



Green Whistle gets the Green Light

Investor Presentation

Gordon Naylor – Chair

Brent MacGregor - CEO

3 March 2022 - 10am AEDT

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https://us02web.zoom.us/webinar/register/WN_h_JHE2

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Removal of Full Clinical Hold allowing Phase III trial to commence

The Journey So Far

- First request for FDA Meeting in February 2016
- Pentrox Clinical Trial placed on Hold in August 2018
- Formal Review (Type C) Meeting in January 2021
- MVP Clinical Hold Response Submitted in December 2021
- Numerous technical exchanges leading to.....

FDA Feedback on 1 March 2022

“We have completed the review of your submissions and have concluded that the clinical trial may be initiated”

Trial Specifics

Protocol – treatment of moderate to severe acute trauma pain in pre-hospital participants

- First patient enrolled late 2022
- Expected study duration - 2 years
- 10 sites to be selected
- 200 patients in total
- Study costs *circa* A\$12m



Key Takeaways

- The lifting of the hold is **unconditional**
- In anticipation we had commenced clinical trial preparations
- We expect registration and launch in FY26
- Selfie is the intended launch product
- A US launch will drive a second wave of expansion succeeding the current EU growth





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