



## Results Announcement: Phase 2 Clinical Trial of VF001 for Venous Leg Ulcer Healing

### Summary:

- The Phase 2 trial of VF001 for the treatment of venous leg ulcer failed to meet all endpoints.
- Analysis demonstrated no clinically meaningful or statistically significant difference in measures of wound healing, compared with placebo.
- Ongoing development of VF001 for all indications halted.
- Factor Therapeutics to limit further activity to maintaining existing intellectual property portfolio.
- Investor conference call scheduled for 11.00 am AEST, Wednesday, November 14<sup>th</sup>, 2018.

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**Brisbane, Australia 14<sup>th</sup> November 2018:** Factor Therapeutics Limited (ASX: FTT, the “Company”), a clinical-stage biotechnology company developing therapeutics for advanced wound care, today announced results of the Company’s Phase 2 clinical trial, VF00102, for the treatment of venous leg ulcers (VLUs).

VF00102 was a randomised, placebo-controlled, multicentre Phase 2 study that evaluated the addition of study drug (VF001), applied weekly for up to 12 weeks, to standard care (dressings and compression bandaging) for patients with VLUs. 157 patients were recruited at 21 sites across the USA and randomised to receive standard care plus either low (28 micrograms per mL) dose VF001, high (280 micrograms per mL) dose VF001 or placebo.

Across all three measures of healing evaluated in the study – reduction in wound size (Figure 1), the proportion of patients whose ulcers fully healed (Figure 2) and the time to achieve full healing (Figure 3) – treatment with VF001 did not provide any additional benefit when compared with placebo plus standard care. All three study groups showed a similar safety profile. The top-level findings are presented at the end of this announcement.

Dr Rosalind Wilson, CEO of Factor Therapeutics, said, “We undertook this trial with the goal of determining whether VF001 could improve healing for patients with venous leg ulcers and we have answered that question; unfortunately, the results clearly demonstrate that it does not. Although the trial was well designed and executed, the outcome is that there is no clinical justification to progress further with the development of this asset, for this indication.”

Dr Cherrell Hirst, Chairman of the Board, said, “This disappointing news means that we will cease development of VF001 in all indications and, in the immediate term, limit our activity to maintaining the company’s existing intellectual property portfolio. The Australian Directors have indicated their willingness to remain in place, without remuneration. In addition to maintenance of the intellectual property portfolio, the Board will proceed to review all options available to, and in the best interests of, the Company and its shareholders.”

“We thank all of our shareholders for their continued support through the challenges we have faced over a number of years in pursuing the potential of our technology. We thank our staff for their incredible dedication – they have done their utmost to achieve success for the Company and our shareholders. Finally, we thank our investigators, trial staff, our partners and especially the patients, for their commitment and continued support throughout the trial,” Dr Hirst concluded.

As part of an overall downsizing, Dr Wilson will step down as CEO in due course, following agreement with the Board on suitable transition arrangements.

Shareholders are invited to join an investor conference call at 11.00 am AEST on Wednesday, November 14<sup>th</sup>, 2018.

## Key Study Results

Figure 1. Reduction in Wound Area over 12 weeks of Treatment (Mean R, Median L).

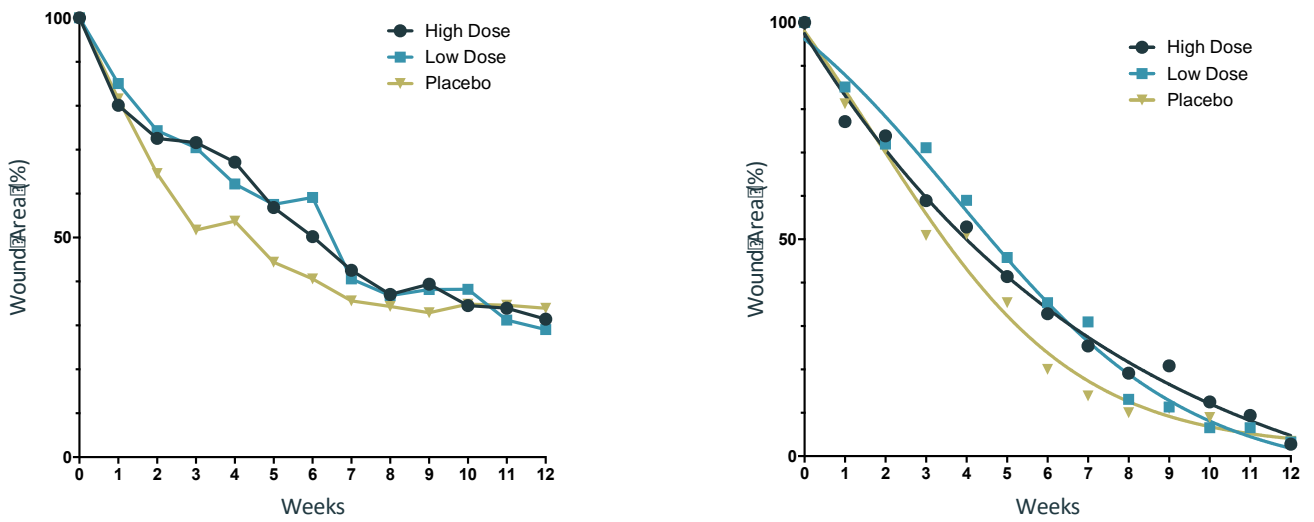


Figure 2. Proportion of Patients with Complete Ulcer Healing.

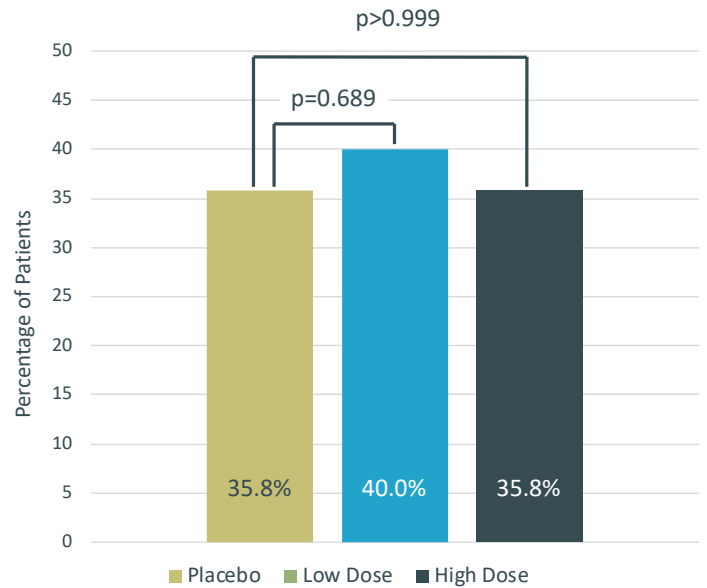
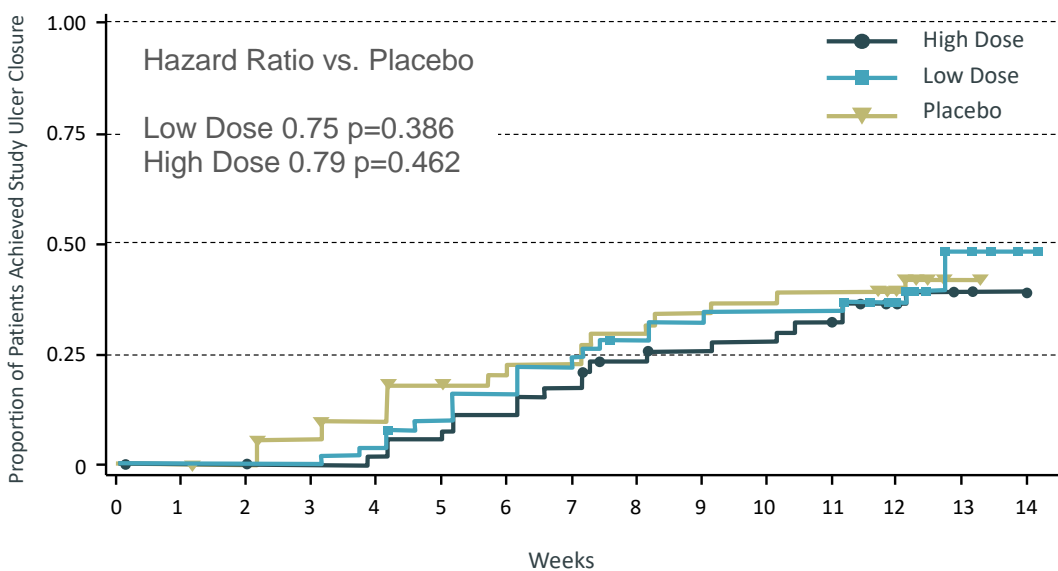


Figure 3. Time to Complete Ulcer Healing.



-ENDS-

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**About Factor Therapeutics**

Factor Therapeutics Limited ("Factor") is a biotechnology company that is developing treatments for acute and chronic wound healing applications. Factor is a clinical stage company with its lead program (VF001) in Phase 2 for the treatment of venous leg ulcers (VLUs). The company is also developing solutions for a variety of interventional wound care and serious orphan dermatology conditions. The company's platform technology originates from the Institute of Health and Biomedical Innovation at the Queensland University of Technology (QUT), Australia. Factor's shares are traded on the Australian Securities Exchange (ASX) under the ticker FTT. For more information, please visit <https://factor-therapeutics.com>