

## **RepliCel Submits Clinical Trial Application for its Dermatological Product**

**Autologous cell therapy, RCS-01, to be investigated as a potential treatment for aged, UV-damaged skin**

**VANCOUVER, BC – February 23, 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 the submission of a Clinical Trial Application (CTA) to the German Competent Authority, the Paul-Ehrlich-Institut (PEI), requesting clearance to initiate a Phase 1 clinical trial investigating the use of RCS-01 to treat patients suffering from aged and UV-damaged skin. RCS-01 is a cell-based product highly expressive of type 1 collagen comprised of autologous, cultured fibroblast cells isolated from the non-bulbar dermal sheath (NBDS) of the hair follicle.

The study, entitled, “Randomized, double-blind, placebo-controlled, single-centre, phase 1 safety study of intra-dermal injections of RCS-01 in male and female subjects (50 to 65 years old)”, addresses the inherent deficit of active fibroblasts required for the production of type 1 collagen, elastin and other critical extracellular dermal matrix components found in youthful skin. If cleared to proceed, the proposed trial will be conducted at the IUF Leibniz-Institut für umweltmedizinische Forschung GmbH in Germany.

“Skin aging is caused by a reduction in metabolically active fibroblasts, disorganization of collagen fibrils and decreased production of collagen, elastin and other glycoproteins that provide structural support and stability to the extra cellular matrix. We believe that RCS-01 has the potential to reverse the signs of aging by providing RepliCel’s UV-naïve collagen-producing fibroblast cells directly into affected areas of the skin. This trial is an important step toward the development of a cell-based treatment for fine wrinkle lines which are typically seen in the face, hands and other UV-affected areas,” commented Dr. Rolf Hoffmann, RepliCel’s Chief Medical Officer.

“RCS-01 is the second product, utilizing our hair follicle-derived fibroblasts, that we anticipate entering clinical testing in 2015 - the first being RCT-01 for chronic tendinosis. While the primary endpoint of this trial is to demonstrate the safety of RCS-01 injections into the skin, the trial is also designed to collect quantitative and qualitative data demonstrating the product’s effects, at a molecular level, on skin aging and UV-damage,” stated David Hall, RepliCel’s CEO. “This fibroblast-based program should be viewed as a broad platform which we will apply to multiple indications characterized by tissue damage and incomplete healing. We anticipate data from these NBDS trials (RCS-01 and RCT-01) will contribute to the early establishment of the commercial value of our fibroblast platform.”

“Initiation of this trial is another milestone in our 18-month strategy to create maximum value around the company’s fibroblast program,” stated Lee Buckler, RepliCel’s Vice-President of Business and Corporate Development. “In addition to our clinical trial programs, our team is working on manufacturing optimization involving state-of-the-art bioreactor technology and serum-free media, development of a proprietary injector device to reduce the human variability of our product injections, and pre-clinical research validating the immune-privilege of both our cell platforms in order to support the potential for allogeneic use of RepliCel’s products.”

Further details of the clinical program evaluating intra-dermal injections of RCS-01 will be provided once it has been cleared by the PEI.

### **About Skin Aging**

Skin is considered one of the most prominent indicators of one's age and health. Maintenance of healthy skin is dictated by intrinsic and extrinsic factors. While intrinsic factors (i.e. chronologic age, sex and genetic makeup) cannot be modified, the adverse effects caused by extrinsic factors such as UV radiation and smoking can be prevented or minimized by lifestyle modification. Although these extrinsic effects can be modulated, the extent to which they can be modified varies significantly among individuals, which largely depends on one's ability to detoxify and repair such damages.

Damage or loss of fibroblasts in the skin leads to reduction in overall production of collagen, elastin and other extracellular matrix ("ECM") components such as hyaluronic acid and glycosaminoglycan which provide structural support and stability to the ECM. Collagen, in particular, plays a significant role in providing the dermis with tensile force and elasticity that is reflected in a 'youthful' appearance. This structurally important protein is produced mainly by fibroblasts in the dermis. The interactions between fibroblasts and ECM proteins are orchestrated by specialized cell surface receptor proteins, called integrins, which extracellularly bind type I collagen and intracellularly bind cytoskeletal contractile proteins via anchor protein complexes. The mechanical tension maintained in the dermis by 'pulling' cytoskeletal contractile forces and 'resisting' collagen fibrils provides fibroblasts a flattened/spread-out appearance, which is characteristic of a younger dermis. In contrast, fibroblasts in an aged dermis have a collapsed appearance due to reduced cytoplasm and lack of cell attachment to collagen fibrils, which are often fragmented in the elderly dermis, thus limiting tensile capacity.

RepliCel's RCS-01 product holds promise as a treatment for intrinsically or extrinsically aged/damaged skin 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 tissues which elicit efficient replication potential in culture. Furthermore, the proprietary culture conditions in which RCS-01 is manufactured enables these cells to maintain plasticity. This plasticity allows the cells to adapt to the microenvironment and respond to the mechanical or surrounding stimuli after injection, leading to robust production of type 1 collagen and elastin and their proper alignment within the tissue.

The market for dermal fillers currently represents almost 6 million procedures per year and expenditures of almost \$2 billion in 2013 according to statistics provided by the American Society of Plastic Surgeons.

### **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 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. Shiseido Company, Limited has an exclusive license for RCH-01 in certain Asian countries including Japan, China and South Korea. All product candidates are based on RepliCel's innovative technology utilizing cell 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 in 2015 in addition to Shiseido's own clinical trial of RCH-01 and the device in late prototype development. Visit [www.replicel.com](http://www.replicel.com) for additional information.

For more information please contact:

**CORPORATE/MEDIA:**

Tammey George, Director of Communications

Telephone: 604-248-8696

[tg@replifel.com](mailto:tg@replifel.com)

[www.replifel.com](http://www.replifel.com)

**INVESTOR RELATIONS:**

R. Lee Buckler, Vice President of Business and Corporate Development

Telephone: 604-248-8693

[info@replifel.com](mailto:info@replifel.com)

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