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 CHUGAI PHARMACEUTICAL CO., LTD.

 Roche Group



## Chugai and TWO CELLS Announce a License Agreement for "gMSC<sup>®</sup>1," a Regenerative Cellular Medicine for Chondrogenesis in the Knee

TOKYO and HIROSHIMA, April 25, 2016 -- Chugai Pharmaceutical Co., Ltd. [Head Office: Chuo-ku, Tokyo; Chairman & CEO: Osamu Nagayama] (Chugai) and TWO CELLS Co., Ltd. [Head Office: Hiroshima-shi, Hiroshima; President & CEO: Ko-ichiro Tsuji] (TWO CELLS) announced that on April 25, 2016, both companies concluded a licensing agreement regarding gMSC<sup>®</sup>1, a regenerative cellular medicine for chondrogenesis in the knee, created by TWO CELLS. Under this license agreement, Chugai will obtain joint development and exclusive distribution rights of gMSC<sup>®</sup>1 in Japan, and also, reserve preferential negotiating rights for overseas. In return for this license agreement, TWO CELLS will receive an upfront fee, milestone and royalty payments from Chugai.

This agreement obligates TWO CELLS to conduct clinical studies intended to obtain the initial approval in Japan, and manufacture and supply gMSC<sup>®</sup>1. Meanwhile, Chugai will take advantage of its clinical development experience, and proceed with clinical development in cooperation with TWO CELLS. At the same time, Chugai shall be responsible for filing regulatory approval, marketing and clinical studies after the initial approval.

"We are pleased to conclude this license agreement with TWO CELLS on gMSC<sup>®</sup>1, an innovative regenerative cellular medicine for chondrogenesis in the knee," said Tatsuro Kosaka, President and COO of Chugai. "Chugai strongly believes that this product contributes to the treatment of diseases attributable to traumatic knee cartilage injuries."

"We have been engaging in the developments of regenerative cellular medicine with strong will that TWO CELLS contributes to the treatment of many patients suffering from insusceptible disease, by using expanded mesenchymal stem cell (MSC) cultured with our serum free medium," said Ko-ichiro Tsuji, president & CEO of TWO CELLS. "The regenerative cellular medicine gMSC<sup>®</sup>1 was developed under collaboration with Osaka University and Hiroshima University, with a slogan that Hiroshima will be one of the hubs for regenerative cellular medicine in the world, and it is the first allograft stem cell product developed from Hiroshima."

In June 2012, Chugai and TWO CELLS had previously concluded an agreement on Chugai's acquisition of new stocks issued by TWO CELLS, and an agreement for preferential negotiating rights on tissue-engineered medical products for chondrogenesis using synovium-derived MSC which has been developed by TWO CELLS. Also, in June 2014, Chugai and TWO CELLS concluded another agreement on Chugai's acquisition of new stocks issued by TWO CELLS, and

amendment of the agreement for preferential negotiating rights, and have been preparing for the domestic development of tissue-engineered medical products for chondrogenesis in the knee. This license agreement will enable Chugai and TWO CELLS to make a head start in materializing regenerative medicine for chondrogenesis in the knee using allogeneic synovium-derived MSC.

**About "gMSC<sup>®</sup>1," a tissue-engineered medical product for chondrogenesis in the knee:**

gMSC<sup>®</sup>1 is a tissue-engineered medical product currently developed by TWO CELLS and was created for the purpose of regenerative chondrogenesis using synovium-derived mesenchymal stem cell (MSC). This product is a scaffold-free allogeneic 3D artificial tissue of MSC provided by TWO CELLS with its 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. TWO CELLS 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<sup>®</sup>1.

**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 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 2015 of Chugai totalled 498.8 billion yen and the operating income was 90.7 billion yen (IFRS Core basis).

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

**About TWO CELLS**

TWO CELLS 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 peri-MSC culturing technique and a system for regenerative medicine. Currently, TWO CELLS is cooperating with universities, public/private institutions, and domestic and foreign healthcare companies, and with its mission to bring regenerative medicine to the world, engaging in various projects concerning (a) Hospital-based regenerative medicine, (b) Central regenerative medicine, and (c) Intellectual property.

TWO CELLS has developed an automatic cell culture system "YURIKAGO" for regenerative therapy, and "Serum-free medium STK® series for MSC" (which is distributed by DS Pharma Biomedical Co., Ltd.).

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

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