



CELLTHERAPY
REGENERATIVE MEDICINE FOR LIFE

Press release (10th May 2016)

Cell Therapy Ltd. Grants Japan License To Daiichi Sankyo For Its Heart Regeneration Medicine, Heartcel™

CARDIFF, Tuesday 10th May, 2016 – Cell Therapy Ltd. (CTL) today announced the granting of the Japan license for its innovative cardiac regeneration medicine, Heartcel™ (immuno-modulatory progenitor [iMP] cells) to Daiichi Sankyo. Daiichi Sankyo will undertake all development, regulatory and commercial activities for iMP cells in the territory of Japan only, while CTL retains its worldwide rights outside of Japan as well as global manufacturing responsibilities. Under the terms of the agreement, CTL receives a £12.5 million upfront licensing fee and additional milestone payments and royalties.

"After a competitive process, we are delighted to partner with Daiichi Sankyo in Japan. The accelerated regulatory pathway for regenerative medicines in Japan enables faster patient access, making it a natural priority for us," said Ajan Reginald, Chief Executive Officer, CTL. "This allows CTL to focus on U.S. and European Phase 3 trials and accelerating the development of our pre-clinical pipeline."

"CTL's in-house technology focuses on the discovery of novel tissue-specific cellular medicines. We are delighted that Daiichi Sankyo share our belief in iMP cells' potential in heart regeneration," commented Professor Sir Martin Evans, Nobel Laureate and CTL's Chief Scientific Officer. "This partnership is a validation of Cell Therapy's novel approach and discovery technology."

iMP cells are an advanced therapeutic medicinal product (ATMP) and investigational allogeneic regenerative medicine.¹ Heart failure affects approximately 26 million people worldwide. The condition features a progressive degenerative scarring of the heart associated with significant mortality and morbidity.² iMP cells were injected into the cardiac scar during bypass surgery in a Phase 2 clinical trial of 11 severe heart failure patients at high risk of incomplete re-vascularisation (ICR).¹ At 12 months following treatment, results demonstrated the following change from baseline: a 30% improvement in heart function (left ventricular ejection fraction), a 40% decrease in cardiac scar area and significant improvement in quality of life (characterised by a 50% increase in 'Minnesota Living with Heart Failure' score).^{1,3} At 36 months following treatment, all patients remained alive.^{1,3}

About Cell Therapy Ltd.

Cell Therapy Limited (CTL) is a private British regenerative medicine company that has discovered and developed a pipeline of novel cellular medicines in areas of high unmet clinical need. CTL was founded in 2009 by Nobel Laureate Professor Sir Martin Evans and former Roche Global Head of Emerging Technologies Ajan Reginald. CTL's disruptive technology platform drives in-house discovery and manufacture of a pipeline of novel tissue-specific regenerative medicines. CTL is currently in the process of re-branding under the name Celixir.

About Heartcel™

Heartcel™ consists of immuno-modulatory progenitor (iMP) cells, a cardiac-specific cellular medicine which has successfully completed European Phase 2 trials. Phase 3 trials are set to begin in 2016.

This Cell Therapy Ltd. press release contains "forward-looking statements" referring to the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. The statements included within this press release are based on current expectations about future beliefs and the reader is cautioned not to rely on these forward-looking statements. Cell Therapy Ltd. makes no guarantee in regards to the regulatory future of iMP cells and whether it will gain regulatory approval or achieve commercial success. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Cell Therapy Ltd. Risks and uncertainties include, but are not limited to: challenges inherent in new product development, including obtaining regulatory approvals; competition, including technological advances, new products and patents attained by competitors; challenges to patents; changes in behavior and spending patterns or financial distress of purchasers of health care products and services; changes to regulations and domestic and foreign health care reforms; and general industry conditions, including trends toward health care cost containment.

The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

References

1. Data presented at the *International Society of Stem Cell Research (ISSCR) Annual Conference* in Stockholm, 24th June, 2015. Available at: <http://tinyurl.com/jldmygy>.
2. Heart failure: Preventing disease and death worldwide. European Society of Cardiology, 2014. Available at: https://www.escardio.org/static_file/Escardio/Subspecialty/HFA/WHFA-whitepaper-15-May-14.pdf.
3. Data presented at the *European Society of Gene and Cell Therapy Annual Congress* in Helsinki, 18th September, 2015. Available at: <http://tinyurl.com/hbjdqu9>.

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