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TWOCELLS and KAKEN Announce a License Agreement for “gMSC®1”, the Allogenic Synovial Mesenchymal Stem Cell-Derived Three-Dimensional Artificial Tissue



TWOCELLS Co., Ltd. [Head Office: Hiroshima city, Hiroshima; President & CEO: Masaya Matsumoto] and Kaken Pharmaceutical Co., Ltd. [Head Office: Bunkyo-ku, Tokyo; President: Hiroyuki Horiuchi] announced that both companies concluded a license agreement regarding gMSC®1, the allogenic synovial mesenchymal stem cell-derived three-dimensional artificial tissue created by TWOCELLS. Under this agreement, Kaken will obtain joint development and exclusive marketing rights of regenerative medical product gMSC®1 in the field of orthopedics in Japan. In consideration for this agreement, TWOCELLS will receive an upfront payment, development costs related to such development, and development and sales milestone payments of up to approximately 7 billion yen. In addition, after the product is launched, TWOCELLS will receive royalties from KAKEN based on the amount of sales.

Under this agreement, TWOCELLS will conduct clinical trials aimed at obtaining initial approval in Japan, and will be responsible for the manufacturing, supply of gMSC®1, New Drug Application, and regulatory authorities correspondence for obtaining approval. Meanwhile, KAKEN will collaborate with TWOCELLS to promote clinical development and market the product after the initial approval.

This license agreement will enable TWOCELLS and KAKEN to make a head start in materializing regenerative medicine for chondrogenesis using allogeneic synovium-derived MSC.

About "gMSC®1," the allogenic synovial mesenchymal stem cells derived three-dimensional artificial tissue:

gMSC®1 is a tissue-engineered medical product currently developed by TWOCELLS and was created for the purpose of regenerative chondrogenesis using synovium-derived mesenchymal stem cell (MSC). This product is an allogeneic 3D artificial tissue of MSC (without external scaffold addition) provided by TWOCELLS with its own technologies and serum-free medium (STK®1 and STK®2), which is expected to provide an effective treatment for cartilage regeneration. TWOCELLS has received supports from JST (Japan Science and Technology Agency), NEDO (New Energy and Industrial Technology Development Organization), METI (Ministry of Economy, Trade and Industry) and AMED (Japan Agency for Medical Research and Development) which in the research and development of gMSC®1.

About TWOCELLS

TWOCELLS is a biotech-startup company established in 2003, spinning out of Hiroshima University, based on a pre-venture project "Team for regenerative medicine of osteocartilaginous tissues" founded and run by JST (Japan Science and Technology Agency) in 2000 to 2003. The company's mission is to bring regenerative medicine to the world, and by particularly targeting MSC, which is a type of somatic stem cells, it is engaging in the developments of MSC-related culturing techniques and systems/products for regenerative medicine. Currently, TWOCELLS has developed "Serum-free medium STK® series for MSC" and gMSC®1, the allogenic synovial mesenchymal stem cell-derived three-dimensional artificial tissue for traumatic cartilage injury and osteochondritis dissecans and conducted domestic Phase III clinical trials.

For more information concerning TWOCELLS, please see <https://www.twocells.com/english/>.

About Kaken Pharmaceutical Co., Ltd.

Kaken is an R&D driven pharmaceutical company, established in 1948, and its corporate philosophy is to help improve the quality of life of patients by serving as many people as possible to return smiles of happiness to their faces, through supplying superior pharmaceuticals. The Company has a particularly strong presence in the field of orthopedics, and its main product, "Artz", contributes to improvement in patients with osteoarthritis of the knee and shoulder. The Company also take on challenge of new modalities as announced in the "Long-Term Business Plan 2031". For more information, please visit <https://www.kaken.co.jp/english/>

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