

## FIRST PATIENT DOSED IN EYE DISEASE CLINICAL TRIAL

- The first patient has been dosed with PYC's investigational drug candidate designed to stop the progression of the blinding eye disease Retinitis Pigmentosa Type 11 (RP11)
- This is the first time a drug candidate with the potential to modify the course of RP11 has been dosed in a human
- RP11 is a progressive and irreversible blinding eye disease with onset in childhood
- RP11 has an estimated >\$1 billion p.a. addressable market¹ and there are no available therapies for patients with this disease

## PERTH, Australia and SAN FRANCISCO, California - 30 June 2023

PYC today announced that it has completed dosing of the first patient with its drug candidate VP-001 as part of the Platypus Study – a Phase 1 Single Ascending Dose (SAD) study designed to assess the safety and tolerability of VP-001 in the blinding eye disease Retinitis Pigmentosa Type 11 (RP11).

The RP11 patient who received VP-001 was dosed with a 3  $\mu$ g single administration to one eye via an intravitreal (into the eye) injection. A further two RP11 patients are expected to be dosed as part of the low (3  $\mu$ g) dose cohort followed by a 4-week safety review period. The Safety Review Committee will review the safety data from the first dose cohort at the completion of the review period and determine whether the next dosing cohort (mid dose - 10  $\mu$ g) may proceed.

PYC will advise the market of the outcome of the Safety Review Committee as the next key milestone of this study.

# 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  $\sim 1$  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.

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<sup>&</sup>lt;sup>1</sup> 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.

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 the Phase 1 Single Ascending Dose (SAD) Study

The Phase 1 open label study will be conducted to evaluate the safety and tolerability of a single dose of VP-001 to a single eye administered intravitreally in participants over the age of 18 with confirmed *PRPF31* mutation-associated retinal dystrophy (RP11 patients).

Three groups of patients will be administered a single dose (low, mid & high dose) with each cohort consisting of 3 patients with RP11. The Safety Review Committee (SRC) for the study will review the safety data for each cohort of patients dosed with VP-001, 4 weeks after the first dose is administered. When the final patient in the relevant cohort has progressed through the SRC, the trial will progress to the next cohort/dosing group.

On completion of the dosing of the highest tolerated dose cohort, a 24-week safety followup assessment will be conducted to assess treatment-emergent serious adverse events.



#### PYC's CEO Dr Rohan Hockings commented on the first patient being dosed:

"We're incredibly eager to see the potential benefit our VP-001 drug candidate can deliver for RP11 patients who have a substantial unmet need. This is an outstanding milestone for PYC that is the culmination of an incredible amount of scientific nous and hard work from the team."

#### **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**<sup>2</sup>.

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 <u>pyctx.com</u>, or follow us on <u>LinkedIn</u>.

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

### 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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