RepliCel™

NEWS RELEASE

# RepliCel Life Sciences Cleared to Initiate Clinical Trial of RCS-01 for Dermal Rejuvenation

## Patient recruitment will take place at the IUF Leibniz-Institut für umweltmedizinische Forschung GmbH in Germany

**VANCOUVER, BC – September 1, 2015 – RepliCel Life Sciences Inc. (OTCQB: REPCF) (TSX.V: RP)**, a clinical stage regenerative medicine company focused on the development of autologous cell therapies, today announced it has received approval from the Paul Ehrlich Institute (PEI), the regulatory body responsible for approving all cell-based clinical trials in Germany, to conduct its RCS-01 skin rejuvenation clinical trial. PEI approval clears the way for site initiation and patient recruitment to be conducted at the IUF Leibniz-Institut für umweltmedizinische Forschung GmbH in Germany. To learn more about the trial or to determine if you meet eligibility criteria, please visit https://www.clinicaltrials.gov/ or click here.

"We are pleased to have received PEI's approval to conduct our skin rejuvenation trial. We believe RCS-01 provides a better alternative to fillers currently available on the market that include hyaluronic acid and the results of which fade over a relatively short period. RepliCel's autologous cell therapy uses a subject's own replicated fibroblast cells to rebuild the collagen, elastin and other glycoproteins that provide structural support and stability to the extra cellular matrix – potentially returning skin back to its youthful appearance," commented Dr. Rolf Hoffmann, Chief Medical Officer. "According to the American Society of Plastic Surgeons, 5,497,212 injectable procedures were performed in 2014 costing $2,317,396,347. We believe RepliCel's autologous product will be preferred by most patients who would rather inject a filler comprised of their own fibroblast cells into their skin."

"RCS-01 initiation approval in Germany represents a second clinical trial based on RepliCel's non-bulbar dermal sheath fibroblast (NBDS) platform to be initiated this year, the first being RCT-01 in Canada. Given the estimated time frame for enrollment and interim data reveal of both programs, we can look forward to results in the second half of 2016," stated David Hall, CEO. "The design of both trials is to provide safety, clinically relevant, and quantitative biologic data to support licensing discussions while demonstrating the further potential for expanding medical indications for our NBDS platform."

This phase 1 trial in healthy volunteers will investigate the potential of RepliCel's skin rejuvenation product, RCS-01, to treat intrinsic aging of the skin, skin wrinkling and solar degeneration of the skin. RepliCel's non-bulbar dermal sheath-derived fibroblast therapy (RCS-01) provides a promising treatment for these conditions by providing UV-naïve collagen-producing cells directly to affected areas. RepliCel's unique manufacturing technology allows for isolation of fibroblasts derived from anagen-hair follicle mesenchymal tissue, which elicit efficient replication potential in culture. Furthermore, the proprietary culture conditions in which RCS-01 is manufactured should enable these cells to maintain their inherent ability to adapt to their microenvironment and respond to the surrounding stimuli after injection, leading to robust, natural production of type 1 collagen, elastin and other extracellular proteins within the tissue. The goal is to develop a first-of-its-kind treatment for fine wrinkles on sun-damaged skin.

**Trial Design**

The study is projected to include 30 participants, male and female. Participants will be selected based on their health status, current/past medications and ability to adhere to protocol-related requirements. After providing informed consent at the first visit, participants will be evaluated against the study inclusion/exclusion criteria and will provide blood samples for screening assessments. If suitable for participation, a biopsy will be taken from the scalp from which RSC-01 will be prepared, and four treatment evaluation sites will be identified on the buttocks – two on each side. Participants will be randomized into one of two treatment groups; one will receive injections of RCS-01 or placebo or a 'sham' injection (a needle penetration without injection of liquid) while the other (placebo group) will only receive placebo or a 'sham' injection. The primary purpose of this study is to assess the safety profile of RCS-01 injections compared to placebo injections. The study will also measure the impact RCS-01 injections have on skin markers related to aging through evaluation of gene expression profiles. This trial design is intended to deliver data related to how, and the degree in which the product injection improves the fullness of the extracellular matrix supporting the skin. This data will be critical to designing future trials intended to affect the skin's appearance in areas of aesthetic importance.

**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 populations isolated from a patient's own healthy hair follicles. The company has also developed a propriety injection device optimized for the administration of its products and licensable for use with other dermatology applications. Visit www.replicel.com for additional information.

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This press release contains projections and forward-looking statements, as that term is defined under applicable securities laws. Statements in this press release, which are not purely historical, are forward-looking statements and include (i) that RCS-01 will provide a better alternative to existing fillers in the market, (ii) that RCS-01 will return skin back to its youthful appearance, (iii) that RCS-01 will be preferred over other fillers, (iv) delays in receiving results in the second half of 2016. 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 information, including: 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 Shiseido obtaining approval for its clinical trial; 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 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, 2014 and other periodic reports filed from time-to-time with the Securities and Exchange Commission on Edgar at www.sec.gov and with the British Columbia Securities Commission on Sedar at www.sedar.com.

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