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Amryt Pharma PLC

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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 FILSUVEZ 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.

Price: 209

Market Cap: £340.26 m

1 Year Share Price Graph

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.

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