

## **Positive Results from RepliCel's RCS-01 Phase I Skin Trial are the Company's Most Compelling to Date**

**Interim trial results lead researchers to conclude that the injection of RCS-01 is not only very safe, but also has the potential to reverse effects of aging skin, representing a natural alternative to existing anti-aging treatments**

**VANCOUVER, BC** – April 4, 2017 – RepliCel Life Sciences Inc. (OTCQB: REPCF) (TSXV: RP) (FRA:P6P2) (“RepliCel” or the “Company”) is pleased to report statistically and clinically significant positive data from the interim analysis of its phase I study evaluating RCS-01 for the treatment of aging and sun-damaged skin.

The primary objective of this trial was to establish a complete safety profile for intradermal injections of RCS-01 (RepliCel's type 1 collagen-expressing, hair follicle-derived fibroblasts [“NBDS cells”]) at six months post-injection. Participants in the Germany-based study did not report any serious adverse events at the interim point of the trial. Researchers also gathered compelling positive proof-of-concept data indicating the product's potential for skin rejuvenation.

The study was neither powered for, nor was expected to show statistically significant results of efficacy. However, the nearly two-fold increase in gene expression of collagen-related biomarkers in the skin, after a single injection of RCS-01, was so profound with a single RCS-01 injection, that the results are considered statistically significant. The study observed the impact of the injection on ten different biomarkers that, in peer-reviewed medical literature, are highly correlated with skin aging and chronically sun-damaged skin. Notably, gene expression markers, such as tissue inhibitor of metalloproteinases (TIMP), showed significant changes expected to correlate with increased collagen fibers. Increased collagen production, and reduced collagen degradation, is associated with fewer wrinkles and the repair of sun-damaged skin.

“This type of positive effect on TIMP gene expression, which is related to protection against collagen degeneration, is rarely observed. In my experience, after decades of performing these tests, this is an exceptional finding, particularly for a safety trial with a small sample size,” stated Prof. Dr. med Jean Krutmann, Scientific Manager of the IUF Leibniz Research Institute for Environmental Medicine where the study was conducted. “The promising results demonstrate the potential of RCS-01 to promote skin rejuvenation. An increase in collagen markers of this nature would be expected to translate into clinically measurable and aesthetically visible effects.”

Krutmann concluded: “Replication of these results in a larger trial would confirm our view of the product's potential as a more natural alternative to Botulinum toxins and fillers that only temporarily prevent and reverse the signs of aging.”

“This study not only showed an excellent safety profile, but also provides compelling proof-of-concept

that RepliCel's RCS-01 cells are, by nature, very good collagen producers in the skin," stated Dr. Rolf Hoffmann, RepliCel's Chief Medical Officer. "We are highly encouraged by the findings and eager to demonstrate the correlation between the change in these biomarkers and clinically important endpoints such as wrinkle depth, in a larger multi-centre trial studying optimal dose and treatment frequency."

"As a practicing dermatologist," Hoffmann continued, "the potential of RCS-01 represents a leap-forward in the way we look at skin anti-aging, especially for the fine wrinkles in UV-damaged skin where we have no long-lasting treatment today. Of importance is the fact that, because RCS-01 is comprised of cells derived from tissue at the back of the patient's scalp, these cells are not only very good collagen producers, but also UV-protected and therefore more functionally active."

"In my opinion," Hoffmann concluded, "this is the first example of a treatment potentially capable of rejuvenating UV-damaged skin."

"This is the most compelling data we have announced to date," stated RepliCel CEO and President, R. Lee Buckler. "Longer term, this data is very complementary to our focus on commercializing a next-generation dermal injector and its targeted application not only with RCS-01, but also with other aesthetic products on the market today. We look forward to discussing these findings and the potential of our products with a number of aesthetic-focused institutional investors and major multinational licensing partners who have already expressed interest in our programs."

### **About Aging and UV-damaged Skin Markets**

Ultra-violet (UV) light exposure from the sun is responsible for up to 80% of visible facial skin aging. According to statistics from the American Society for Plastic Surgeons, \$2.5 billion was spent on facial aesthetics in 2013 and this is predicted to grow to over \$5.4 billion by 2020. Dermal filler procedures are growing over 15% annually.

### **About the RCS-01 Study**

The clinical trial was a randomized, double-blind, placebo-controlled, single-centre, phase I safety study of intradermal injections of RCS-01 in healthy subjects. The primary endpoint was to assess the local safety profile by recording and evaluating adverse events reported at the treatment evaluation sites. Secondary safety measures related to any reporting of systemic adverse events and assessment of histopathological abnormalities of the treatment sites. Secondary endpoints also included evaluating any changes in expression of numerous genetic markers (using real-time PCR) related to intrinsic skin aging, skin wrinkling and solar degeneration of skin.

After trial inclusion, all participants provided a biopsy from the scalp from which RCS-01 was prepared at a central GMP manufacturing site. Study participants were randomized to one of two treatment subgroups that received intradermal injections of either RCS-01 or placebo. Each participant had four treatment evaluation sites identified on their buttocks, two on each side to allow for a within-subject comparison of single and triple injections of RCS-01 with placebo respectively. Participants in the RCS-01 Subgroup received injections of RCS-01 or placebo or a 'sham' injection (a needle penetration without injection of liquid). Participants in the Placebo Subgroup were randomized to receive only injections of placebo or sham injections to compare the systemic safety profile to the RCS Subgroup.

Baseline evaluations of subjects' overall health and skin condition at treatment sites on their buttocks were performed before receipt of injections at Day 0. In addition to injections delivered at Day 0, the pre-selected treatment evaluation sites received intradermal injections of RCS-01 or placebo (cryomedium) or a sham injection four and eight weeks after Day 0 according to a randomization schedule for a total of three injections per treatment site.

All participants returned/will return to the clinic for at least nine visits to monitor safety. Assessment of the local safety profile was performed by the investigator before each injection visit, two to four days after injection, and 12 and 26 weeks after injection. The investigator was asked to examine each treatment site for the presence or absence of local adverse events and grade them with respect to relatedness to treatment, severity and seriousness. Other study assessments included recording of vital signs at each visit and routine laboratory assessments at screening, injection visits and at the Week 26 time point. At the 12-week time point, nine randomly selected participants provided biopsies from all injection sites for gene expression analysis of skin markers related to aging. At Week-26 (cut-off date of the interim analysis), the remaining participants provided biopsies of all injection sites for histopathological analysis.

All reported pre-defined local adverse events related to injection or sham were transient and mainly mild in intensity only. No other related local or systemic adverse events were reported. No clinically relevant abnormal laboratory results or abnormal vital signs were reported up to the cut-off date of this interim analysis. Histopathological assessments of treatment evaluation site biopsies were all judged to be normal by a blinded investigator.

#### **About Prof. Dr. med Jean Krutmann**

Prof Dr. med Jean Krutmann is Professor of Dermatology and Environmental Medicine and Director of the IUF Leibniz Research Institute for Environmental Medicine at the Heinrich-Heine-University Düsseldorf. He is a coordinator of the Leibniz Research Alliance "Healthy Aging" (a strategic alliance of 23 Leibniz institutes). His research is in the field of derma-toxicology and immune-dermatology with special emphasis on environmentally-induced skin diseases and skin aging. Prof. Krutmann is author or co-author of more than 200 papers. He is the recipient of the International Arnold-Rikli-Award, the Albert Fleckenstein Award, the Paul Gerson Unna Award, the Oscar Gans Award, the C.E.R.I.E.S. Research Support Award and the Dermopharmacy Innovation Award. He is a visiting and adjunct professor of dermatology at the Nagoya City University, Japan, Case Western Reserve University, Cleveland, Ohio and University of Alabama, Birmingham, AL, USA. He is a member of the National Academy of Science of Germany and Xu Guang Qi Lecturer, Shanghai Institute for Biological Sciences (CAS), Shanghai, China.

#### **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 for 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 is also developing a proprietary injection device (RCI-02) optimized for the administration of its products and licensable for use with other dermatology applications. Please visit <http://replixel.com/> for additional information.

**For more information, please contact:**

Lee Buckler, CEO and President

Telephone: 604-248-8693 / [lee@replixel.com](mailto:lee@replixel.com)

**Forward-looking information**

Certain statements in this news release are forward-looking statements, which reflect the expectations of management regarding the results of the RCS-01 Phase 1 skin trial. Forward-looking statements consist of statements that are not purely historical, including any statements regarding beliefs, plans, expectations or intentions regarding the future. Forward looking statements in this news release include: statements relating to the anti-aging potential of RCS-01, its ability to promote skin rejuvenation, and its potential as a more natural alternative to Botulinum toxins and fillers; the Company's expectation that significant changes to gene expression markers are expected to correlate with increased collagen fibers; that increased collagen production and reduced collagen degradation should potentially lead to fewer wrinkles and the repair of sun-damaged skin; that RepliCel's RCS-01 cells are by nature very good collagen producers in the skin; the potential correlation between changes in biomarkers and clinically important endpoints; that the potential of RCS-01 represents a leap-forward in skin anti-aging; the potential application for other aesthetic products; and the expected timing of return of trial participants for analysis and the process to be undertaken in connection with same. 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 [www.sec.gov](http://www.sec.gov) and with the British Columbia Securities Commission on SEDAR at [www.sedar.com](http://www.sedar.com).

Neither TSX Venture Exchange nor its Regulation Services Provider (as that term is defined in policies of the TSX Venture Exchange) accepts responsibility for the adequacy or accuracy of this release.

##