

The Quest for Advanced Regenerative Medicine

Foreign Firms Drawn by Japan's Expedited Approval System

Regenerative medicine is drawing attention as a form of treatment using people's cells and a method that can be used for testing new pharmaceuticals. Japan has been leading the world in this field, as exemplified by the research into induced pluripotent stem cells (iPS cells) by Dr. Shinya Yamanaka, winner of the 2012 Nobel Prize in Physiology or Medicine. The global market for regenerative medicine is seen as growing to a huge JPY 38 trillion (USD 345 billion) by 2050. In Japan, government and industry are working hand in hand to advance this field with measures including bold regulatory reform and active promotion of investment by foreign corporations.

In November 2014 Japan became the first country in the world to adopt an expedited approval system for regenerative medical products and to allow outsourced cell culturing. Two products were approved under the new system within a year of its adoption. Thanks to this system, it has become possible in some cases to secure approval of new regenerative medical products in Japan prior to their approval in other countries.

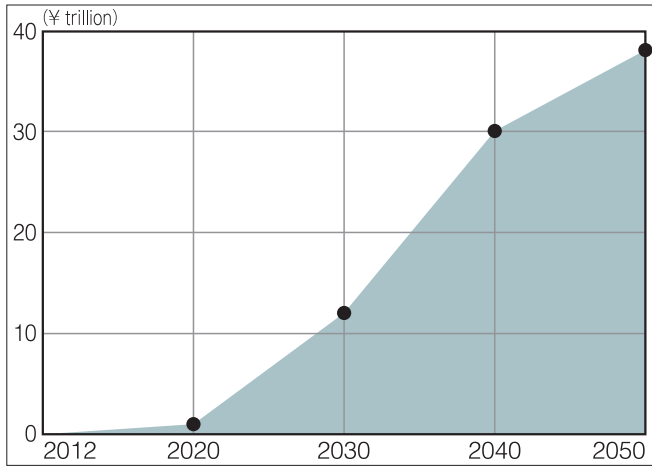
In 2015 three government ministries—the Ministry of Education, Culture, Sports, Science and Technology; the Ministry of Health, Labour and Welfare; and the Ministry of Economy, Trade and Industry—joined in establishing the Japan Agency for Medical Research and Development. Through this agency the three ministries have created a unified setup for promotion of research and development. Meanwhile, the Japan External Trade Organization (JETRO) has taken the lead in efforts to support foreign companies that invest in regenerative medicine in Japan, with some JPY 1 billion (USD 9 million) in financial support available. Thanks to such initiatives, foreign companies have come to see Japan's regenerative medicine market as offering opportunities.

Japanese industry is also welcoming the entry of foreign participants. As early as 2011, companies involved in this field joined in launching the Forum for Innovative Regenerative Medicine (FIRM) to serve as a pipe connecting the relevant companies and research institutions, both Japanese and foreign. FIRM's Representative Director and Chairman Yuzo Toda stresses, "Japan, with its aging population, has a strong need for regenerative medicine, and it also has the technological strength to develop practical applications based on research results."

According to FIRM, some foreign companies are now considering making Japan the initial market for their new regenerative medical products so as to achieve quick practical use for them. Toda declares, "Conditions are in place for realization of Japan-made, world-first products. FIRM's role is to serve as an incubator for the regenerative medicine industry. We want to advance initiatives to open up this new field, working in tandem with Japanese and foreign companies."

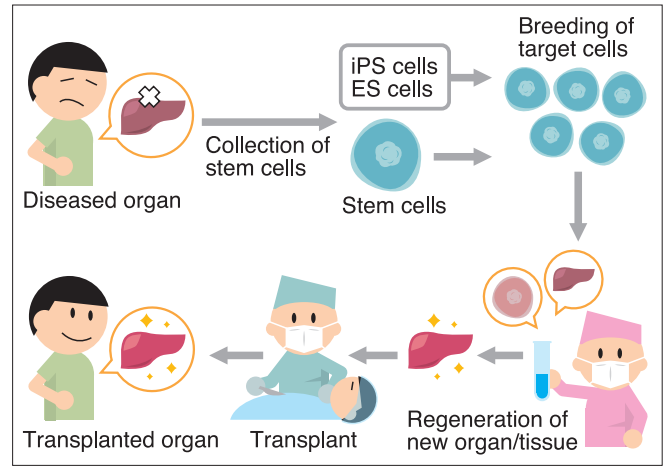
FIRM has established a partnership with the Alliance for Regenerative Medicine (ARM), America's trade association for regenerative medicine. It also has tie-ups with Sweden, Britain, and Australia, and Canada will soon join the list. Japan's initiatives in the field of regenerative medicine are developing international breadth.

Global scale of the regenerative medicine market



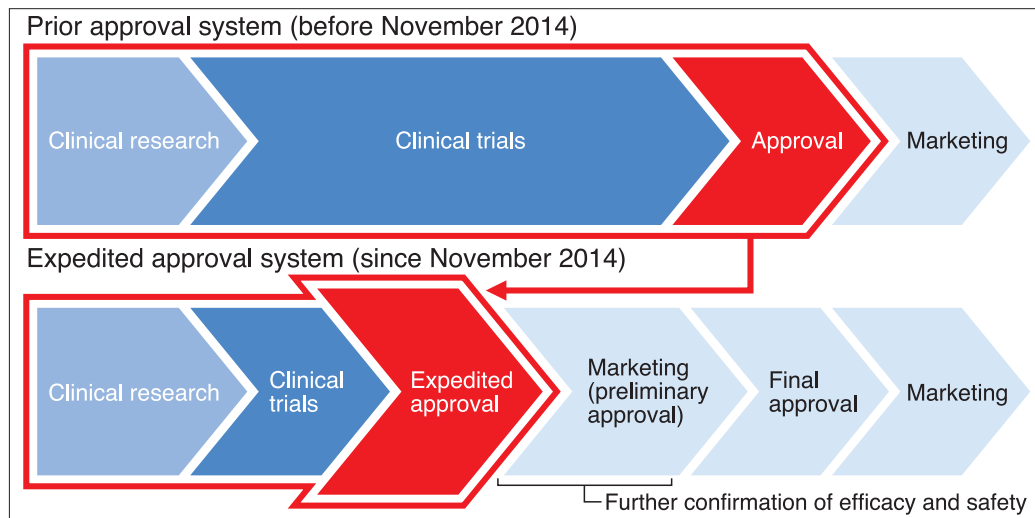
The future scale of the global market for regenerative medicine is forecast to grow to JPY 1 trillion (USD 9 billion) by 2020 and JPY 38 trillion (USD 345 billion) by 2050.

A medical field drawing global attention



Examples of regenerative medicine using iPS cells, embryonic stem cells, and somatic stem cells, now drawing attention for its potential in curing previously untreatable conditions.

Shortening of development period under expedited approval system



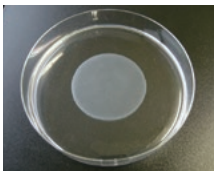
By comparison with the previous approval process, this system provides for a major shortening of the time required for approval of pharmaceuticals, subject to further confirmation after marketing, followed by a review of the approval.

Two regenerative medical products approved

JCR Pharmaceuticals:
TemCell (allogenic mesenchymal stromal cells)



Terumo: HeartSheet (autologous skeletal muscle cells)



Yuzo Toda, Representative Director, Chairman Forum for Innovative Regenerative Medicine (FIRM)

FIRM, with 185 corporate members as of January 2016, is working to close gaps in awareness and regulations regarding regenerative medicine among industry, academia, government, and citizens, as well as to show specific ways forward.

