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Chugai Pharmaceutical Co., Ltd.

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Completion of Enrollment in Phase III Comparative Study for Investigational Regenerative Cellular Medicine (gMSC[®]1) for Knee Chondrogenesis Using Allogeneic 3D Artificial Tissue of MSC

TOKYO, October 27, 2021 -- [Chugai Pharmaceutical Co., Ltd.](#) (TOKYO: 4519) and TWOCELLS Co., Ltd. (Head Office: Hiroshima City, Hiroshima; President and CEO: Toshiki Hiura; hereafter, TWOCELLS) announced completion of target enrollment into a Phase III comparative study for an investigational regenerative cellular medicine for chondrogenesis in the knee (development number "gMSC[®]1"), with surgery on the 70th patient.

This study examines the safety and efficacy of transplanting gMSC[®]1, a three-dimensional artificial tissue of allogeneic MSCs, in comparison with microfracture surgery for patients with symptomatic traumatic cartilage defects or osteochondritis dissecans in the knee. The enrollment had started on November 29, 2017 and completed with the 70th surgery, fully enrolling the target number of patients. Going forward, the primary endpoints of histological evaluation of the cartilage and subjective symptoms will be analyzed at week 52 after surgery.

“The articular cartilage in the knee plays an important role in assisting with smooth leg movement. It has a very limited regenerative capacity, and various methods of treatment are under investigation for damages on the cartilage. gMSC[®]1 aims to repair the cartilage in the knee as a regenerative cell therapy which does not require the patient’s own tissue taken from their joint, potentially paving the way for solving unmet medical needs in existing treatments. We hope that the assessment ahead will prove the value of gMSC[®]1, Chugai's first regenerative medicine project, and its benefit for patients,” said Dr. Osamu Okuda, President and CEO of Chugai.

Toshiki Hiura, President and CEO of TWOCELLS, said, “Despite significant impact from COVID-19 pandemic, we have successfully completed enrollment in the study. Supported by the partnership with Chugai, we, here in Hiroshima, are smoothly advancing the development of basic technologies required for allogenic tissues, the provision of tissues from donors and establishing a GCTP-compatible facility to manufacture final products in Japan for the first time. We will build commercial production capacity as early as possible and strive to make regenerative medicine a familiar treatment option.”

Chugai and TWOCELLS concluded a licensing agreement for gMSC[®]1 in 2016. Under the agreement, TWOCELLS is conducting the clinical trial, and responsible for manufacture and supply of gMSC[®]1. Chugai has joint development and exclusive distribution rights for gMSC[®]1 in Japan and is responsible for regulatory application.

To provide more patients with an innovative treatment option as soon as possible, Chugai and TWOCELLS will work on the practical application of the cartilage regenerative therapy using allogenic synovium-derived mesenchymal stem cell, which is the first of its kind in the world.

<Reference>

TWOCELLS and Chugai Announce Performing Surgery of the First Patient in Phase III Trial for “gMSC[®]1,” a Regenerative Cellular Medicine for Chondrogenesis in the Knee (press release on November 29, 2017)

https://www.chugai-pharm.co.jp/english/news/detail/20171129170000_50.html

Chugai and TWO CELLS Announce a License Agreement for "gMSC[®]1" a Regenerative Cellular Medicine for Chondrogenesis in the Knee (press release on April 25, 2016)

https://www.chugai-pharm.co.jp/english/news/detail/20160425150000_144.html

Sources of reference for the study:

Japan Pharmaceutical Information Center (JAPIC) Drug Information Database

<http://www.clinicaltrials.jp/user/cteSearch.jsp>

About gMSC[®]

gMSC[®]1 is a tissue-engineered medical product currently developed by TWOCELLS and was prepared for the regenerative chondrogenesis using synovium-derived mesenchymal stem cell (MSC) in collaboration with Osaka University and Hiroshima University. This product is a scaffold-free allogeneic 3D artificial tissue of MSC provided by TWOCELLS with their own technologies and serum-free medium (STK[®]1 and STK[®]2), which is expected to provide an effective treatment for cartilage regeneration. Development of gMSC[®]1 has been supported by JST (Japan Science and Technology Agency), NEDO (New Energy and Industrial Technology Development Organization), the Ministry of Economy, Trade and Industry, and AMED (Japan Agency for Medical Research and Development).

About Chugai

Chugai Pharmaceutical is one of Japan’s leading research-based pharmaceutical companies with strengths in biotechnology products. Chugai, based in Tokyo, specializes in prescription pharmaceuticals and is listed on the 1st section of the Tokyo Stock Exchange. As an important member of the Roche Group, Chugai is actively involved in R&D activities in Japan and abroad. Specifically, Chugai is working to develop innovative products which may satisfy the unmet medical needs.

About TWOCELLS

TWOCELLS is a bio-venture company established in Hiroshima in 2003, aiming to promote regenerative medicine so that patients may have a new treatment option. By particularly targeting MSC (mesenchymal stem cell), it is engaging in the development of cellular medicine with MSC, peri-MSC culturing technique and a system for regenerative medicine.

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