AMRYT PHARMA PLC

("**Amryt**" or the "**Company**")

AMRYT ANNOUNCES POSITIVE TOP LINE RESULTS FROM PIVOTAL PHASE 3 "EASE" TRIAL OF FILSUVEZ® IN EPIDERMOLYSIS BULLOSA

- Primary endpoint met with statistical significance (p-value = 0.013)
- FILSUVEZ® demonstrated a good safety profile
- EASE is the first Phase 3 trial to demonstrate a statistically significant increase in speed of wound healing in Epidermolysis Bullosa
- Rolling US regulatory submissions already underway with FDA with priority review request planned
- EU regulatory submission planned with request for accelerated assessment
- FILSUVEZ®, a topical therapeutic gel, has the potential to be the first treatment approved for Epidermolysis Bullosa

Analyst and investor call today at 08.30 ET/13.30 BST

DUBLIN, Ireland, and Boston MA, 9 September 2020, Amryt (Nasdaq: AMYT, AIM: AMYT), a global, commercial-stage biopharmaceutical company dedicated to developing and commercializing novel therapeutics to treat patients suffering from serious and life-threatening rare diseases, is very pleased to announce positive top line results from its pivotal Phase 3 EASE trial of FILSUVEZ® (previously AP101 /Oleogel-S10) for the treatment of dystrophic and junctional Epidermolysis Bullosa ("EB"). The primary endpoint of the trial was met (p-value = 0.013). EASE is the largest Phase 3 trial ever conducted in EB.

Dr Joe Wiley, CEO of Amryt Pharma, commented: *"This positive outcome of the Phase 3 EASE trial marks another significant milestone for Amryt as we seek approval for FILSUVEZ® and represents a potentially important advancement for patients and families living with this rare and distressing disorder. If approved, we intend to leverage our existing global infrastructure to commercialize FILSUVEZ®.*

We are proud to present these positive and encouraging results, demonstrating that FILSUVEZ® could make an important difference to the lives of patients. We would like to extend our gratitude to all of the patients, their families, carers and physicians for their participation in the EASE trial and we look forward to working with regulatory authorities to make FILSUVEZ® available as the first approved therapeutic treatment for EB patients. All of the team at Amryt are very excited by today's news and the impact this may have in our efforts to help patients with this very distressing condition."

EB is a rare, chronic and distressing genetic skin disorder that causes the skin layers and internal body linings to separate and affects infants, children and adults. The global incidence of EB is estimated to be approximately 1 in 20,000, which implies that there are as many as 30,000 affected individuals in the US and over 500,000 worldwide. There are currently no approved treatments. The global market opportunity for EB is estimated by the Company to be in excess of $1.0 billion.

EASE Results

The EASE trial (NCT03068780) is the largest ever global Phase 3 trial conducted in patients with EB, performed across 58 sites in 28 countries. It comprises a 3 month double-blind randomised controlled phase followed by a 24 month open-label, single-arm phase. Patients with EB target wounds of between 10 and 50cm^2 in size that were present for > 21 days and < 9 months were randomized in the double-blind phase to study treatment in a 1:1 ratio and wound dressings applied according to standard of care.

223 patients were enrolled into the trial including 156 pediatric patients. Of those that completed the double-blind phase, 100% entered the open label safety follow up phase.

The primary endpoint of the trial was to compare the efficacy of FILSUVEZ® versus control gel according to the proportion of patients with complete closure of the target wound within 45 days of treatment. The primary endpoint was achieved with statistical significance (p-value = 0.013). This represents the first ever successful Phase 3 top line readout in EB. It is also the fourth time FILSUVEZ® has demonstrated accelerated wound healing in a Phase 3 trial.

While the key secondary endpoints did not achieve statistical significance, a number of favourable differences were observed. In addition, substantial further secondary endpoint data is expected and will be analysed over the coming weeks.

Next Steps

The Company will now evaluate and analyse the full data set from the trial and will present results at an upcoming scientific symposium.

Amryt intends to complete the submission of its rolling New Drug Application ("NDA") to the US Food and Drug Administration ("FDA") and request priority review for FILSUVEZ®. FILSUVEZ® previously received Fast Track Designation and Rare Paediatric Disease Designation from the FDA. This means that if an NDA for FILSUVEZ® is approved, the Company expects to be eligible to apply for a Rare Pediatric Disease Priority Review Voucher that can be used, sold or transferred. Amryt also intends to pursue an accelerated assessment in the EU. Regulatory submissions in the US and the EU are expected to be filed by late Q1 2021.

FILSUVEZ® has been granted Orphan Drug status for the treatment of EB in the EU and the US. Should FILSUVEZ® be granted approval, it should be entitled to Orphan Drug exclusivity for the treatment of EB, extending seven years in the US and ten years in the EU from the date of approval in the respective jurisdictions.

Dr Mark Sumeray, Chief Medical Officer of Amryt commented: *"The conduct of a global clinical trial involving 58 centres in 28 countries in such a rare serious and predominantly pediatric disease has been a challenging but enormously important undertaking. It is very gratifying to see the first results from the trial provide evidence of the effect of FILSUVEZ® on the speed of wound healing in such a complex clinical situation. We look forward to further data over the next few weeks."*

Brett Kopelan, Executive Director of debra of America and President of Debra International, commented: *"The very positive results of the largest international clinical trial conducted in EB is an incredibly exciting development and a very important milestone for the global EB community. I want to thank the entire team at Amryt for the commitment and fortitude it took to complete this trial. The proven ability to address the hallmark manifestation of this devastating disease, chronic wounds that don't heal, in such an efficacious manner and as a therapy applied as part of the standard of care will undoubtedly lead to a meaningful quality of life improvement for patients living with the "worst*

disease you've never heard of". As the executive director of debra of America and as the President of Debra International, but more importantly as the father of a 13 year-old daughter with recessive dystrophic EB, I couldn't be more enthused."

Professor Johannes Kern, of Royal Melbourne Hospital and Principal Investigator of the trial commented: *"I have had the privilege of working with a number of patients and their families affected by EB which is an incredibly distressing condition for all of those involved. I am very excited by the possibility that a treatment such as FILSUVEZ® could potentially accelerate wound healing and alleviate the symptoms for those affected."*

The Amryt Management team will host an analyst and investor call today at **08.30 ET / 13.30 BST** to discuss the news and answer questions.

Dial-in details for the call:

Standard International Number	+44 (0) 203 009 5709
United States (Local)	+1 646 787 1226
United Kingdom (Local)	+44 (0) 844 493 6766
Ireland (Local)	+ 353 (1) 506 0626
Confirmation Code	**8769437**

A playback facility will be available from September 9, 2020 at 1330 ET / 1830 BST – September 16, 2020 at 1330 ET / 1830 BST. Access details as follows: Confirmation Code: 8769437 | US: + 1 917 677 7532 | UK/International: +44 (0) 3333 00 9785 | Ireland : +353 (1) 553 8777.

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About Amryt

Amryt is a biopharmaceutical company focused on developing and delivering innovative new 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.

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, Columbia, Argentina and Japan (under the trade name Juxtapid®) and in the EU (under the trade name Lojuxta®). HoFH is a rare genetic disorder which

impairs the body's ability to remove low density lipoprotein ("LDL") cholesterol ("bad" cholesterol) from the blood, typically leading to abnormally high blood LDL cholesterol levels in the body from before birth - often ten times more than people without HoFH - and subsequent aggressive and premature cardiovascular disease.

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®) 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. Metreleptin is also approved for lipodystrophy in Japan. Generalised and partial lipodystrophy are rare disorders characterised by loss or lack of adipose tissue resulting in the deficiency of the hormone leptin, produced by fat cells and are associated with severe metabolic abnormalities including severe insulin resistance, diabetes, hypertriglyceridemia and fatty liver disease.

Amryt's lead development candidate, FILSUVEZ® is a potential treatment for the cutaneous manifestations of EB, a rare and distressing genetic skin disorder affecting young children and adults for which there is currently no approved treatment. FILSUVEZ® has been granted Rare Pediatric Disease Designation and has also received a Fast Track Designation from the U.S. Food and Drug Administration. The global market opportunity for EB is estimated by the Company to be in excess of $1.0 billion.

In March 2018, Amryt in-licenced a pre-clinical gene-therapy platform technology, AP103, which offers a potential treatment for patients with Recessive Dystrophic Epidermolysis Bullosa, a subset of EB, and is also potentially relevant to other genetic disorders.

For more information on Amryt, including products, please visit 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. Davy (John Frain, Daragh O'Reilly) act as Joint Broker to the company.

Forward-Looking Statements

Statements in this announcement with respect to Amryt's business, strategies, timing for completion of and announcing results from the EASE trial, the potential impact of closing enrollment in the EASE trial, as well as other statements that are not historical facts are forward-looking statements involving risks and uncertainties which could cause the actual results to differ materially from such statements. 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.