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Interview with Professor Keith Harding

Biomedical company, **Tissue Therapies Limited (ASX: TIS)** has released the following transcript of the recorded interview with Professor Keith Harding that was played at the 2010 Annual General Meeting of Tissue Therapies Limited, held today.

Professor Harding is the Director of the Wound Healing Research Unit and Professor of Rehabilitation Medicine at Cardiff University in Wales and is widely acknowledged as the foremost international researcher / clinician into wound healing, with particular emphasis on chronic wounds. He is an Advisor to the Board of Tissue Therapies and is overseeing the current EU venous ulcer human trial of VitroGro®.

This interview was recorded when Professor Harding visited Brisbane briefly on Friday 8 October 2010. Unfortunately his schedule did not allow him to attend the Annual General Meeting today.

Q: *Tell us briefly about your association with Tissue Therapies and more about your role.*

Keith Harding: Okay. I am a clinician who has been interested in wound healing for many years. I run an academic department of wound healing in a UK university, I am providing consultative advice to Tissue Therapies and more recently I am acting as a principal investigator of a clinical trial of VitroGro that is being undertaken both in Europe and Australia. I have known Tissue Therapies for around 4 years now. I became aware of the company when I saw some of the results of their pre-clinical data that were being presented at scientific meetings.

Q: *You must get many requests to trial or endorse new treatments. What made you take VitroGro seriously and get involved more closely with its development?*

Keith Harding: The problem with wound healing is that it has been around for many, many centuries. There have been many attempts over recent years to come up with solutions to the problem of non-healing wounds. Unfortunately many of the early attempts at novel and new therapies for this particular problem have suffered from a lack of good basic science to underpin the product and many of those products have arrived and failed. The one thing that I have found impressive in working with Tissue Therapies is that they seem to have commitment to understanding the science and managing the development of the product in a structured way that doesn't go anywhere unless the science is there to support the data.

Q: *So what is your perspective on the early VitroGro trials?*

Keith Harding: I have been around this subject for nearly 30 years. I have seen a lot of new products come and go. The one thing that was impressive both from the preclinical data and the early clinical studies is that in the clinical studies particularly, there seemed to be a greater consistency of response in the patients that were exposed to this product, far more consistent than I've seen with other biological therapies that I personally have been involved in trialling or evidence that I have reviewed in other capacities.

Q: *You will lead European trials for VitroGro. What will they entail and when do you expect results?*

Keith Harding: The studies that I am going to be leading on are a combination of European and Australian centres where we will be looking at taking patients with venous leg ulcers and evaluating up to 40 patients with two doses, either weekly or twice weekly applications of the active ingredient, to see if that has an impact on healing of those ulcers when those patients are treated with a standard form of graduated compression which is accepted by most people as the cornerstone of managing that particular disease. We do hope that we will be able to show additional benefits in terms of healing or reduction in size of the patients that have been exposed to VitroGro. The practicality and effectiveness of once weekly versus twice weekly are important questions that will need to be answered to determine the utility of this product as it goes forward. We would hope to get the early data available by the end of first quarter 2011. It is important to recognize that undertaking these studies do require a lot of regulatory hurdles to be overcome and then to find suitable patients but we are confident that we will be able to produce data by first quarter 2011.

Q: *What do you think the potential for VitroGro is if trials continue to support the early evidence?*

Keith Harding: The potential for VitroGro if the evidence that emerges supports the data that is already there is enormous. In many parts of the world many patients with wounds are still treated with very simple basic therapies. It is increasingly recognized that there are many aberrations in that healing process that can occur in a wide range of wound types that are based in abnormalities in the biological response to injury. If VitroGro can correct that abnormality, the potential for replacing a lot of the basic treatment or working in combination with basic treatment to get better clinical results is enormous and I think it is much more important to recognize although there is benefit for Tissue Therapies as an organization, I am confident there will be many patients who will benefit from this biologically based therapy which will hopefully continue to show the promising results we've seen in early clinical studies.

Q: *And Keith, what do you see as the most important markets?*

Keith Harding: In addition to the different geographical markets that might exist, and I would see this product obviously first being used if it's proven to be effective in the so-called developed countries – mainland Europe, North America – but also that having significant potential for emerging markets, particularly countries such as China, but in addition to the geographical location I do think there is the potential for using this therapy to correct the situation where the biology of wound healing is aberrant, and those would be mainly diabetic foot ulcers, venous leg ulcers, and although there are difficulties in undertaking the major clinical investigations in patients with pressure ulcers, would hopefully be seen to having a role in the whole range of chronic wounds. Future potential

correction or enhancement of that biological response to injury would provide the opportunity for using this type of therapy in patients with acute wounds or wounds where they are at risk of major problems occurring postoperatively, particularly if the patient has co-morbidities, diseases such as diabetes, obesity or who are smokers, that may increase their risk of wound problems post surgery.

Q: *Keith, Tissue Therapies is a very small company in comparison with well known pharmaceutical giants, what will its next steps need to be if VitroGro fulfills its early promise and where do you see the company's future?*

Keith Harding: Although Tissue Therapies is a small company compared to many of the larger players in this area, the one thing that is impressive is that Tissue Therapies seem to have a genuine interest, focus and passion in trying to provide a sound basis and evaluation of the product that they have. My hope - and I'm not a spokesperson for Tissue Therapies - is that they will continue that focus, they will continue that passion, and I would anticipate that the success of VitroGro will be significant, but I would also hope that it will be the first generation of a series of biologically based therapies that may be developed by this company as it goes forward, and I would expect that because of the complexity of the customer base that the company will have to deal with, is that they would probably be talking to major companies and developing a partnership arrangement so they will have enough bodies on the ground, enough sales staff to go out and provide the education and training for clinicians who may be seeing patients with wounds.

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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 other cell culture uses.

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