

US FDA DESIGNATES PYC'S LEAD AS A FAST TRACK DEVELOPMENT PROGRAM

- PYC is a clinical-stage biotechnology company developing a pipeline of first-in-class precision medicines for patients who have genetic diseases and no treatment options available
- The Company is currently evaluating the safety/tolerability and efficacy of an investigational drug candidate with disease-modifying potential in patients with a blinding eye disease of childhood called Retinitis Pigmentosa type 11 (RP11) for which there are no existing treatments
- PYC's drug candidate for the treatment of RP11 has today been designated a Fast Track development program by the US Food and Drug Administration (FDA)
- The purpose of the Fast Track designation is described by the FDA as being 'to get important new drugs to the patient earlier'¹
- This drug candidate is now eligible for *Accelerated Approval* and *Priority Review* along with a range of other benefits²

PERTH, Australia and SAN FRANCISCO, California – 2 August 2023

PYC Therapeutics Limited (ASX:PYC) today announces that the VP-001 program, the first investigational drug candidate designed to address Retinitis Pigmentosa type 11 (**RP11**) to progress to human trials, has received Fast Track designation from the US Food and Drug Administration (**FDA**).

The Fast Track process is "designed to facilitate the development, and the review of drugs to treat serious conditions and fill an unmet medical need" with Fast Track status "often leading to earlier drug approval and access by patients"³.

Benefits of the Fast Track designation include:

- Increased frequency of meetings with the FDA to discuss the drug's development plan;
- Eligibility for Accelerated Approval and Priority Review, if relevant criteria are met; and
- The potential for a Rolling Review in support of a New Drug Application⁴.

¹ US FDA. Fast Track designation explanation available on the FDA website

² Additional criteria need to be met in relation to each additional designation

³ <https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track>

⁴ <https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track>

PYC will utilise the Fast Track designation to work with the FDA on advancing this important drug program towards patients on an accelerated timeline.

PYC's CEO Dr Rohan Hockings commented:

"We welcome the opportunity to work with the FDA to progress this important drug candidate towards becoming the first treatment option available for patients with RP11 with disease-modifying potential"

About VP-001 – the first potential treatment for Retinitis Pigmentosa Type 11

RP11 is a blinding eye disease that begins in childhood and ultimately leads to legal blindness in middle age. The disease affects ~1 in every 100,000 people and is caused by insufficient expression of the *PRPF31* gene in the retina.

There are currently no treatment options available for patients with RP11 nor are there any in clinical development.

VP-001 is a precision therapy that aims to restore the expression of the *PRPF31* gene back to levels required for the normal function of the retina. VP-001 utilises PYC's proprietary drug delivery technology to overcome the major challenge for RNA drugs by ensuring that sufficient drug reaches its target inside the cells affected by RP11.

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**⁵.

The Company was the first to progress a drug candidate for a blinding eye disease of childhood into human trials and is now progressing multiple 'fast-follower' programs into the clinic. For more information, visit pyctx.com, or follow us on LinkedIn and Twitter.

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.

⁵ Advancing Human Genetics Research and Drug Discovery through Exome Sequencing of the UK Biobank
<https://doi.org/10.1101/2020.11.02.2022232>

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

CONTACTS:

INVESTORS and MEDIA
info@pyctx.com