

RepliCel Reignites its First-in-Japan Strategy

Next-stage trials in Japan present market launch opportunities for RepliCel's skin and tendon products

VANCOUVER, BC, CANADA – 19 March, 2019 – RepliCel Life Sciences Inc. (OTCQB: REPCF) (TSXV: RP) (FRA:P6P2) (“RepliCel” or the “Company”), a company developing next-generation technologies in aesthetics and orthopedics, is pleased to announce the resumption of their First-in-Japan strategy.

The Company, working with industry leaders, CJ PARTNERS, have initiated a program in Japan to realize its goal of launching its cell therapy products in Japan sooner than would be possible anywhere else in the world. Because of this unique opportunity, the Company's next-phase trials will be conducted in Japan.

Unlike anywhere else in the world, one well-designed cell therapy trial in Japan, approved by their regulatory authorities, has the potential to lead to product market launch. The strategy to bring its products to market first in Japan spans the Company's entire portfolio. While the Company's RCH-01 for hair loss due to androgenic alopecia may be launched in Japan much earlier if Shiseido decides to do so, current planning anticipates the potential for all four products to be on the market in Japan by 2022.

RepliCel is leveraging a history of working in Japan which began in 2013 when the Company laid the foundation for its First-in-Japan strategy as one of the first foreign regenerative medicine companies to have a Japanese partnership. RepliCel followed that in 2015 as one of the first foreign regenerative medicine companies to initiate a consultation process, under the new regulations for regenerative medicine products, with Japan's PMDA (Pharmaceuticals and Medical Device Agency).

Again in 2016, RepliCel's licensee, Shiseido Company, was one of the first companies to fund, and manufacture a product for use in, a clinical study under the newly enacted Act for the Safety of Regenerative Medicine (ASRM).

While 2017 and 2018 saw RepliCel focus activity in Europe, Canada, and China, only weeks after the Board recently authorized a resumption of its First-in-Japan strategy, the Company has already initiated:

- the continuation of its regulatory review process with the PMDA for the Company's cell therapy platform;
- planning for a clinical trial of its RCT-01 product for the treatment of tendinopathy;
- planning for the clinical trial of its RCS-01 product for skin rejuvenation;
- preparations to submit the application to the PMDA for approval to market the Company's dermal injector (RCI-02) upon it being CE-marked.

“With the regulatory reform for regenerative medicines now firmly entrenched,” states Colin Lee Novick of CJ PARTNERS, “there is an exciting maturity impacting the evolution of the cell therapy industry in Japan

as never seen before. We are seeing another wave of foreign-domestic partnership, an emerging trend of foreign companies sponsoring their own clinical development in Japan, and a dramatic increase of domestic-sponsored clinical activity. This is beginning to materially impact patients, health care providers, investors, biopharma companies, and ancillary industries in ways which were only imagined in 2013 when the reforms were first drafted. It is an exciting time for both foreign and domestic stakeholders who decide to invest in Japan's rapidly developing regenerative medicine sector."

RepliCel's First-in-Japan Strategy: A Portfolio View

RCT-01 for chronic tendinopathy - A Japanese clinical trial of RepliCel's RCT-01 treatment for tendinopathy is aimed at obtaining conditional approval from Japan's regulatory authority to market the product and obtain medical insurance reimbursement there for up to seven years before an application for final approval is required.

RCS-01 - A clinical study of the Company's RCS-01 treatment for the rejuvenation of aging and sun-damaged skin is expected to lead to a launch of the product in Japan under the nation's Act for the Safety of Regenerative Medicine.

RCI-02 - RepliCel's next-generation, dermal injector, a medical device designed to deliver optimized and controlled injection of cell therapies and other injectables, is expected to be launched in Europe, Hong Kong and other markets accepting CE mark approval next year. The marketing approval application for the injector will be submitted in Japan as soon as possible once the CE mark application is submitted. The device will be marketed for the injection of various dermatology treatments but is expected to be critical to delivery of the Company's RCS-01 treatment.

RCH-01 – A Japanese clinical study of RepliCel's RCH-01 treatment for hair loss due to androgenic alopecia, approved by Japan's Ministry of Health, Labour and Welfare, has been the subject of a clinical study recently completed at Tokyo Medical University Hospital and Toho University Medical Center Ohashi Hospital. The market is now keenly watching Shiseido Company, RepliCel's licensee of the product for Asia, for any signal regarding its launch of that product in Japan.

Resources About Cell Therapy in Japan

Video: "Invest in Japan: Medical Industry" - https://youtu.be/IVym_W0ADYo

Video: "Has Japan's Regenerative Medicine Experiment Paid Off?" - <https://youtu.be/eT8hjzyuzl>

Article: "Regenerative Medicine Environment -A Guide to Understand the Pathways to Get Approval in Japan" - https://firm.or.jp/_rmit/wp-content/uploads/2018/10/Japans-RM-Environment-2018.pdf

Article: "Japan's regulatory gamble and what it means for the Industry" - http://www.cj-partners.com/en/news/files/000025_en_01.pdf

About RepliCel Life Sciences

RepliCel is a regenerative medicine company focused on developing cell therapies for aesthetic and orthopedic conditions affecting what the Company believes is approximately one in three people in industrialized nations, including aging/sun-damaged skin, pattern baldness, and chronic tendon degeneration. These conditions, often associated with aging, are caused by a deficit of healthy cells required for normal tissue healing and function. These cell therapy product candidates are based on RepliCel's innovative technology, utilizing cell populations isolated from a patient's healthy hair follicles.

The Company's product pipeline is comprised of RCT-01 for tendon repair, RCS-01 for skin rejuvenation, and RCH-01 for hair restoration. RCH-01 is exclusively licensed in Asia to Shiseido Company. RepliCel and Shiseido are currently co-developing the product in Japan. RepliCel maintains the rights to RCH-01 for the rest of the world. RCT-01 and RCS-01 are exclusively licensed in Greater China to YOFOTO (China) Health Company. RepliCel and YOFOTO are currently co-developing these products in China. RepliCel maintains the rights to these products outside of Greater China.

RepliCel has also developed a proprietary injection device, RCI-02, and related consumables, which is expected to improve the administration of its cell therapy products and certain other injectables. YOFOTO has exclusively licensed the commercial rights for the RCI-02 device and consumables in Greater China for dermatology applications and is expected to first launch the product in Hong Kong upon it being CE marked. Please visit www.replicel.com for additional information.

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