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Amryt Pharma plc
("Amryt" or the "Company")

Amryt receives IND approval from FDA for AP101 enabling the opening of US clinical trial sites

Amryt, a biopharmaceutical company focused on rare and orphan diseases, today announces that the US Food and Drug Administration ("FDA") has granted Investigational New Drug ("IND") clearance for AP101. This enables the Company to begin opening US clinical trial sites as part of its ongoing global EASE Phase III clinical trial in Epidermolysis Bullosa ("EB").

EB is a rare genetic skin disorder that can cause skin to blister and tear from the slightest friction or trauma and can, in some cases, cause blistering and erosion of the epithelial lining of internal organs. EB is chronic, potentially disfiguring and life limiting. There are approximately 500,000 people living with EB worldwide and there are currently no approved treatments.[1]

AP101 is currently in a Phase III clinical trial (EASE), the largest ever global Phase III study conducted in patients with EB. Trial sites are already open across Europe, Australasia, Latin America and the Middle East and an interim efficacy data readout is due later this year with the top-line data readout expected in Q2 2019.

Joe Wiley, CEO of Amryt Pharma, commented: *"As part of the study design, it was always planned that US trial sites would become part of our EASE Phase III clinical trial. We are pleased with today's IND clearance from the FDA as it will accelerate patient enrolment into the largest ever global EB trial undertaken. Moreover, the FDA's decision is positive news for eligible American sufferers of this rare condition who can now participate in the study."*

[1] https://www.debra.org.uk/what-is-eb/what-is-eb

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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 or orphan diseases.

Lojuxta is an approved treatment for adult patients with the rare cholesterol disorder - Homozygous Familial Hypercholesterolaemia ("HoFH"). This disorder 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 narrowing and blocking of blood vessels, heart attacks and strokes, even at a very young age if not properly diagnosed or receiving adequate treatment. Lojuxta is indicated as an adjunct to a low-fat diet and other lipid-lowering medicinal products with or without LDL apheresis in adult patients with HoFH.

Amryt holds an exclusive licence to sell Lojuxta (lomitapide) across the European Economic Area, Middle East and North Africa, Switzerland, Turkey, Israel, Russia, the Commonwealth of Independent States and the non-EU Balkan states.

Amryt's lead drug candidate, AP101, is a potential treatment for Epidermolysis Bullosa ("EB"), a rare and distressing genetic skin disorder affecting young children and adults for which there is currently no treatment. It is currently in Phase III clinical trials. The European and US market opportunity for EB is estimated to be in excess of €1 billion.

Amryt's earlier stage product, AP102, is focused on developing novel, next generation somatostatin analogue ("SSA") peptide medicines for patients with rare neuroendocrine diseases, where there is a high unmet medical need, including Acromegaly and Cushing's disease.

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, please visit amrytpharma.com