



# Replicel's Successful RCT-01 Tendon Repair Clinical Trial Shows Signs of Healing Chronic Tendon Problems

# First-in-human clinical study meets primary endpoint demonstrating product safety and clinical potential for tendon regeneration and healing

**VANCOUVER, BC – March 28, 2017** – RepliCel Life Sciences Inc. (OTCQB: REPCF) (TSXV: RP) (FRA:P6P2) ("RepliCel" or the "Company") is pleased to report compelling safety and clinical data from its phase 1/2 tendon repair study investigating the use of RepliCel's type 1 collagen-expressing, hair follicle-derived fibroblasts (RCT-01) as a treatment for Achilles tendinosis.

The clinical trial met its goal of establishing a complete safety profile at 6 months and showed no serious adverse events related to the study treatment or injection procedure.

Additionally, each of the treated participants, all of whom suffered chronic tendon pain and loss of function over an extended period of time with no recovery from standard treatments, showed numerous clinically important improvements by various measures including tendon composition, blood supply, physical function and pain sensation.

"Chronic tendinosis is a state of tendon degeneration that is very difficult to reverse, as evidenced by the many therapies used to try and treat it," stated Dr. Ross Davidson, an orthopedic surgeon, former clinical professor at the Department of Orthopaedics at the University of British Columbia, and past head physician and orthopaedic consultant for the Vancouver Canucks (of the National Hockey League (NHL)).

"This study shows exciting clinical improvements in patients with clinically diagnosed chronic Achilles tendinosis who were unresponsive to standard treatments, and who had suffered for many months (in some cases, years) with frequent pain and loss of function. Not only did the study show several clinically important improvements in pain and function scores, but several ultrasound measures clearly demonstrate a marked improvement in tendon structure; something rarely seen in patients with this condition," said Davidson.

"With further clinical studies, this new technology could represent a cutting-edge advancement in kickstarting a healing process that results in tendon regeneration. For the first time, we may have a treatment that shows signs of reversing the underlying problem, versus just treating the symptoms. This could be a game-changer in sports medicine," Dr. Davidson concluded.

The most clinically material improvements observed from the study are summarized as follows:

#### VISA-A Scale of Achilles Tendon Injury Severity

Participants treated with RCT-01 in the per protocol population who completed the VISA-A evaluation 6 months after receipt of injections showed clinically relevant signals of healing



including an overall 15.3% improvement in total score compared to baseline. Two patients showed select measures of near-complete recovery in function (by VISA-A scoring).

#### **VAS Scale of Pain Severity**

Four out of five participants treated with RCT-01 who completed questionnaires 6 months after injection showed clinically relevant signals of improvement in pain on loading (running/jumping) based on VAS score. Average improvement in VAS score for the four participants was 62.9% over baseline VAS score.

Three out of five participants treated with RCT-01 who completed questionnaires 6 months after injection showed improvement in pain on palpation based on VAS score. Average improvement in VAS score for the three participants was 55.2% over baseline VAS score.

Two patients showed select measures of near-complete elimination of pain (by VAS scoring).

"This trial was to show the safety of injection of hair follicle-derived non-bulbar dermal sheath cells (NBDS)," stated RepliCel's Chief Medical Officer, Dr. Rolf Hoffman, "as well as to repeat the landmark trials of our collaborators who injected skin-derived fibroblasts together with PRP (platelet-rich plasma) in different tendinopathies. We believe the cause of healing (mechanism of action) in those studies was the cellular collagen production and not the PRP which, in our view, has little clinical or commercial potential as a therapeutic product or treatment for tendon repair."

"I am very pleased that in this trial we see some early signals of regenerative healing in some patients and because of its similar pathogenesis, there is every reason to believe the ability to heal Achilles tendons will extend to numerous applications including repairing the patellar tendon of the knee (jumper's knee), both tendons of elbow (tennis elbow, golfer's elbow), and the rotator cuff," observed Dr. Hoffmann. "Furthermore," he concluded, "when we have established that our cell therapy heals chronic tendon injury, it may then be used by physicians for more acute injury with the goal of an approved label for these additional treatments in the future."

"This is a major step forward in the Company's development of a series of products which leverage the exciting collagen-producing capacity of these cells," stated RepliCel CEO, Lee Buckler. "Our management and clinical team are very excited about the data from this trial and the potential for further development and clinical testing of this product to treat patients without good options for the tendon degeneration, pain and loss of function they are experiencing."

Buckler concluded: "We have captured the medical and investment communities' attention and see the results of this much anticipated, proof-of-concept clinical study as an opportunity to advance therapies for patients and incrementally add value for shareholders in the months ahead."

## **About Achilles Tendinopathy**

Achilles tendinopathy is a condition that causes pain, swelling and stiffness of the Achilles tendon that joins your heel bone to your calf muscles. It is thought to be caused by repeated tiny injuries to the Achilles tendon. These may occur for a number of reasons, including overuse of the tendon; for example, in runners. Treatments range from physiotherapy, to anti-inflammatory medications, to surgery. For many people, symptoms of Achilles tendon injury usually clear within three to six months of starting treatment. However, for some people the injury does not respond to treatment and progresses



to chronic tendinosis. There is an estimated incidence rate of 656,211 new cases of mid-portion Achilles tendinopathy each year in North America alone, according to statistics published in the *British Journal of Sports Medicine*.

# **About the RCT-01 Tendon Repair Study**

The study was designed to demonstrate the safety of a single injection of RepliCel's RCT-01 into the Achilles tendon. While the study was not designed to be statistically significant for efficacy, multiple measures of efficacy were incorporated to give insights into the product's potential and to assist in guiding future development decisions. Measures of whether the product may be working included testing and scoring patient pain in various settings, evaluating overall function, blood flow changes in the tendon, and changes in the overall density and composition of the tendon as measured by ultrasound imaging. For further trial details see: <a href="https://www.clinicaltrials.gov/ct2/show/NCT02330146">https://www.clinicaltrials.gov/ct2/show/NCT02330146</a>.

The first-in-human study involved patients clinically diagnosed with chronic Achilles tendinosis. The primary purpose of this single-centre, phase 1/2 randomized (3:1), double blind, placebo-controlled trial was to assess the safety profile of RCT-01 injections, as compared to placebo injections. The study also measured the potential efficacy and impact injections had on tendon structure and function and the symptoms of Achilles tendinosis. The study was led by principal investigator Dr. Rob Lloyd-Smith, MDCM of the University of British Columbia (UBC) and was conducted at the UBC Sports Medicine Clinic in Vancouver, BC, Canada. Data from such a trial, not designed for statistical significance, often signals clinically significance, which is extremely informative for future product development and clinical trial design. The goal of the study was to establish sufficient evidence of safety to allow the Company to proceed with well-powered phase 2 studies investigating optimal dosing, treatment frequency, effect duration, etc.

As was expected with injecting 1.5mL into the Achilles tendon, all study participants who received injections (less one RCT-01-injected participant) reported at least one adverse event related to treatment regardless of treatment administered (RCT-01 or placebo). The adverse events were either soreness at the injection site or the observation of a partial thickness tear in the tendon post-injection. Most reports of soreness resolved shortly after receiving injections.

#### **About Tendon Treatment Clinical Efficacy Measurements**

#### VISA-A

The VISA-A scale aims to evaluate the clinical severity for patients with chronic Achilles tendinopathy. It is a questionnaire which evaluates symptoms and their effect on physical activity. It can be used to compare different populations with chronic Achilles tendinopathy and facilitate comparisons between studies. It can be used to determine the patient's clinical severity. The VISA-A represents a clinically validated, reliable and disease-specific questionnaire to measure the condition of the Achilles tendon, but it is not a diagnostic tool. The final version of the questionnaire was named the Victorian Institute of Sport Assessment-Achilles Questionnaire.

#### VAS

A Visual Analogue Scale (VAS) is often used in epidemiologic and clinical research to measure the intensity or frequency of various symptoms. It is an instrument that measures a characteristic or attitude that is believed to range across a continuum of values and cannot easily be directly measured. For example, the amount of pain that a patient feels ranges across a continuum from none to an



extreme amount of pain. From the patient's perspective, this spectrum appears on a continuum, in that their pain does not take discrete jumps, as a categorization of none, mild, moderate and severe would suggest. It was to capture this idea of an underlying continuum that the VAS was devised.

#### About Dr. Ross Davidson

Dr. Davidson is the former Director, Post Graduate Programmes in Sports Medicine at the University of Auckland, and a member of the New Zealand Orthopaedic Association and the Canadian Orthopaedic Association. He is the past president of the National Hockey League Physicians Society, past head physician and orthopaedic consultant for the Vancouver Canucks Hockey Club (NHL), past orthopaedic consultant to the Vancouver Grizzlies Basketball Team (NBA), past orthopaedic consultant to Allan McGavin Sports Medicine Centre, and past orthopaedic consultant to the Canadian Football League Players Association. Dr. Davidson held the position of clinical professor, department of orthopaedics at the University of British Columbia until 2000.

## **About RepliCel Life Sciences**

RepliCel is a regenerative medicine company focused on developing autologous cell therapies that address conditions caused by a deficit of healthy cells required for normal tissue healing and function. The Company's product pipeline is comprised of three clinical-stage products: RCT-01 for tendon repair, RCS-01 for skin rejuvenation and RCH-01 hair restoration. RCH-01 is under exclusive license by Shiseido Company for certain Asian countries

All product candidates are based on RepliCel's innovative technology, utilizing cell populations isolated from a patient's healthy hair follicles. RepliCel has also developed a proprietary injection device (RCI-02) optimized for the administration of its products and licensable for use with other dermatology applications. Please visit http://replicel.com/ for additional information.

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# Forward-looking information

This press release contains forward-looking statements and information that involve various risks and uncertainties regarding future events, including, but not limited to, statements regarding (i) that RCT-01 has the ability to heal Achilles tendons, (ii) that RCT-01 will extend to numerous applications including repairing the patellar tendon of the knee (jumper's knee), both tendons of elbow (tennis elbow, golfer's elbow), and the rotator cuff, (ii) that the results of this clinical study will act as an opportunity to advance therapies for patients and incrementally add value for shareholders over the months ahead.

These statements are only predictions and involve known and unknown risks which may cause actual results and the Company's plans and objectives to differ materially from those expressed in the forward-looking statements, including: the risk that there will be delays enrolling clinical trial participants; the risk that the Company will receive negative results from the Company's clinical trials; the effects of government regulation on the Company's business; risks associated with future approvals for clinical trials; risks associated with the Company obtaining approval for its clinical trial in Germany; risks associated with the Company obtaining all necessary regulatory approvals for its various programs in Canada, the USA and Germany; risks associated with the Company's ability to obtain and protect rights to its intellectual property; risks and uncertainties in connection with the outstanding issues alleged by Shiseido in connection with the License and Co-development Agreement; risks and uncertainties associated with the Company's ability to raise additional capital; and other factors beyond the Company's control.



Although the Company believes that the expectations reflected in the forward-looking statements are reasonable, it cannot guarantee future results, levels of activity or performance. Further, any forward-looking statement speaks only as of the date on which such statement is made and, except as required by applicable law, the Company undertakes no obligation to update any forward-looking statement to reflect events or circumstances after the date on which such statement is made or to reflect the occurrence of unanticipated events. New factors emerge from time to time, and it is not possible for management to predict all of such factors and to assess in advance the impact of such factors on the Company's business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statement. Readers should consult all of the information set forth herein and should also refer to the risk factor disclosure outlined in the Company's annual report on Form 20-F for the fiscal year ended December 31, 2015 and other periodic reports filed from time-to-time with the Securities and Exchange Commission on Edgar at <a href="https://www.sec.gov">www.sec.gov</a> and with the British Columbia Securities Commission on SEDAR at <a href="https://www.sedar.com">www.sedar.com</a>.

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