

23 October 2020

## FDA response to Orphan Drug Designation request

PYC Therapeutics Limited (ASX:PYC) (**PYC** or the **Company**) has received a response from the US Food and Drug Administration's (FDA) Office of Orphan Product Development (OOPD) requesting data using the Company's lead drug (VP-001) in an animal model of RP/retinal dystrophy due to PRPF31 mutations or in patients with the disease before considering the Company's request for orphan drug designation further. PYC submitted an orphan drug designation request for VP-001 to the FDA's OOPD on 30 July 2020 and the OOPD responded on 23 October 2020 with the request described above.

The Company will consider whether there is an appropriate animal model available that will provide the data requested in light of VP-001's specific mechanism of action and/or whether to defer the provision of further data in response to the OOPD's request until the 'first in human' efficacy read-outs are available. The request for further information by the OOPD does not impact on either:

- i) the benefits of orphan drug designation should it be granted to VP-001; nor
- ii) the development pathway or timeline for VP-001 through to market.

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

**ENDS** For further information, please contact:

### INVESTORS

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### About PYC Therapeutics

*PYC Therapeutics (ASX: PYC) is a drug development company solving a major challenge in the development of a revolutionary new class of drugs – delivering large drugs into cells. Cell*

*Penetrating Peptides (CPPs) can overcome 'the delivery challenge' and provide access for a wide range of potent and precise drug 'cargoes' to the 'undruggable genome' – the highest value drug targets that exist inside cells. PYC Therapeutics is using its CPP platform to develop a pipeline of novel therapies with an initial focus on inherited retinal diseases.*

### **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.

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