

Cytori's Celution system gets Aus TGA nod

12 August 2013 | Regulatory | By BioSpectrum Bureau



Singapore: Cytori Therapeutics received notice from the Australian Therapeutic Goods Administration (TGA) that its Celution system has been approved for commercial use through inclusion on the Australian Registry of Therapeutic Goods for autologous re-implantation or re-infusion of a patient's adipose-derived regenerative cells (ADRCs). The Celution system produces autologous (a patient's own) ADRCs at the point-of-care, which may then be used for a range of injuries or conditions.

During the past two years Dr David Chin of Queensland Australia worked with Cytori under a TGA Authorized Prescriber Approval to treat a variety of conditions particularly in the area of soft tissue injury and limited blood flow.

Mr David C Oxley, VP, emerging markets, Cytori Therapeutics, said that, "Following an intensive two year review by the TGA hospitals and physicians in Australia will have full commercial access to the only closed-system point-of-care device which produces clinical-grade ADRCs for re-implantation or re-infusion into the patient. This approval establishes the foundation for enabling treatment of critical unmet medical needs across a variety of indications for patients in Australia."

Dr Chin added, "We have had very favourable outcomes in the 80 plus patients treated using the Celution system. Cases include breast reconstruction and patients who no longer wish to have silicone breast implants. Additional medical conditions such as rheumatoid arthritis and soft tissue sports medicine related injuries are included."

"I can attest to the healing power of these cells based on the positive outcomes in my own clinical practice. In total my experience includes a variety of presenting conditions over two years. Being able to access the patient's own adipose derived regenerative cells during a single procedure opens up a whole dimension of acute and chronic medical conditions that may be addressed including some previously considered untreatable under conventional treatment modalities," he added.