

For reference purposes only – Japanese version prevails in case of any discrepancy

June 2, 2025

License Agreement for “gMSC[®]1”, the Allogenic Synovial Mesenchymal Stem Cell-Derived Three-Dimensional Artificial Tissue

Kaken Pharmaceutical Co., Ltd. (“Kaken” or the “Company”, Head Office: Bunkyo-ku, Tokyo; President and Representative Director, Hiroyuki Horiuchi), announced that it has entered into a license agreement regarding gMSC[®]1 (the “Product”), the allogenic synovial mesenchymal stem cell-derived three-dimensional artificial tissue created by TWOCELLS Co., Ltd. (“TWOCELLS”, Head Office: Hiroshima city, Hiroshima; President & CEO, Masaya Matsumoto) on June XX, 2025.

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, Kaken will make TWOCELLS an upfront payment, development costs related to such development, and development and sales milestone payments of up to approximately seven billion yen. In addition, after the Product is launched, the Company will pay TWOCELLS royalties based on the amount of sales.

Kaken will support TWOCELLS in the developing of the Product in order to obtain marketing authorization in Japan as a regenerative medicine. After obtaining the marketing authorization approval, Kaken will market the Product supplied by TWOCELLS.

Kaken has explored opportunities for collaboration with specialized companies that are working on new modalities, with the aim of realizing regenerative medicine, as a measure to challenge new fields in the R&D Transformation of its “Long-Term Business Plan 2031¹⁾”. With this agreement, both companies will accelerate the joint development of the Product and strive to bring new treatment options to patients with orthopedic conditions.

¹⁾ Kaken “Long-term Business Plan 2031”: https://www.kaken.co.jp/english/invest/policy/long_term.html

About TWOCELLS

TWOCELLS Co., Ltd. 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 about TWOCELLS, please visit <https://www.twocells.com/english/>.

News Release



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 cartilage repair using synovium-derived mesenchymal stem cell (MSC). This product is an allogeneic three-dimensional 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.

Cautionary notes regarding forward-looking statement

This release contains forward-looking statements on the Kaken group’s business. They are projections based on information available at the time this release was prepared, and may differ from actual results due to a variety of factors. In addition, although this release includes information related to pharmaceutical products (including those under development), these statements are not intended to be advertisement or medical advice.