J-TEC Received Government Approval to Manufacture and Sell
Autologous Cultured Cartilage JACC® in Japan

On July 27, 2012, Japan Tissue Engineering Co., Ltd. (also known as J-TEC), which is headquartered in Gamagori, Aichi, Japan and represented by Yosuke Ozawa, received an approval by Japan's Ministry of Health, Labour and Welfare (MHLW) for manufacturing and sales of autologous cultured cartilage JACC® in Japan. JACC® is a tissue-engineered medical product with the aim of improving people’s quality of life.

**OUTLINE OF APPROVAL**

<table>
<thead>
<tr>
<th>Approval Number</th>
<th>22400BZX00266000</th>
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<tbody>
<tr>
<td>Approval Date</td>
<td>July 27, 2012</td>
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<tr>
<td>Generic Name</td>
<td>Human Autologous Tissue for Transplantation</td>
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<tr>
<td>Product Name</td>
<td>JACC®</td>
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<td>Structure, Principle</td>
<td>This product is autologous cultured cartilage created by sampling the patient's own cartilage tissue, culturing separated cartilage cells in atelocollagen, for use by the same patient.</td>
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<td>Purpose, Indications</td>
<td>Relief of symptoms of traumatic cartilage defects and osteochondritis dissecans (exclude osteoarthritis) for knee joints. The use of this product is limited to patients with a defect area of over 4cm² with no alternative therapy.</td>
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**BACKGROUND**

Due to its lack of blood vessels, cartilage tissue does not cure well once it is damaged in an accident or injury. Drugs and surgery to relieve symptoms has thus been the standard of care. On the other hand, different kinds of joint problems have been on the rise due to various sports injuries and aging of the society, emphasizing the need for radical therapy. Under the conviction that autologous cultured cartilage will make great contribution to the quality of life of these patients, J-TEC has introduced related techniques from Professor Mitsuo Ochi, MD. (Professor of Orthopaedic Surgery in the Hiroshima University Graduate School of Biomedical Sciences), the pioneer in this field who has demonstrated the efficacy of autologous cultured cartilage through intensive clinical research, and committed to the commercialization of such medical product.

Professor Ochi started therapy for knee-joint cartilage defects using tissue-engineering technique in Japan since 1996, and has experience of over 100 cases of clinical treatment. His research results are highly evaluated among academies all over the world. Since 2003 he has advised J-TEC on the development of autologous cultured cartilage in his capacity as a consultant.
ABOUT JACC®
A small amount of cartilage cells is obtained from an unloaded part of the patient's own knee joint. The cells are then cultivated in atelocollagen, a gel-like material, before being implanted into the defect. This method is characteristic in two aspects: The three-dimensional cultivation in a gel produces a cartilage tissue with a stable shape, which, unlike fluidal material, does not leak after being implanted. The other characteristic is that the use of patient's own cells significantly reduces the risk of immunologic rejection.
Some part of the development of this product was approved by Japan Science and Technology Agency (also known as JST) as one of its contract development projects. The result was accredited as successful in February 2008.

INFLUENCE ON FINANCIAL STATUS
This matter has been progressing as planned, and does not have influence on projections for J-TEC's financial figures of the second quarter and full-year of the fiscal year that ends in March 2013.

FOR MORE INFORMATION ON THE CONTENTS OF THIS PRESS RELEASE:
Norio Sakakibara
PIR Manager, Corporate Planning,
Corporate Management & Administration Dept.
Japan Tissue Engineering Co., Ltd.
E-mail: jtec-info@jpte.co.jp