



CELLTHERAPY
REGENERATIVE MEDICINE FOR LIFE

Press release (30th June 2015)

Cell Therapy Ltd announces positive Phase II clinical trial results of Tendoncel™, a first-in-class topical regenerative medicine for severe tendon injury

Cardiff, UK, June 30 2015 – Cell Therapy Ltd (“CTL”), a development stage pharmaceutical company with a portfolio of late stage allogeneic (‘off the shelf’) regenerative medicines, has reported positive Phase II results for Tendoncel™, a novel, topical regenerative medicine for severe tendon injury repair. Tendoncel™ is CTL’s second product following successful results from the Heartcel™ heart failure trial.

The Phase II, double-blind, placebo-controlled randomized trial studied Tendoncel™ in 34 patients suffering from chronic grade 3 lateral epicondylitis, (severe) tendon injury. Patients were treated daily with topical Tendoncel™ or analogue placebo gel for 21 days, with six week and three month follow-up. The trial endpoint is improvement in tendon injury, assessed with two validated metrics DASH (Disabilities of the Arm, Shoulder and Hand) and PRTEE (Patient-Rated Tennis Elbow Evaluation). (See full abstract below).

Reported today were the clinical relevant and statistically significant improvements:

- 70% improvement in DASH (Disabilities of the Arm, Shoulder and Hand)
- 74% improvement in PRTEE (Patient-rated Tennis Elbow Evaluation)
- No serious adverse events
- No change in IgE levels (assessment of any potential systemic effects)

The trial results demonstrate Tendoncel™ is a safe and efficaciously topical regenerative therapy in grade 3 (severe) lateral epicondylitis, with potential applications in a broad range of tendon injuries including shoulder and Achilles injuries. (See abstract below).

Tendoncel™ is the second product in CTL’s portfolio of allogeneic, tissue-specific regenerative cellular medicines, isolated and discovered in-house by Nobel Prize winner Sir Martin Evans. The portfolio also includes Heartcel™, for myocardial regeneration that successfully completed Phase II trials in severe heart failure in 2014.

Dr. Sabena Sultan, Director of Research and Development, Cell Therapy Ltd, commented: *“Patients using the non-invasive Tendoncel™ topical gel for 21 days experienced a clinically relevant and statistically significant improvement in their tendon injury. Reporting an average improvement of 70% on the DASH disability scale and 74% improvement on the PRTEE scale, Tendoncel’s results exceed those expected of injectable treatments and have the advantage of painless topical application.”*

Ajan Reginald, Chief Executive Officer of Cell Therapy Ltd., commented: *“These trial results demonstrate Tendoncel™ to be efficacious and safe in chronic tendon injury. Tendoncel™ is a remarkable breakthrough as a regenerative medicine in gel formulation, which we hope will help the millions of patients that suffer severe tendon injuries. As the second product to complete PII trials, Tendoncel™ strengthens Cell Therapy Ltd’s pipeline of late stage products, which have all been discovered and developed in-house.”*

Notes to editors

Abstract:

Tendoncel Phase II Placebo controlled Randomized Clinical Trial results of a novel allogeneic regenerative topical medicine in treatment of Chronic Tendon injury

Abstract: Cell Therapy Ltd has developed a novel topical gel for the treatment of severe (grade III) Tendon injury - Tendoncel.

Tendoncel is a patented regenerative allogeneic gel that incorporates a unique combination of platelet growth factors in a cellulose-derived gel, which consequently controls growth factor release, to optimise bioavailability and dose.

Preclinical in-vitro studies have shown Tendoncel to significantly enhance the proliferation of fibroblasts compared to positive controls. Tendoncel contains a unique combination of growth factors including; PDGF-BB, VEGF, PDGF-AA, thrombospondin and angiopoietin and can be stored for up to 3 months. Growth factors derived from platelet lysate have been shown to facilitate healing in cutaneous and soft tissue injuries but with variable efficacy.

Thus we investigated Tendoncel in a double blind placebo controlled Phase II clinical trial in lateral epicondylitis tendon injury. Patients were randomized to receive either treatment- Tendoncel, or placebo gel for once daily application for 21 days with follow up over a period of 3 months. The Tendoncel treatment cohort showed a statistically and clinically significant improvement in DASH (70%) and PRTEE (74%, functional questionnaires to assess efficacy) with no serious adverse events or change in IgE levels (assess any systemic effects).

In conclusion, Tendoncel, a novel allogeneic regenerative topical medicine, is both efficacious and safe in the treatment of severe tendon injury - lateral epicondylitis.

About Cell Therapy Ltd

Cell Therapy Limited (CTL) is a Cardiff-based pharmaceutical company focused on the discovery and development of regenerative medicines in areas of high unmet patient need. CTL was founded in 2009 by Nobel prize winner Professor Sir Martin Evans and Ajan Reginald, former Global Head of

Emerging Technologies at Roche, and includes world-class scientists and clinicians led by experienced management, an active Board and a scientific advisory committee of world experts.

CTL has developed a novel and proprietary platform, based on the stem cell discoveries of Sir Martin Evans, which can isolate tissue-specific stem cells from donor blood, and is developing a range of allogeneic therapies for different indications. Its lead product, Heartcel™, has demonstrated unprecedented survival rates in patients with advanced heart failure in a Phase II clinical trial. Cell Therapy's heart failure product franchise also includes Myocardion, and targets the 20 million patient heart failure market. Cell Therapy is also developing Tendoncel™, a topical regenerative medicine for tendon repair, and Skincel™, a regenerative dermatology therapy.

About Lateral Epicondylitis

Lateral epicondylitis, commonly known as chronic tendon injury or “tennis elbow”, is an inflammation of the outer part of the elbow in which the muscles and tendons become damaged from repetitive use, leading to pain and tenderness. The condition can be caused by repetitive use in physical exercise or work. Current treatment options are limited.