PYC Therapeutics

6 March 2023

US FDA CLEARS PYC TO COMMENCE THE FIRST EVER HUMAN TRIAL IN RETINITIS PIGMENTOSA TYPE 11

- PYC has advanced the **first drug candidate** for the treatment of a blinding eye disease called Retinitis Pigmentosa type 11 (RP11) **into human trials**
- The progress comes with the US Food and Drug Administration (FDA) clearing PYC's Investigational New Drug (IND) application for its RP11 drug candidate
- PYC plans to begin **dosing RP11 patients** with this drug candidate **in 2Q 2023**
- There are **no treatment options** currently available for patients with RP11 which represents an estimated **>$1 billion p.a. addressable market**[1]

PERTH, Australia and SAN FRANCISCO, California – 6 March 2023

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**[2].

The US Food and Drug Administration (FDA) has cleared PYC's Investigational New Drug (IND) application for its investigational drug candidate (known as VP-001[3]) directed towards the treatment of Retinitis Pigmentosa type 11 (RP11). This milestone represents the first potential treatment option to enter human trials for this disease. PYC has now applied for human ethics approval before commencing to enrol patients in the clinical trial and anticipates dosing the first RP11 patient with VP-001 in 2Q23.

Human studies will commence with a single ascending dose protocol treating an estimated 10 to 15 RP11 patients with the objective of establishing a safe and well-tolerated dose to progress into multi-dose trials next year.

PYC's CEO Dr. Rohan Hockings commented on the development: "*This is very exciting for the RP11 patient community and an outstanding achievement by the PYC team. The validation of PYC's platform technology as we move ahead into human trials has implications for the Company's entire pipeline of first-in-class and potentially disease-modifying drugs. The potential for patient-impact now extends well beyond RP11".*

[1] Estimated market in Australian dollars based on a target patient population of 7,500 in the Western World and median orphan drug pricing of US$150,000 per patient per annum

[2] Advancing Human Genetics Research and Drug Discovery through Exome Sequencing of the UK Biobank https://doi.org/10.1101/2020.11.02.20222232

[3] VP-001 is owned by PYC's 95.2% owned subsidiary, Vision Pharma, with the remaining 4.8% shareholding in Vision Pharma being held by the Lions Eye Institute

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 precision medicines for patients with major unmet needs in genetic disease. The Company's platform combines a novel drug delivery technology with the rapidly growing RNA therapeutic class to create a pipeline of first-in-class drugs that address the root cause of the targeted disease.

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.

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

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