



ASX ANNOUNCEMENT

14 July 2011

Strong New Clinical Trial Data

Biomedical company, **Tissue Therapies Limited (ASX: TIS)** has announced receipt of clinical results from the multi-centre international wound healing study led by key opinion leader Professor Keith Harding and Dr Girish Patel of the world renowned Cardiff University Wound Healing Clinic.

The data shows that for the 24 evaluated venous ulcer patients treated with VitroGro® to date:

- 8 patients achieved complete healing and an additional 2 patients achieved $\geq 98\%$ healing
- out of 24 evaluable patients, 22 (92%) were partially or completely healed in 12 weeks. (One patient was unchanged and 1 patient worsened.)
- The average reduction in wound size was 65% with a median of 72% after 12 weeks of treatment
- The average time venous ulcers had not responded to expert care before VitroGro® treatment was 37 months with a median¹ of 10 months
- The average age of patients that have completed treatment so far is 71 years with a median of 73

The EU clinical study is evaluating weekly or twice weekly VitroGro® treatment of venous leg ulcer patients who have not responded to compression therapy which is the current standard of care.

The objective of this study is to recruit 40 evaluable patients. A total of 53 patients have been recruited, all of whom had not responded to expert care for at least 4 weeks, many for much longer. Final patients are now completing treatment and analysis of the data is well under way.

28 patients have completed the study to date, with 4 being excluded from the data analysis due to active wound infection or significant medical complications unrelated to VitroGro®.

¹ The median is the middle number of the data set

In addition, for all 53 patients recruited into the study:

- No adverse events related to VitroGro® have been reported
- 19 patients are still completing 12 weeks of treatment
- 6 patients have been withdrawn from the study due to medical problems unrelated to VitroGro®, or have been lost to follow up
- Completion of the data analysis for all patients is forecast for the end of September 2011 and the final report will be submitted as part of the EU approval filing planned for later this year.

Dr Steven Mercer, the CEO of Tissue Therapies said, “Given that we now have data from a total of 58 venous ulcer patients from 3 clinical trials, I am very confident that we will have the data necessary for a successful submission for EU approval for sale, on time and as planned later this year when final manufacturing stability data is available. This positions us well for completion of a commercial partnership agreement later this year and for our planned first sales in the EU during the second quarter of 2012.”

The preliminary data confirms the results of the earlier Australian and Canadian human trials by showing that VitroGro® restarts or accelerates healing of chronic venous ulcers that don't respond to expert care, with reduction of ulcer size as well as improved wound characteristics and pain reduction.

Dr Mercer added, “Once again VitroGro® is producing decisive results in patients who have not responded to expert care in some cases for many years.”

“Unlike our previous studies these patients typically have a considerable history of recurrent ulceration and have complicated wounds that would not be expected to heal. They also have co-existing conditions in addition to the underlying disease in their arteries or veins, which together make this study a more challenging test.”

A number of patients reported significant pain at enrolment and experienced an improvement in their pain as treatment progressed. Pain is a significant issue and a source of frustration for patients as well as clinicians and pain improvement is evidence supporting improved quality of life and cost effectiveness, which is important for achieving reimbursement in Europe and the US.

Professor Harding has advised Tissue Therapies that he is pleased with the preliminary data. “It is important to acknowledge that undertaking major investigations in chronic wounds is difficult and it is important to rely on the views of experienced investigators. When I test a new wound care technology I normally expect one third of patients to get worse, one third to stay the same and one third to improve.”

“I am hopeful that when our analysis is complete we can continue to show the promising results we've seen from VitroGro® so far. I do think there is potential for using this therapy to correct the situation where the biology of wound healing is aberrant and we also hope to see indications of a role for VitroGro® in other types of wounds.”

Enthusiastic feedback has also been received from the nursing staff involved in the VitroGro® study. They have been impressed with the consistent performance of VitroGro®, particularly the visible and quick improvement seen in challenging cases combined with ease of use and pain reduction.

Tissue Therapies has also announced achievement of ISO 13485:2003 and ISO 9001:2008 management system certification for the development and manufacture of medical devices for wound healing.

Dr Mercer said, "Our patients and customers can be assured our products meet the highest standards. The examination of our systems identified no deficiencies and underpins the comprehensive work undertaken by our science team and key contractors." ISO 13485 is a globally recognised quality system standard required to develop, manufacture and market medical devices for wound care.

The clinical research photography below shows typical results from this clinical trial. Photographs on the left are taken at enrolment and those on the right at completion of 12 weeks of treatment with VitroGro®.

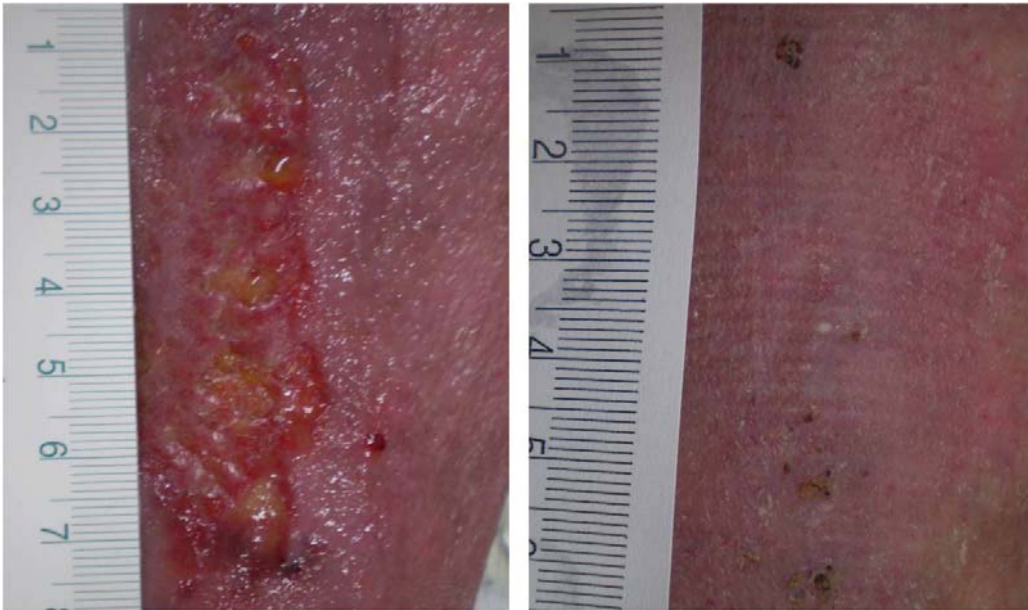
Male, 68 years old:

VitroGro® treatment initiated healing in this recalcitrant ulcer of 30 years duration, producing a reduction in depth of 2 mm. The condition of the wound bed, the wound base and health of surrounding skin was improved. Inflammation was also improved. A caramel or straw-coloured gel presumed to be new extracellular matrix can be seen covering the wound.



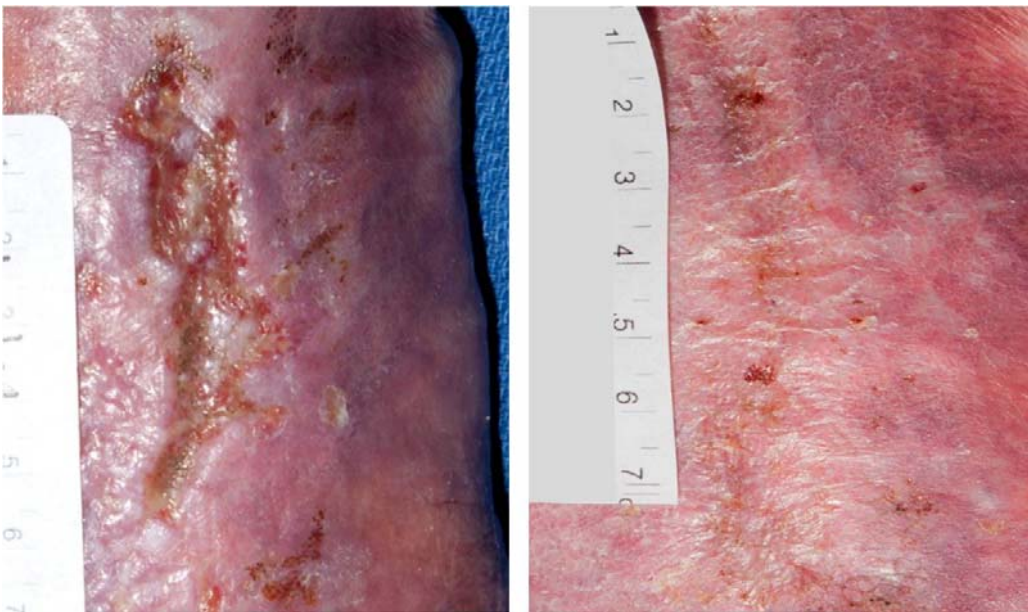
Male, 75 years old:

This ulcer of 2 months duration completely healed within 5 weeks. The patient's pain level significantly improved in the first 2 weeks.



Male, 75 years old:

This ulcer of 8 months duration healed after 6 weeks of treatment.



Male, 81 years old:

This recalcitrant ulcer of 11 years duration reduced in size by 98% after 12 weeks of treatment.



Female, 91 years old:

This recalcitrant ulcer of 2 years and 5 months duration reduced in size by 52% after 12 weeks of VitroGro® treatment. Inflammation and the condition of the skin surrounding the wound was improved. A caramel or straw-coloured gel presumed to be new extracellular matrix can be seen covering the wound.



Female, 61 years old:

This ulcer of 8 months duration healed after 5 weeks of treatment.



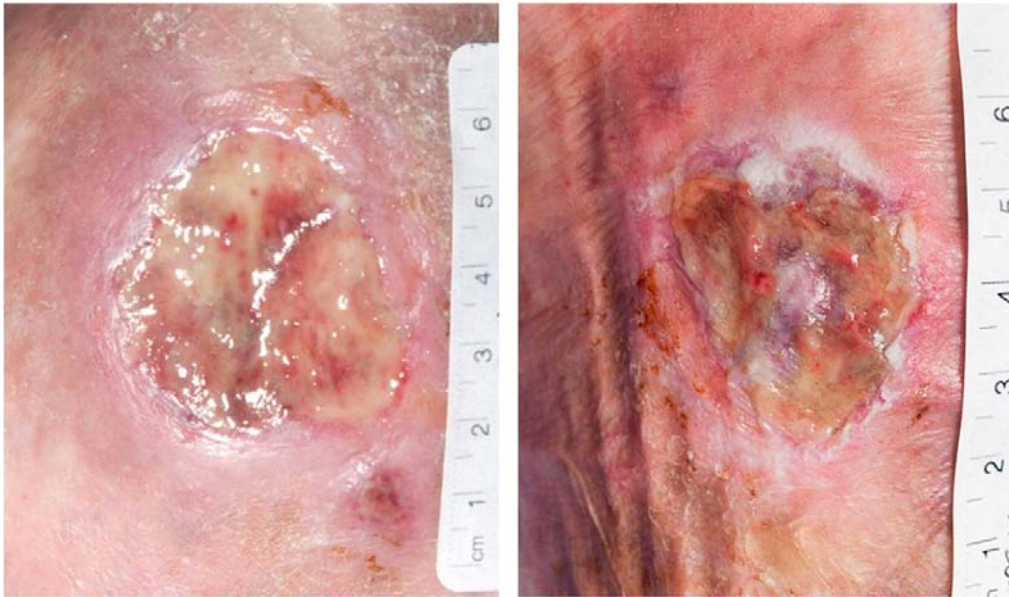
Female, 53 years old:

This recalcitrant ulcer of 7 years duration healed completely.



Male 75 years old:

This recalcitrant ulcer of 12 months duration reduced in size by 45% after 12 weeks of VitroGro® treatment.



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Further information: Dr Steven Mercer
CEO, Tissue Therapies Limited
Telephone: +61 (0)7 3839 9938

Email: s.mercer@tissuetherapies.com

About Tissue Therapies Limited

Tissue Therapies Limited is an Australian company developing biomedical technologies for wound healing, tissue repair, cell culture and other applications.

The Company has worldwide exclusive rights to commercialise VitroGro®, a technology developed by cell biology, tissue engineering and protein engineering experts at the Institute of Health and Biomedical Innovation (IHBI) at the Queensland University of Technology (QUT) for enhancing cell growth and migration. VitroGro® has particular commercial applications in wound healing, tissue regeneration, cell-based therapies and cell culture.

Based on its VitroGro® technology, Tissue Therapies is developing more effective treatments for acute and chronic wound healing applications including chronic skin ulcers and burns.

Tissue Therapies is also proceeding with the development of other commercial applications for VitroGro® and other technologies for the treatment of psoriasis, scar prevention and treatment and potential treatments for various cancers including those of the breast, colon and prostate.

VitroGro® also provides a fundamental, transforming technology for completely defined cell culture reagents (ie. containing no purified animal or human proteins) to sustain and enhance the growth of live cells for emerging cell-based therapies, along with research and industrial cell culture markets internationally.

More information: www.tissuetherapies.com