



ASX ANNOUNCEMENT

26 March 2015

Update on CE Mark for VitroGro® ECM

Biomedical company, Tissue Therapies Limited (**ASX: TIS**) has announced that during a formal oral hearing held in London on 25 March 2015, the Committee for Medical Products for Human Use (CHMP) stated to the Company that it wanted additional data regarding one of the components of VitroGro® ECM.

The CHMP did not express concerns about the performance of VitroGro® ECM, but is seeking additional data from the Company.

Tissue Therapies will attend an EMA Scientific Advisory Working Party (SAWP) meeting during May 2015 to agree on the studies that will satisfy the request for additional data.

The company is pleased that EMA and the Notified Body are assisting the Company to determine a definitive solution.

Given this, Tissue Therapies (in consultation with the Notified Body, BSI) has withdrawn its application for a Scientific Opinion in respect of VitroGro® ECM, but not the CE Mark application. Consequently, the approval (CE Mark) of VitroGro® ECM for the European market will be delayed.

Tissue Therapies will provide an update once it has a clearer understanding of the studies needed to provide the additional data to the Notified Body and CHMP and the expected timing of these.

Dr Steven Mercer, the CEO said, "The decision to withdraw the request for Scientific Opinion does not impact Tissue Therapies' ongoing plans to obtain approval for VitroGro® ECM in the USA. The procedure for US FDA approval for the use of VitroGro® ECM is different from that for CE Mark.

VitroGro[®] ECM: a healing promoter for chronic wounds

- VitroGro[®] ECM is a synthetic matrix protein that is used to promote healing in chronic wounds.
- Chronic wounds are a burden to both the patient and healthcare systems and have been described as “major and snowballing threat to public health and the economy” and therefore require the attention of advanced therapies to address the problem ^[1].
- Chronic wounds are those in which the normal healing process becomes stalled resulting in prolonged inflammation. Typically these wounds do not respond well to standard therapies because the growth of new skin to cover the wound is compromised.
- The growth of new skin is an anchorage dependent process that requires a protein matrix to which skin cells can attach. The prolonged inflammation in chronic wounds damages the protein matrix required for cell attachment and inhibits its restoration delaying or halting healing. Healing can be reinstated in chronic wounds by replacing this damaged matrix with a substitute that promotes healing.
- VitroGro[®] ECM contains a portion of the vitronectin protein that is specifically active in adhering to other proteins in the wound bed and providing sites for the attachment of skin cells. VitroGro[®] ECM also contains the growth factor IGF-I that helps support the growth (migration and proliferation) of attached cells. This design targets the stages of normal healing at which chronic wounds stall, promoting healing by replacing the damaged protein matrix of chronic wounds, providing sites for skin cell attachment, which restores the anchorage dependent growth of skin cells that is required for healing.

[1] Chandon K Sen *et al.* Human skin wounds: A major and snowballing threat to public health and the economy. Wound Repair and Regeneration 2009.

About Tissue Therapies Limited

Tissue Therapies Limited is a biomedical technology company that is developing significantly more effective treatments for acute and chronic wound healing applications, including chronic skin ulcers and burns.

Tissue Therapies Limited is commercialising VitroGro[®] ECM, a technology created by cell biology, tissue engineering and protein engineering experts at the Institute of Health and Biomedical Innovation at the Queensland University of Technology. The company is also developing treatments for psoriasis, scar prevention and various cancers including those of the breast, colon and prostate. Tissue Therapies Limited's shares are traded on the Australian, Berlin and Frankfurt stock exchanges.

More information: www.tissuetherapies.com