ materially from those anticipated in the forward-looking statements. The company assumes no responsibility to update forward-looking statements or adapt them to future events or developments.

Analog Pharma and Dipharma S.A. operates respectfully of any third party IP rights and/or regulatory exclusivities that may exists in each specific country.

This press release may contain information on pharmaceuticals that are not currently approved or available in your country or region.

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