Recent Advances of the Commercialization for Tissue Engineered and Regenerative Products in Korea: Update 2020

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In Korea, there are launching in market as ~ eighteen products related with regenerative medicinal products including cell therapy products and tissue engineered products (TEMPs) from 2001 up to now. First approved one on 2001, Chondron as autologous chondrocytes for the treatment chondyle defects are sailing steadily around last 20 years. Also, keratinocyte from autologous or allogenous as Haloderm™ and Kaloderm™ have been developed the treatment of burn patients resulting in relatively success treatment for patients. Hearticellgram-AMI™ developed by FCB-Pharmicell was approved by the Ministry of Food and Drug Safety (MFDS, KFDA) as the world’s first stem cell treatment for clinical use for heart attack patients in July 2011. MFDS approved two treatments such as Medipost’s Cartistem™ for the treatment of osteoarthritis using allogenic adult bone marrow derived stem cell (BMSC) and Anterogen’s Cupistem™ for the treatment of Crohn’s disease using autologous adult adipose derived stem cell (ADSC), registering both as the world’s second and third authorized stem cell procedures in Jan 2012. Also Nueronata for the treatment of ALS using BMSC has been introduced in market. Among these, the Cartistem treatment is the world’s first allogeneic stem cell treatment which is advantageous because it has a higher mass-production potential and consistent treatment efficacy.

Even though these activities might be still infancy for the industrialization in Korea including CAR-T cell therapy for cancer treatment, it looks like a good sign for the treatment for patients. Commercialized products have been limited in cell therapy products rather than TEMPs since cell therapy can be only the injection of stem cell via vein or aorta to injury site. From Fall 2020, the special law of regenerative medicine will be activated in Korea.

In this presentation, we will discuss about the main hurdle of FDA approval at each country, recent trends of commercialization circumstances for the worldwide as well as the future direction of the development of TEMPS.