

RepliCel Life Sciences Announces Initiation of Clinical Site and Participant Recruitment for European Skin Aging Study

Clinical trial site located at IUF Leibniz-Institut für umweltmedizinische Forschung GmbH in Germany

VANCOUVER, BC – September 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, today announced that its European Phase 1 study ([NCT02391935](https://clinicaltrials.gov/ct2/show/study/NCT02391935)) of intradermal injections of RCS-01 to treat aged and sun damaged skin has been initiated 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 anticipate fast patient enrollment and 6-month data in autumn 2016. We look forward to analyzing the safety of triple injections of our autologous cellular product, RCS-01, as a potential treatment for intrinsic aging, wrinkling and solar degeneration of the skin,” stated Dr. Rolf Hoffmann, Chief Medical Officer & Director of RepliCel. “We will also be measuring 10 different biomarkers related to skin aging which will give us a good indication of the changes in the skin. The repair of damaged skin at the cellular level, via the natural cell-based production of type 1 collagen and other important matrix molecules, would fundamentally change the aesthetics market currently flooded with dermal products that temporarily reverse the signs of aging using fillers and hyaluronic acids.”

“This RCS-01 trial initiation represents the second clinical trial of RepliCel’s non-bulbar dermal sheath fibroblast (NBDS) platform to be initiated this year, the first being RCT-01 in Canada for chronic tendinosis. Given the estimated time frame for enrollment and interim data reveal of both programs, we anticipate results in the second half of 2016,” stated Lee Buckler, Vice President Business and Corporate Development. “Both clinical trials are designed to provide the company with much data to support our current NBDS platform licensing discussions as well as demonstrate a basis for the potential expansion into other medical indications.”

About the Study

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 RCS-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 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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