

**Toward Expansion of Indication to Include Secondary Knee Osteoarthritis from Trauma, Etc.
Submission of CTN for Clinical Trial of Autologous Cultured Cartilage “JACC”**

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Japan Tissue Engineering Co., Ltd.

Japan Tissue Engineering Co., Ltd. (a Fujifilm Group company; President: Ken-ichiro Hata, “J-TEC”, hereafter) has submitted clinical trial notification for a clinical trial of regenerative medical product “Autologous Cultured Cartilage JACC” for secondary knee osteoarthritis from trauma,^{*1} etc., to the Pharmaceuticals and Medical Devices Agency (PMDA) today.

This clinical trial aims to expand the indication for “JACC”, which is already used in the treatment of traumatic cartilage defects and osteochondritis dissecans of the knee joint.

Knee osteoarthritis is a disease in which the cartilage is gradually worn down and become deformed, causing pain. It is classified as either primary, where the cause is not clearly known, or secondary, where the cause can be identified as trauma from sports activities or an accident, and the symptoms progress with age and obesity, etc.

At present, symptomatic treatment of secondary knee osteoarthritis with anti-inflammatory analgesics, etc., is used to alleviate clinical symptoms such as pain, but it is difficult to inhibit the progression of symptoms. In more serious cases, therapeutic approaches are limited to high tibial osteotomy, where the angle of the knee is corrected by cutting into the tibial bone,^{*2} and total knee replacement, where the knee joint is replaced with a prosthesis.

J-TEC obtained marketing approval for “JACC” as a regenerative medical product indicated for traumatic cartilage defects and osteochondritis dissecans in 2012, and it has been covered by national health insurance as Japan’s first regenerative medical product in the field of orthopedic surgery since 2013.

Aiming to expand the indication for “JACC”, J-TEC has now submitted clinical trial notification for a clinical trial involving secondary knee osteoarthritis. In this trial, “JACC”, which is manufactured by culturing cartilage cells taken from the patients themselves, will be implanted to the defective part of the joint. “JACC” can be expected to improve clinical symptoms and inhibit the progression of symptoms, and J-TEC aims to expand the indication as soon as possible by speedily proceeding with the clinical trial.

J-TEC plans to conduct the trial at a total of 10 sites, including Hiroshima University and Shimane University.

*1: Knee osteoarthritis is a disease in which the cartilage is gradually worn away and deformed by age or obesity, etc., causing pain. The number of knee osteoarthritis patients in Japan is estimated at about 8.2 million. Among these, patients with secondary knee osteoarthritis caused by trauma, etc., are said to account for about 10 percent.

*2: A treatment method that redistributes a load biased toward the medial side of the joint by cutting the bone from the medial side of the tibia toward the lateral side and inserting and fixing in place an artificial bone graft, etc.

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