Organized by:

JETRO Japan External Trade Organization

CCRM Centre for Commercialization of Regenerative Medicine

Japan's Regenerative Medicine Market

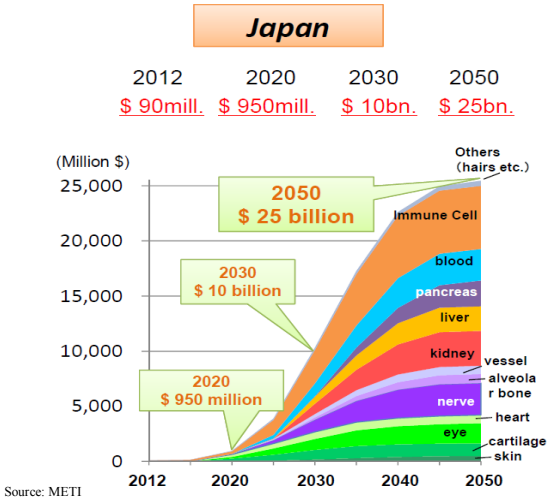
Supported by:

OIRM Ontario Institute for Regenerative Medicine

International Society for Cellular Therapy ISCT

Both Canada and Japan are putting great efforts into supporting the **regenerative medicine (RM) sector** to promote further research, to support the **commercialization** of RM products and to create an environment where RM develops into a fully **established industry**.

On Jan. 29, 2016, the Toronto office of the Japan External Trade Organization (JETRO) and the **Centre for Commercialization of Regenerative Medicine (CCRM)**, with the support of the Ontario Institute for Regenerative Medicine (OIRM) and the International Society for Cellular Therapy (ISCT), organized a seminar in Toronto with a **distinguished line-up of speakers** to explain about Japan's new regulatory environment for the **approval of RM products** in Japan, to survey the existing RM-related linkages between Canada and Japan, and to **outline future activities** designed to bring the two RM communities even closer together.



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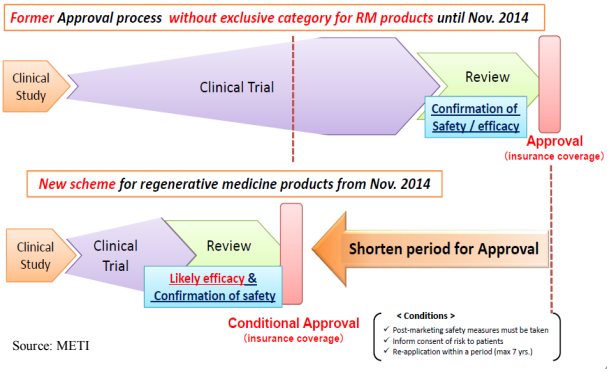

Source: METI

For presentations and other material on Japan's RM market:

www.jetro.go.jp/canada/progs/japanrmmarket.html

FIRM

The keynote speaker from Japan, Dr. Fusako Nishigaki, a representative of Astellas Pharma and a key member of Japan's Forum for Innovative Regenerative Medicine (FIRM), explained that, by 2050, the RM market in Japan is expected to reach US$25b.

Japan's Nov. 2014 Pharmaceutical and Medical Devices Act established a new separate category for RM products and an expedited approval system through which, with likely efficacy and safety confirmed, one can get conditional market approval and be reimbursed prior to full approval.

At the same time, Japan's Act on the Safety of Regenerative Medicine enabled medical institutions to outsource cell and tissue processing, which previously could only be carried out in medical institutions, thereby creating a new market.

Two RM products have been approved in Japan less than 1 year after the introduction of these new laws: JCR Pharma received regular approval for their treatment of Acute GVHD; Terumo received conditional approval for its autologous skeletal myoblast sheets, cultured from a patient's own thigh muscle to be transplanted to the patient's heart.

Many foreign companies are entering into collaborations with Japanese firms such as Nikon-Lonza, Fujifilm-Cellular Dynamics, Healios-Athersys and Shiseido-RepliCel.

FIRM, established in 2011 and compromised of 183 companies, is playing an active role in facilitating international partnerships and, through its Regenerative Medicine Industrialization Task Force (RMIT), is willing to find potential partners for foreign firms with their member companies.

RepliCel™

Lee Buckler, President & CEO of RepliCel Life Sciences, explained about his 2013 licensing partnership with Japanese cosmetic giant Shiseido to develop its cell therapy for pattern baldness. Shiseido has built a new PMDA certified cell-processing facility in Kobe, has completed Phase 1 trials in Japan and he expects Phase 2 trials to begin soon.

RepliCel is looking for licensing partners for its other cell therapy products for dermal rejuvenation and tendon repair, as well as a unique dermal injector device.

Mr. Buckler believes that the new regulations have made Japan a high priority for even small companies. Japan is very receptive to RM technology right now, Japanese government support is very good, including that of JETRO, and Japan's PMDA regulator is very proactive on how to engage them.

CCRM Centre for Commercialization of Regenerative Medicine

Dr. Michael May, President & CEO of CCRM as co-host and MC of the event, highlighted the fact that both Canada and Japan are leaders in the field of RM and he emphasized that it was important for Canada and Japan to work closely together.

Internationally, Dr. May explained that CCRM is looking to build HUBs in countries such as Japan, the U.S., Australia, China and Israel. The aim is to create critical mass and to bundle I.P. in order to create the partnerships needed to bring cell therapies to market.

CCRM is expanding its linkages into Japan: Japanese companies such as Nikon, MediNet and Cellular Dynamics Int., acquired by Fujifilm, are CCRM members; it is evaluating technology with Japanese firm 360IP Japan; it is looking to hold a workshop with Japanese regulators; and, as announced at the seminar, CCRM hopes to sign an MoU with FIRM in the near future.

OIRM Ontario Institute for Regenerative Medicine

Dr. Janet Rossant, Executive Director of OIRM, noted that Ontario is the home of stem cells, which were discovered in Toronto, and that now Ontario has a strong stem cell ecosystem of 170 scientists. Already, there are 8 clinical trials in RM being conducted in Ontario with 647 patients focussed on brain/nerves, blood, joints, heart, spine and the digestive system.

Dr. Rossant also gave the audience an overview of the 3 academic joint research projects under way as part of the 2013-2018 Canada-Japan Joint Program in Epigenetics of Stem Cells funded by the Canadian Institutes of Health Research (CIHR) and the Japan Agency for Medical Research and Development (AMED), one of which she is leading. Such academic tie-ups, including for example the work between Dr. Andre Nagy and Dr. Shinya Yamanaka's team in Kyoto on pluripotency, has led to many exchanges of faculty and students between Canada and Japan as well as Canadian trained faculty now based in Japan. This academic research may lead to future commercial opportunities.

JETRO Japan External Trade Organization

As well as supporting foreign RM companies to set up operations or JVs in Japan, for example in order for them to do clinical trials there, JETRO has a new ¥1 billion subsidy programme to help foreign RM firms establish global innovation sites in Japan as well as to conduct demonstration experiments and feasibility studies in Japan in collaboration with Japanese partners.