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RECENT ADVANCES OF THE COMMERCIALIZATION FOR TISSUE ENGINEERED AND REGENERATIVE PRODUCTS IN KOREA AND GLOBAL; UPDATE 2018

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SUMMARY

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 10 years. Also, keratinocyte from autologous or allogenuous as HalodermTM and KalodermTM have been developed the treatment of burn patients resulting in relatively success treatment for patients during last 7 ~ 10 years.

Very recently, Hearticellgram-AMITM developed by FCB-Pharmicell was approved by the Korea Food & Drug Administration (KFDA) as the world's first stem cell treatment for clinical use for heart attack patients in July 2011. KFDA approved two treatments such as Medipost's CartistemTM for the treatment of osteoarthritis using allogenic adult bone marrow derived stem cell (BMSC) and Anterogen's CupistemTM 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. On July 30th, 2014, Neuronata-RTM has been approved for the treatment of amyotrophic lateral sclerosis (ALS) using BMSC by KFDA. 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, 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. 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.

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