

# RepliCel Life Sciences Receives Approval to Conduct Clinical Trial for Patients with Chronic Achilles Tendinosis

# The University of British Columbia Clinical Research Ethics Board Clears Clinical Trial to Proceed with Site Initiation and Patient Recruitment

VANCOUVER, BC – April 15, 2015 – RepliCel Life Sciences Inc. (OTCQB: REPCF) (TSX.V: RP), a clinical stage regenerative medicine company focused on the development of autologous cell therapies, announced today that it has received approval from the University of British Columbia (UBC) Clinical Research Ethics Board (CREB) to conduct a phase 1/2 clinical trial at the UBC Hospital.

The trial, entitled, "A randomized, double-blind, placebo-controlled, single-centre study to evaluate the efficacy and safety of RCT-01 in men and women with unilateral, chronic Achilles tendinosis" (also known as the "ReaCT study"), will investigate the potential of RepliCel's tendon repair product, RCT-01, to treat chronic tendon injury. CREB approval clears the way for site initiation and patient recruitment into the clinical trial.

The ReaCT study will be led by an affiliated researcher, Dr. Rob Lloyd-Smith, with the Vancouver Coastal Health Research Institute (VCHRI). "VCHRI is very pleased to be supporting biotechnology in British Columbia and play a role in the development of a potential technology in cell therapy," says Dr. Robert McMaster, Executive Director of VCHRI and Vice-President of Research with Vancouver Coastal Health.

The study will include 28 participants with chronic Achilles tendinosis. Study participants will receive ultrasound-guided injections of either RCT-01 or placebo (on a 3:1 treatment-to-placebo ratio) directly into areas of injury within the Achilles tendon. Participants' overall health and tendinosis will be monitored over a six month period while they undergo post-treatment physiotherapy to help facilitate recovery from their Achilles tendinosis.

"I am very excited to be involved in this world-class study investigating the use of RepliCel's autologous cell therapy for the treatment of chronic tendinosis," stated Jack Taunton, MD, Professor Emeritus Faculty of Medicine, Division of Sports Medicine at the University of British Columbia and Director Sports Medicine at Fortius Sport & Health, acting in the capacity of clinical trial medical monitor. "For several decades, I have been proud to be part of a group of clinicians in Vancouver conducting cutting-edge research looking for better ways to treat patients with various tendinopathies. We believe cell therapy – and in particular hairderived fibroblasts which are highly expressive of type 1 collagen – represents a promising approach to treating these patients and generating better, quicker, and longer-lasting outcomes than current treatment options. While patients will be followed-up for longer periods, by early 2016 we expect to have data giving us a clear indication of the potential for this treatment to regenerate tendon in ways currently not possible."

"With UBC CREB approval, we can immediately take the steps needed to open this trial to patient recruitment and treatment. This is an important milestone in management's plan to create significant value in the company through mid-2016," stated Darrell Panich, Vice President of Clinical Affairs for RepliCel.

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RCT-01 is the first of two products from RepliCel's non-bulbar dermal sheath (NBDS) fibroblast platform currently slated to be tested in clinical trials in 2015. Subject to regulatory clearance, the second product, RCS-01, will be evaluated as a potential treatment for aged and UV-damaged skin. The company filed an application to conduct a phase 1 clinical trial of RCS-01 with the German competent regulatory authority on February 23, 2015 and is now awaiting clearance. RepliCel's NBDS fibroblast program is a broad platform that has the potential to extend into other indications characterized by impaired tissue healing and a deficit of type 1 collagen.

RepliCel is actively targeting commercialization partners for both of these products, particularly in Asian markets at this time. The company owns all rights to these product candidates and is in active prosecution of a full spectrum of intellectual property protection around key aspects of the cell source, manufacturing, use and composition of matter.

## **About Chronic Achilles Tendinosis**

Chronic Achilles tendinosis is a degenerative disease of the tendon. It is caused by a cycle of injury, improper healing and re-injury. It can result in ongoing pain and loss of function. Tendinosis is often caused by sports related injuries, occupational overuse, aging and poor general health. Chronic Achilles tendinosis affects both physically active and inactive individuals accounting for 30 to 50% of all sports injuries and 50% of occupation-related disorders in the United States.

Healthy functioning tendon is comprised largely of highly structured type 1 collagen supported by the repair and maintenance functions of resident fibroblasts. In chronic tendinosis, it is believed that the resident fibroblast population is insufficient to complete the required healing. The basis of the RCT-01 treatment is to augment the resident fibroblast population in the damaged tendon with fibroblasts which are easily isolated (from the hair follicle), readily expanded, and highly expressive of the type 1 collagen and other extracellular proteins needed to reignite the healing process and support the regeneration of tendon.

### About the UBC Clinical Research Ethics Board (CREB)

The UBC CREB reviews clinical research conducted at UBC's Vancouver campus and at Vancouver Coastal Health Authority sites including UBC Hospital, Vancouver General Hospital and GF Strong. Activities that fall under UBC CREB review include: the administration or testing of drugs, medical devices, medical imaging or diagnostic techniques; and the taking of blood or other specimens. It also includes the analysis of laboratory, physiological, kinesiological or biological data obtained from physical interventions, medical records or clinical studies involving the linkage of data from existing databases.

### About Vancouver Coastal Health Research Institute (VCHRI)

VCHRI, a world leader in translational health research, is the research body of Vancouver Coastal Health Authority. VCHRI includes three of BC's largest academic and teaching health sciences centres — Vancouver General Hospital, UBC Hospital, and GF Strong Rehabilitation Centre — as well as many other hospitals and public health agencies across Vancouver Coastal Health. VCHRI is academically affiliated with UBC Faculty of Medicine and is one of Canada's top funded research centres receiving between \$80-100 million in research funding annually. Over 1500 personnel are engaged in a variety of research centres, programs and evolving research areas. www.vchri.ca

### **About RepliCel Life Sciences**

RepliCel is a regenerative medicine company focused on developing autologous cell therapies that address diseases caused by a deficit of healthy cells required for normal healing and function. The company's RCT-01, RCS-01, and RCH-01 cell therapies are designed to treat chronic tendinosis, damaged or aging skin, and pattern baldness. All product candidates are based on RepliCel's innovative technology utilizing cell

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populations isolated from a patient's own healthy hair follicles. The company is also developing a propriety injection device optimized for the administration of its products and licensable for use with other dermatology applications. The company's product pipeline is comprised of multiple clinical trials anticipated to launch through Q1 2015 in addition to Shiseido's own clinical trial of RCH-01 and the device in late prototype development. Visit <u>www.replicel.com</u> for additional information.

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This press release contains forward-looking information that involve various risks and uncertainties regarding future events, including statements regarding our approach and our technology, expected and planned upcoming milestones and events, and the timing of trials. Such forward-looking information can include without limitation statements based on current expectations involving a number of risks and uncertainties and are not guarantees of future performance of RepliCel. There are numerous risks and uncertainties that could cause actual results and RepliCel's plans and objectives to differ materially from those expressed in the forward-looking information, including: approval to conduct clinical trials; approval from the University of British Columbia's Clinical Ethics Review Board; delays enrolling clinical trial participants; negative results from the Company's clinical trials; the effects of government regulation on the Company's business; risks associated with the Company's ability to obtain and protect rights to its intellectual property; risks and uncertainties and future events could differ materially from those anticipated in such information. These and all subsequent written and oral forward-looking information are based on estimates and opinions of management on the dates they are made and are expressly qualified in their entirety by this notice. Except as required by law, RepliCel does not intend to update these forward-looking statements.

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