



# FDA GRANTS PRIORITY REVIEW FOR NEW DRUG APPLICATION FOR OLEOGEL-S10 FOR THE TREATMENT OF EPIDERMOLYSIS BULLOSA

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## FDA Grants Priority Review for New Drug Application for Oleogel-S10 for the Treatment of Epidermolysis Bullosa

*PDUFA date of November 30, 2021 set for Oleogel-S10*

**DUBLIN, Ireland, and Boston MA, June 3, 2021,** Amryt (Nasdaq: AMYT, AIM: AMYT), a global, commercial-stage biopharmaceutical company dedicated to acquiring, developing and commercializing novel treatments for rare diseases, today announces that the U.S. Food and Drug Administration (“FDA”) has granted Priority Review for Amryt’s New Drug Application (“NDA”) for Oleogel-S10 for the treatment of Epidermolysis Bullosa (“EB”). Oleogel-S10 is a potential treatment for the cutaneous manifestations of Junctional and Dystrophic EB, a rare and distressing genetic skin disorder affecting young children and adults for which there is currently no approved treatment.

Priority Review is granted by the FDA to applications for medicines that, if approved, would provide significant improvements in the effectiveness or safety of the treatment, diagnosis, or prevention of serious conditions when compared to standard applications. In general, the FDA’s Priority Review designation accelerates the review time from ten months to a goal of six months from the date of acceptance of the filing.

The FDA has set a Prescription Drug User Fee Act (“PDUFA”) target action date for the Oleogel-S10 NDA of November 30, 2021.

Oleogel-S10 previously received Fast Track Designation and Rare Pediatric Disease Designation from the FDA. If the NDA for Oleogel-S10 is approved, the Company will apply for a priority review voucher.

**Joe Wiley, CEO of Amryt Pharma, commented:** *“We are very pleased that the FDA has confirmed priority review of our NDA for Oleogel-S10. Confirmation of a target PDUFA date of November 30, 2021 keeps us on track for a potential approval this year. If approved, Oleogel-S10 could potentially be an important treatment option for patients suffering from EB, a serious and debilitating disease for which there are currently no approved treatments and our launch plans for Oleogel-S10 are well advanced.”*

## **About Amryt**

Amryt is a global commercial-stage biopharmaceutical company focused on acquiring, developing and commercializing innovative treatments to help improve the lives of patients with rare and orphan diseases. Amryt comprises a strong and growing portfolio of commercial and development assets.

Amryt's commercial business comprises two orphan disease products – metreleptin (Myalept®/ Myalepta®) and lomitapide (Juxtapid®/ Lojuxta®).

Myalept®/Myalepta® (metreleptin) is approved in the US (under the trade name Myalept®) as an adjunct to diet as replacement therapy to treat the complications of leptin deficiency in patients with congenital or acquired generalized lipodystrophy (GL) and in the EU (under the trade name Myalepta®) as an adjunct to diet for the treatment of leptin deficiency in patients with congenital or acquired GL in adults and children two years of age and above and familial or acquired partial lipodystrophy (PL) in adults and children 12 years of age and above for whom standard treatments have failed to achieve adequate metabolic control. For additional information, please follow this [link](#).

Juxtapid®/Lojuxta® (lomitapide) is approved as an adjunct to a low-fat diet and other lipid-lowering medicinal products for adults with the rare cholesterol disorder, Homozygous Familial Hypercholesterolaemia ("HoFH") in the US, Canada, Colombia, Argentina and Japan (under the trade name Juxtapid®) and in the EU, Israel and Brazil (under the trade name Lojuxta®). For additional information, please follow this [link](#).

Amryt's lead development candidate, Oleogel-S10 (Filsuvez®) is a potential treatment for the cutaneous manifestations of Junctional and Dystrophic Epidermolysis Bullosa ("EB"), a rare and distressing genetic skin disorder affecting young children and adults for which there is currently no approved treatment. Filsuvez® has been selected as the brand name for Oleogel-S10. The product does not currently have regulatory approval to treat EB.

Amryt's pre-clinical gene therapy platform, AP103, offers a potential treatment for patients with Dystrophic EB, and is also potentially relevant to other genetic disorders.

For more information on Amryt, including products, please visit [www.amrytpharma.com](http://www.amrytpharma.com).

This announcement contains inside information for the purposes of article 7 of the Market Abuse Regulation (EU) 596/2014. The person making this notification on behalf of Amryt is Rory Nealon, CFO/COO and Company Secretary.

## **Financial Advisors**

Shore Capital (Edward Mansfield, Daniel Bush, John More) are NOMAD and Joint Broker to Amryt in the UK. Stifel (Ben Maddison) are Joint Broker to the company in the UK.

## **Forward-Looking Statements**

This press release may contain forward-looking statements containing the words "expect", "anticipate", "intends", "plan", "estimate", "aim", "forecast", "project" and similar expressions (or their negative) identify certain of these forward-looking statements. The forward-looking statements in this announcement are based on numerous assumptions and Amryt's present and future business strategies and the environment in which Amryt expects to operate in the future. Forward-looking statements involve inherent known and unknown risks, uncertainties and contingencies because they relate to

events and depend on circumstances that may or may not occur in the future and may cause the actual results, performance or achievements to be materially different from those expressed or implied by such forward-looking statements. These statements are not guarantees of future performance or the ability to identify and consummate investments. Many of these risks and uncertainties relate to factors that are beyond each of Amryt's ability to control or estimate precisely, such as future market conditions, the course of the COVID-19 pandemic, currency fluctuations, the behaviour of other market participants, the outcome of clinical trials, the actions of regulators and other factors such as Amryt's ability to obtain financing, changes in the political, social and regulatory framework in which Amryt operates or in economic, technological or consumer trends or conditions. Past performance should not be taken as an indication or guarantee of future results, and no representation or warranty, express or implied, is made regarding future performance. No person is under any obligation to update or keep current the information contained in this announcement or to provide the recipient of it with access to any additional relevant information that may arise in connection with it. Such forward-looking statements reflect the Company's current beliefs and assumptions and are based on information currently available to management.

### **Contacts**

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