

14<sup>th</sup> May 2018

# VF00102 Clinical Trial Update: Recruitment Enters Final Phase

**Brisbane, Australia 14<sup>th</sup> May 2018:** Factor Therapeutics Limited (ASX: FTT, the "Company"), an Australian biomedical company developing therapeutics for advanced wound care, is pleased to announce that recruitment into its Phase 2b study of VF001 for venous leg ulcers (the "VF00102 study") has entered its final phase.

As part of the Company's active management strategy for the trial and with a solid database of more than 90 patients having completed treatment, the Company has consulted with external statistical experts to finalise the trial's analysis plan. The most appropriate statistical approach has been confirmed, leading to a modest reduction in the number of patients that need to be recruited whilst maintaining the overall robustness of the analysis.

Dr Ros Wilson, CEO of Factor Therapeutics, said, "Progress in the last few weeks has been excellent. The low withdrawal rate we have seen throughout VF00102 is a very encouraging sign that our patients and investigators have a positive perception of the study. Together with this confirmation of our statistical analysis approach, our clear focus for recruitment is now to replace the small number of withdrawals and bolster our safety database."

To date the study has enrolled 124 patients and a further 10 are in the screening phase. Achieving this key point in the trial is a clear indicator that successful completion and readout are on track, with recruitment expected to complete at about the end of June.

Dr Wilson added, "This final phase of recruitment is important to not only achieve readout of all the study endpoints, including changes in pain and quality of life scores, but also deliver the additional patients required for re-submission of the CE Mark dossier in Europe."

#### About the VF00102 trial

VF00102 is a Phase 2b study evaluating the benefits of adding VF001 to standard care for healing venous leg ulcers. The study design includes rigorous patient selection criteria to enrol a specific group of patients who are most likely to benefit from the addition of VF001. All patients receive standard care — moist dressings and compression bandaging — throughout the trial. Following a two-week screening period, patients receive either placebo or one of two doses of VF001 for up to 12 weeks and are followed for a further 12 weeks post-treatment. The primary endpoint of the trial is reduction in the size of the wound. Other endpoints include the proportion of patients with full wound closure, time to wound closure, improvements in pain and quality of life; and safety.

#### **About VF001**

VF001 is a liquid, topical treatment for chronic wounds based on two naturally-occurring substances involved in wound healing, vitronectin and IGF-1 (insulin-like growth factor 1). VF001 comprises a portion of human vitronectin linked to IGF-1. The vitronectin component binds to the base of the

wound, creating a biological scaffold to which skin cells attach; IGF-1 provides a signal that stimulates skin cells to multiply (proliferate) and move (migrate) into the wound – cell attachment, proliferation and migration are central processes in wound healing. VF001 is easy to use – a small volume (0.5 ml) is applied to the wound during routine weekly dressing changes.

### **About Factor Therapeutics**

Factor Therapeutics Limited ("Factor") is a biomedical technology 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 II 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 www.factor-therapeutics.com.

## **Corporate and Investor Relations Contact**

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