

Amryt Pharma PLC

07:26 15 Sep 2020

Amryt Pharma set to receive orphan designation for pre-clinical skin treatment

Amryt Pharma PLC (NASDAQ: AMYT, LON:AMYT) looks set to receive orphan designation for its preclinical gene therapy for the rare skin condition dystrophic epidermolysis bullosa, which would provide the company with regulatory and financial incentives.

A European Medicines Agency (EMA) committee has delivered what's called a "positive opinion" on the drug candidate, which is normally followed 30 days later by full ratification.

Orphan status is designed to aid the development and sign-off of life-threatening or chronically debilitating conditions affecting no more than five in 10,000 people. Incentives include ten years' EU exclusivity following approval.

"Receiving this positive opinion from the EMA for our gene-therapy candidate, AP103, is a significant development for patients suffering from epidermolysis bullosa and provides additional momentum to our development pipeline," Amryt chief executive, Dr Joe Wiley said in a statement.

Unlike other gene therapies that rely on viral vectors, the company's technology is based on a polymer-based delivery platform that can be applied directly to the affected area.

This, Amryt believes, offers up the prospect that it can be used for other genetic skin conditions.

AP103 will follow in the slipstream of FILSUEZ for epidermolysis bullosa, which successfully negotiated phase III clinical trials recently.

"These milestones relating to our efforts in epidermolysis bullosa are significant for all Amryt stakeholders as we build a global epidermolysis bullosa franchise and become a leader in rare and orphan diseases," said CEO Wiley.

Amryt said it expects to initiate clinical development of AP103 in the first half of 2022.

Proactive Investors facilitate the largest global investor network across 4 continents in 4 languages. With a team of analysts, journalists & professional investors Proactive produce independent coverage on 1000's of companies across every sector for private investors, private client brokers, fund managers and international investor communities.

Contact us +44 (0)207 989 0813 action@proactiveinvestors.com

No investment advice

The Company is a publisher. You understand and agree that no content published on the Site constitutes a recommendation that any particular security, portfolio of securities, transaction, or investment strategy is suitable or advisable for any specific person. You understand that the Content on the Site is provided for information purposes only, and none of the information contained on the Site constitutes an offer, solicitation or recommendation to buy or sell a

Price: 206

Market Cap: £335.37 m

1 Year Share Price Graph



October 2019 April 2020 October 2020

Share Information

Code: AMYT

Listing: AIM

52 week High Low
250 80

Sector: Pharma & Biotech

Website: www.amrytpharma.com

Company Synopsis:

Amryt Pharma is a commercial stage pharmaceutical company focused on developing and delivering innovative new treatments to help improve the lives of people with rare and orphan diseases.

action@proactiveinvestors.com

security. You understand that the Company receives either monetary or securities compensation for our services. We stand to benefit from any volume which any Content on the Site may generate.

You further understand that none of the information providers or their affiliates will advise you personally concerning the nature, potential, advisability, value, suitability or profitability of any particular security, portfolio of securities, transaction, investment, investment strategy, or other matter.

You understand that the Site may contain opinions from time to time with regard to securities mentioned in other products, including Company-related products, and that those opinions may be different from those obtained by using another product related to the Company. You understand and agree that contributors may write about securities in which they or their firms have a position, and that they may trade such securities for their own account. In cases where the position is held at the time of publication and such position is known to the Company, appropriate disclosure is made. However, you understand and agree that at the time of any transaction that you make, one or more contributors may have a position in the securities written about. You understand that price and other data is supplied by sources believed to be reliable, that the calculations herein are made using such data, and that neither such data nor such calculations are guaranteed by these sources, the Company, the information providers or any other person or entity, and may not be complete or accurate.

From time to time, reference may be made in our marketing materials to prior articles and opinions we have published. These references may be selective, may reference only a portion of an article or recommendation, and are likely not to be current. As markets change continuously, previously published information and data may not be current and should not be relied upon.

The Site does not, and is not intended to, provide investment, tax, accounting, legal or insurance advice, and is not and should not be construed as providing any of the foregoing. You should consult an attorney or other relevant professional regarding your specific legal, tax, investment or other needs as tailored to your specific situation.

In exchange for publishing services rendered by the Company on behalf of Amryt Pharma PLC named herein, including the promotion by the Company of Amryt Pharma PLC in any Content on the Site, the Company receives from said issuer annual aggregate cash compensation in the amount up to Twenty Five Thousand dollars (\$25,000).