Innovatie Attaché Tokio

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Japan working hard on regenerative medicine

Dutch summary

Japan is hard aan de slag met regeneratieve geneeskunde. De ontwikkeling op het gebied van cel- en weefselregeneratie is een van de pilaren van de groeistrategie van de Japanse overheid, die proactief projecten ondersteunt om de internationale concurrentiepositie van het land verder te versterken. Aanpassingen vorig jaar in regelgeving voor farmacie en medische apparatuur moet procedures voor commercialisering van relevante producten versnellen. Een nieuw agentschap vanaf april 2015 gaat activiteiten bij relevante ministeries beter stroomlijnen en het support system versterken.

Bedrijven in de sector profiteren van deze ontwikkelingen. Farmaceutische bedrijven als Fujifilm, maar ook aanbieders van optische en elektronische apparatuur als Nikon, investeren actief en gaan internationale verbanden aan. Tien bedrijven sloegen in juni 2015 de handen ineen: ze vormden een task force die volgend jaar een nieuw onderzoekscentrum voor regeneratieve geneeskunde gaat oprichten, waar ook buitenlandse biotech bedrijven worden uitgenodigd.

Een van de drijvende krachten voor de ontwikkeling van regeneratieve geneeskunde in Japan is Professor Shinya Yamanaka van Kyoto University, die in 2012 de Nobelprijs ontving voor zijn baanbrekende iPS stamcell-onderzoek.

Summary

Japan is working hard on regenerative medicine. The development of cell and tissue regeneration is one of the pillars of the Growth Strategy in Japan and the government is pushing projects to improve competitiveness of this growing industry. The legislation for pharmaceutical and medical device was revised last fall to enable shorten the approval processes for commercialization. A new Agency for Medical Research and Development (AMED, 1) was also established in April 2015 for better crossovers between relevant ministries and strengthen support system of network in the development process. Benefiting from these movements, major pharmaceutical companies and other industries, such as Fujifilm and Nikon are actively investing and collaborating with overseas companies. In June 2015, the ten key companies formed a task force to establish a regenerative medicine development center and are inviting biotech companies from overseas. The opportunity for regenerative medicine has been expanding after Professor Shinya Yamanaka of Kyoto University won the Nobel Prize for iPS cell research in 2012.

Growth Strategy

The regenerative medicine is a pillar of growth strategy in Japan and the government is pushing projects in the development of new drugs and technology to improve competitiveness of this growing industry. The revision of pharmaceutical and medical device law enforced last November and a new approval system was established for priority review and approval for innovative products. As the regenerative medicine receives high
expectations for practical application, the new system will shorten the approval for commercialization as little as three to four years including development after meeting the safety requirements which shortened by approximately six years compared to decades ago. This revision of the law created a separate regulatory pathway for medical devices and could lead less complex approval procedures for some foreign manufacturers.

Better support system

A National Agency, the Japan Agency for Medical Research and Development (AMED, 1) was also established in April 2015. This new organization will engage in R&D in the field of medicine, to maintain an efficient and better environment of R&D, funding, and managing R&D projects with 330 staff. In addition, budgets for research expenses had previously been allocated from three different ministries, Ministry of Science (MEXT), Health (MHLW), and Economy (METI). AMED consolidates these budgets, for the effective management of research. AMED implements these tasks based on the Healthcare Policy determined by the Cabinet and on the Plan for the Promotion of Medical R&D produced by the Headquarters for Healthcare and Medical Strategy Promotion chaired by the Prime Minister.

These movements and globalization accelerated, especially after Professor Shinya Yamanaka of University of Kyoto won the Nobel Prize in 2012 for developing iPS cells, which can grow into any type of human tissue. The transplant surgery for regenerative retina cells in a female patient with age-related macular degeneration was performed in September 2014. The Center for iPS Research Application (Director, Prof. Yamanaka) and Takeda pharmaceutical entered 10 years of collaboration research in April 2015 (2).

Industry benefits

In addition to major pharmaceutical and medical device companies, other industries and venture businesses are entering the market. Japanese companies have been aggressively taking over foreign companies. For example, Fujifilm acquired U.S. based developer and manufacturer, of fully functioning human cells in industrial quantities to precise specifications, Cellular Dynamics International, Inc. in March 15. Nikon and Lonza of Switzerland agreed to collaborate for cell and gene therapy manufacturing in Japan in May 2015. Olympus and Mitsubishi Chemical HD also established regenerative medicine units within the organization to expand the opportunities (3).

Ten companies set up new research lab

Regenerative Medicine Industrialization Task Force (RMIT) announced its plan of ten companies from Japan and abroad to establish a regenerative medicine development center in Kawasaki city in 2017. They are inviting overseas biotech companies to join and collaborate, to pool the technologies and provide regenerative medicine treatments using cultured cells, in order to lead the development and commercialization of regenerative medicine.

The ten companies are; Fujifilm, Astellas Pharma, Janssen Pharma, Regience, Rohto Pharmaceutical, Cell Seed, Wako Pure Chemical, Takara Bio,Tella, MediNet (4). The major areas of the development are cell processing and culturing, cell sheet, material, equipment, reagent and pharmaceutical. The taskforce was established within the Forum for Innovative Regenerative Medicine (FIRM, 5) in Japan which has over 150 member companies
Taking the advantage of these movements in Japan, the plan of the taskforce companies is to actively promote regenerative medicine technologies to overseas from Japan. The development center will be built in the special economic zone in Kawasaki, "Keihin life innovation international strategic zone” in neighboring city of Tokyo (6). The life innovation international center will open in Spring 2016 (7).

**Market outlook**

The global market for regenerative medicine estimated by Ministry of Economy, Trade and Industry (METI), amounts to an annual 100 billion yen ($811 million), and expects to grow rapidly to 1 trillion yen in 2020, and 12 trillion yen in 2030. The cultivation equipment and other related industries that support products and services of regenerative medicine are also expected to increase to 5 trillion yen by 2030 (8).

As the advancement of regenerative medicine is expected to contributes to better medical treatment methods and lower cost on the long term. At the same time, it is important to secure the safety issues and speed up the commercialization. Through the collaborative development for regenerative medicine with overseas biotech companies, it is expected to lead and build expertise and establish the global standard of cell culturing and quality management.

**Source and more information**

4. Activities of the regenerative medicine companies (Alphabetical order):
   - **Astellas Pharma**  
     As a part of the collaborative research for kidney regenerative medicine with Kyoto University’s Center for iPS Cell Research and Application (Director: Prof. Shinya Yamanaka), discovered efficient methods of differentiating nephron progenitor cells from human iPS/ES cells in 2013. An agreement with Osaka University in February 2015, to establish a joint research to develop fundamental technologies for next-generation cell therapies and bringing those technologies to practical use.
   - **Cell Seed**  
     Develops cell-sheets for regenerative medicine for epithelial cell sheet for corneal regeneration, esophageal, periodontal tissue, regenerated cardiac patch and cartilage sheet. Established a subsidiary in Stockholm in June 2015, and will collaborate with Karolinska University Hospital for clinical trial.
   - **Fujifilm**  
     Consolidated subsidiary with Japan Tissue Engineering in 2014 and accelerates the development of RCP(Human-type collagen, synthesized with microorganisms, using genetic engineering technology)—compounds with excellent biocompatibility that can be processed into various formulations—as the "scaffold" to aid cell growth and proliferation, required in regenerative medicine products.
- **MediNet**  
  Announced an agreement in June 2015 to support clinical study at Kyushu University and National Hospital Organization Kyushu Cancer center on manufacture investigational new drug, ATL-DE-101.

- **Regience**  
  In June 2015, announced an agreement with Anritsu corporation to develop regenerative medicine cell products management system and patient personal data store system.

- **Rohto Pharmaceutical**  
  Established a regenerative medicine center in Ryukyu University in Okinawa in June 2015, to progress research of materials for propagating fat mesenchymal stromal/stem to launch products for internal diseases.  
  Reached a research agreement in June 2014, with International Stem Cell Corporation (ISCO), a California-based biotechnology company developing novel stem cell-based therapies, Rohto will evaluate stem cell-derived human cells owned and provided by ISCO in a number of pre-clinical animal models.

- **Takara Bio**  
  Published a research paper studied at Mie University on "Adoptive Transfer of MAGE-A4 T-cell Receptor Gene-Transduced Lymphocytes in Patients with Recurrent Esophageal Cancer" in April 2015.

5. **FIRM**: [http://firm.or.jp/en](http://firm.or.jp/en)

6. "Keihin life innovation international strategic zone“  

7. "Life Innovation Center“ in Japanese  