PYC Therapeutics

27 April 2026

ORPHAN DRUG DESIGNATION GRANTED FOR RP11 DRUG CANDIDATE BY EUROPEAN MEDICINES AGENCY

- **PYC is developing an investigational drug candidate (known as VP-001) that has the potential to become the first approved treatment option for patients with the blinding eye disease Retinitis Pigmentosa type 11 (RP11)[1]**

- **The Company today announces that the European Medicines Agency (EMA) has granted Orphan Drug Designation (ODD) to VP-001**

- **The benefits of ODD designation by the EMA include[2]:**
  - **10 years of European market exclusivity upon approval;**
  - **Provision of scientific advice by the EMA including assistance with the development of the clinical trial protocol required to support approval of the drug candidate; and**
  - **Reduced fees associated with the regulatory review of the drug candidate.**

- **The EMA ODD complements existing special designations conferred on VP-001 by the US Food and Drug Administration (FDA), including:**
  - **Orphan Drug Designation;**
  - **Fast Track Status; and**
  - **Rare Pediatric Disease Designation[3].**

PERTH, Australia and SAN FRANCISCO, California – 27 April 2026

PYC Therapeutics Limited (ASX:PYC) (PYC or the Company) is a precision medicine Company dedicated to changing the lives of patients with genetic diseases who have no treatment options available.

The Company currently has three clinical-stage drug development programs including a drug candidate (known as VP-001) that addresses the underlying cause of Retinitis Pigmentosa type 11 (RP11). PYC is currently progressing VP-001 through a Phase 2 study in RP11. PYC today announces that VP-001 has received Orphan Drug Designation (ODD) from the European Medicines Agency (EMA) – an incentive for the development and authorization of medicines for rare diseases. This designation highlights the urgent need for treatment options for patients with RP11 and the potential of VP-001 to deliver meaningful benefits to RP11 patients across Europe.

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[1] Subject to the risks and uncertainties outlined in the Company's ASX disclosures of 2 February 2026
[2] An overview of the EU Orphan Designation is available at: https://www.ema.europa.eu/en/human-regulatory-overview/orphan-designation-overview
[3] Refer PYC ASX Announcements dated 21 October 2024, 20 January 2025 and 2 August 2023

Next Steps

PYC recently held a Type D meeting with the FDA to align on the requirements for a successful New Drug Application (NDA) for VP-001[4]. Aided by this guidance, the Company is awaiting additional data from the ongoing Phase 2 study in order to optimise the design of a proposed registrational trial for this drug candidate. PYC expects to provide an update on this long-term follow-up data from the ongoing Phase 2 study in Q4 CY26[5].

About PYC Therapeutics

PYC Therapeutics (ASX: PYC) is a clinical-stage biotechnology company creating a new generation of RNA therapies to change the lives of patients with genetic diseases. The Company utilises its proprietary drug delivery platform to enhance the potency of precision medicines within the rapidly growing and commercially proven RNA therapeutic class. PYC's drug development programs target monogenic diseases – the indications with the highest likelihood of success in clinical development[6].

For more information, visit pyctx.com, or follow us on LinkedIn and X.

Forward looking statements

Any forward-looking statements in this ASX announcement have been prepared on the basis of a number of assumptions which may prove incorrect and the current intentions, plans, expectations, and beliefs about future events are subject to risks, uncertainties and other factors, many of which are outside the Company's control. Important factors that could cause actual results to differ materially from assumptions or expectations expressed or implied in this ASX announcement include known and unknown risks. Because actual results could differ materially to assumptions made and the Company's current intentions, plans, expectations, and beliefs about the future, you are urged to view all forward-looking statements contained in this ASX announcement with caution. The Company undertakes no obligation to publicly update any forward-looking statement whether as a result of new information, future events or otherwise.

This ASX announcement should not be relied on as a recommendation or forecast by the Company. Nothing in this ASX announcement should be construed as either an offer to sell or a solicitation of an offer to buy or sell shares in any jurisdiction.

This ASX announcement was approved and authorised for release by the Board of PYC Therapeutics Limited

CONTACT US

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[4] Refer PYC ASX Announcement dated 16 March 2026
[5] Subject to the risks and uncertainties outlined in the Company's ASX disclosures of 2 February 2026.
[6] Advancing Human Genetics Research and Drug Discovery through Exome Sequencing of the UK Biobank https://doi.org/10.1101/2020.11.02.20222232