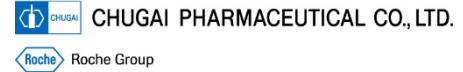




Innovation all for the patients



## **TWOCELLS and Chugai Announce Performing Surgery of the First Patient in Phase III Trial for “gMSC<sup>®</sup>1”, a Regenerative Cellular Medicine for Chondrogenesis in the Knee**

Aiming to deliver new treatment option for patients with cartilage defects in the knee

HIROSHIMA and TOKYO, November 29, 2017 -- TWOCELLS Co., Ltd. [Head Office: Hiroshima-shi, Hiroshima; President & CEO: Ko-ichiro Tsuji] (hereafter, "TWOCELLS") announced that on November 29, 2017, the first patient has been performed surgery in the Phase III comparative trial of “gMSC<sup>®</sup>1”, a Regenerative Cellular Medicine for Chondrogenesis in the Knee.

TWOCELLS has licensed Chugai Pharmaceutical Co., Ltd. [Head Office: Chuo-ku, Tokyo; Chairman & CEO: Osamu Nagayama] (hereafter, "Chugai") for gMSC<sup>®</sup>1. TWOCELLS is obligated to conduct clinical studies intended to obtain the initial approval in Japan including this Phase III trial, and manufacture and supply gMSC<sup>®</sup>1. Meanwhile, Chugai has joint development and exclusive distribution rights of gMSC<sup>®</sup>1 in Japan, and also, reserves preferential negotiating rights for overseas. In addition, Chugai shall be responsible for the application for approval, and marketing and clinical studies after the initial approval.

The object of this study is to compare the safety and efficacy of gMSC<sup>®</sup>1 versus microfracture, as standard treatment, in patients with symptomatic articular cartilage defects or osteochondritis dissecans in the knee, with or without complication e.g. ligament injury and meniscus injury.

“The production technology of our company has potential for supplying gMSC<sup>®</sup>1 for 1,000 – 10,000 patients, allogenic regenerative cellular medicine, from one donor tissue and will be considered to be a new contribution for regenerative medical care. We are thinking the greatest deal of the safety of patients in this Phase III trial to evaluate the safety and efficacy of gMSC<sup>®</sup>1. Clinical trials do not go well without the understanding and cooperation of patients. We hope to see the kind cooperation and get to send gMSC<sup>®</sup>1 to a patient as soon as possible.” said Ko-ichiro Tsuji, president & CEO of TWOCELLS.

“We are pleased that the Phase III trial of gMSC<sup>®</sup>1, an innovative regenerative cellular medicine has been initiated for chondrogenesis in the knee,” said Chugai’s President & COO Tatsuro Kosaka. “Chugai will further collaborate with TWOCELLS to accelerate the development of gMSC<sup>®</sup>1 successfully and file a new drug application as quickly as possible.”

### **About "gMSC<sup>®</sup>1":**

gMSC<sup>®</sup>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<sup>®</sup>1 and STK<sup>®</sup>2), which is expected to provide an effective treatment for cartilage regeneration.

### **About TWOCELLS**

TWOCELLS is a bio-venture company established in 2003 by 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 development of cellular medicine with MSC, peri-MSC culturing technique and a system for regenerative medicine. TWOCELLS has developed "gMSC<sup>®</sup>1, a Regenerative Cellular Medicine for Chondrogenesis in the Knee" (for which TWOCELLS has licensed Chugai), and "Serum-free medium STK<sup>®</sup> series for MSC (for research)" (which is distributed by DS Pharma Biomedical Co., Ltd.). TWOCELLS received the supports from JST (Japan Science and Technology Agency), NEDO (New Energy and Industrial Technology Development Organization), AMED (Japan Agency for Medical Research and Development), METI (Ministry of Economy, Trade and Industry), Hiroshima Prefecture and Hiroshima city and could push our business forward.

The revenue in 2016 of TWOCELLS totalled 800 million yen and the ordinary income was 160 million yen.

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

### **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, mainly focusing on the oncology area.

In Japan, Chugai's research facilities in Gotemba and Kamakura are collaborating to develop new pharmaceuticals, and laboratories in Ukima are conducting research for technology development for industrial production. Overseas, Chugai Pharmabody Research based in Singapore is engaged in research focusing on the generation of novel antibody drugs by utilizing Chugai's proprietary innovative antibody engineering technologies. Chugai Pharma USA and Chugai Pharma Europe are engaged in clinical development activities in the United States and Europe.

The consolidated revenue in 2016 of Chugai totaled 491.8 billion yen and the operating income was 80.6 billion yen (IFRS Core basis).

Additional information is available on the internet at <https://www.chugai-pharm.co.jp/english>.

### **Reference about the trial**

The Japan Pharmaceutical Information Center (JAPIC).

[http://www.clinicaltrials.jp/user/cteSearch\\_e.jsp](http://www.clinicaltrials.jp/user/cteSearch_e.jsp)

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