European Commission approves Mycapssa® for the treatment of Acromegaly

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Mycapssa® will be the first and only oral somatostatin analog approved in the EU

Approval based on MPOWERED Phase 3 trial

DUBLIN, Ireland, and Boston MA, December 5, 2022, Amryt (Nasdaq: AMYT), a global, commercial-stage biopharmaceutical company dedicated to acquiring, developing and commercializing novel treatments for rare diseases, is pleased to announce the European Commission (EC) approval of Mycapssa® in the European Union (EU) for the maintenance treatment of acromegaly in patients who have responded to and tolerated treatment with octreotide or lanreotide. Mycapssa® is already approved in the United States for long-term maintenance treatment in acromegaly patients who have responded to and tolerated treatment with injectable octreotide or lanreotide.

The centralised marketing authorisation will be valid in all EU Member States as well as in Iceland, Liechtenstein, and Norway. The EC approval of Mycapssa® is supported by efficacy and safety data from three Phase 3 studies in acromegaly patients including the pivotal MPOWERED Phase 3 trial.

Dr Joe Wiley, CEO of Amryt Pharma, commented: *"The EC approval of Mycapssa® is a significant development for acromegaly sufferers in Europe and Mycapssa® will be the first and only oral somatostatin analog approved in the EU."*

About the MPOWERED Phase 3 Trial
The MPOWERED trial was a global, randomized, open-label and active-controlled, 15-month trial intended to support approval of Mycapssa® in the EU. Chiasma/Amryt completed enrollment of 146 adult acromegaly patients into the trial in June 2019, of which 92 patients who were deemed responders to octreotide capsules per the protocol following a six-month run-in were randomized to either octreotide capsules (n=55) or injectable somatostatin receptor ligands (iSRLs) (octreotide long-acting release or lanreotide autogel) (n=37). These patients were then followed for an additional nine months in the randomized controlled treatment (RCT) phase. At the end of the RCT phase patients were provided the option to continue into an open label phase and receive Mycapssa®. The study met its primary non-inferiority endpoint. 91% of patients on Mycapssa® maintained insulin-like growth factor 1 (IGF-1) response (95% CI 80-97), throughout the RCT, compared to 100% on iSRLs (95% CI 91-100). Response was defined as the time-weighted average of IGF-1 <1.3 x upper limit of normal (ULN) during the 9-month RCT phase.

In addition to biochemical control, the MPOWERED study explored the effects of treatment on acromegaly symptom control. The overall number of individual active acromegaly symptoms at the end of the randomised treatment phase were similar between the treatment groups with 75% of Mycapssa® patients versus 70% of iSRL treated patients maintaining or reducing their overall number of active acromegaly symptoms compared with start of the randomised treatment phase. In another Phase 3 study (CH-ACM-01), individual symptom scores for swelling of extremities and joint pain showed a statistically significant improvement at the end of treatment with Mycapssa®, compared to the baseline scores where subjects were treated with injectable somatostatin analogues ($p = 0.0165$ and $p = 0.0382$ respectively). MPOWERED similarly showed improvement with Mycapssa® treatment in active acromegaly symptoms from baseline (run-in) to the end of the run-in; swelling of extremities ($p=0.011$) and fatigue ($p=0.031$), for the patients that then enrolled into the randomised phase of the study.

About Acromegaly
Acromegaly typically develops when a benign tumor of the pituitary gland produces too much growth hormone, ultimately leading to significant health problems. Common features of acromegaly are facial changes, intense headaches, joint pain, impaired vision and enlargement of the hands, feet, tongue and internal organs. Serious health conditions associated with the progression of acromegaly include type 2 diabetes, hypertension, respiratory disorders and cardiac and cerebrovascular disease. For many patients with acromegaly, despite being considered biochemically controlled with iSRLs, they still experience persistent acromegaly symptoms.

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 four orphan disease products – metreleptin (Myalept®/ Myalepta®); oral octreotide (Mycapssa®); lomitapide (Juxtapid®/ Lojuxta®); and Oleogel-S10 (Filsuvez®).

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.

Mycapssa® (octreotide capsules) is approved in the US and the EU for long-term maintenance therapy in acromegaly patients who have responded to and tolerated treatment with octreotide or lanreotide. Mycapssa® is the first and only oral somatostatin analog approved by the FDA and the EC. 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, Saudi Arabia and Brazil (under the trade name Lojuxta®). For additional information, please follow this link.

Filsuvez® is approved in the EU and Great Britain for the treatment of partial thickness wounds associated with junctional and dystrophic Epidermolysis Bullosa in

patients 6 months and older.

Amryt's pre-clinical gene therapy candidate, AP103, offers a potential treatment for patients with Dystrophic EB, and the polymer-based delivery platform has the potential to be developed for the treatment of other genetic disorders.

For more information on Amryt, including products, please visit www.amrytpharma.com.

Forward-Looking Statements

This announcement may contain forward-looking statements and 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 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.

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