

## **NEWS RELEASE**

# Targeted Number of Subjects Registered for Cardiovascular Patch Clinical Trial

**Tokyo, Japan, January 27, 2021 ---** Osaka Medical College, Fukui Tateami Co., Ltd. and Teijin Limited announced today that they have completed their registration of registered their targeted number of subjects for an ongoing clinical trial of the OFT-G1 (provisional name) patch for cardiovascular surgery. Participants, who are targeted for participation in a clinical trial that has been under way since May 2019, are patients ranging from infants to adults who are suffering from various congenital heart diseases.

Osaka Medical College, Fukui Tateami and Teijin aim to apply for approval to manufacture and market their cardiovascular patch after evaluating safety and efficacy data covering the one-year periods after each subject undergoes surgery using the OFT-G1 patch.

The OFT-G1 features a revolutionary design incorporating the Osaka Medical College's expertise in cardiovascular surgery, Fukui Tateami's pioneering warp-knitting technology and Teijin's advanced polymer-application technology. Development was supported by a special program launched in 2017 by the Japan Agency for Medical Research and Development (AMED) to facilitate collaboration between medical academia and industry. Also, in April 2018, the Ministry of Health, Labor and Welfare designated the OFT-G1 as a "SAKIGAKE" product qualifying for various incentives to speed up its approval for clinical use.

Treatments have been devised to improve the long-term survival of patients who undergo cardiovascular surgeries for purposes such as replacing defective heart tissue or enlarging narrowed blood vessels (stenosis). Demands are growing for increasingly advanced treatments that are less likely to cause stenosis due to the patient's somatic (physical) growth in areas where patches have been implanted and reoperations due to patch deterioration or calcification after long-term implantation.

The OFT-G1's absorbable portion is naturally replaced with the patients' own tissue after implantation. Also, its strong but expandable structure allows it to conform to the patient's somatic growth. Accordingly, the OFT-G1 is expected to alleviate physical, mental or financial burdens that patients and their families may experience in regard to possible corrective surgeries.

Going forward, Osaka Medical College, Fukui Tateami and Teijin will continue with clinical trials to confirm the clinical effectiveness and safety of the OFT-G1 cardiovascular patch, and thereafter work toward approval as quickly as possible in Japan and then other countries worldwide. Simultaneously, they will continue with

product development efforts aimed at enhancing the quality of life for patients with cardiovascular diseases.

## **About Osaka Medical College**

Established in 1927 as Japan's first five-year higher school of medicine, Osaka Medical College celebrated its 90th anniversary in 2017 having produced more than 9,000 skilled physicians. The College's nursing education program has a similar history, and has trained more than 4,500 nurses. Furthermore, the College will form a promising merger with Osaka University of Pharmaceutical Sciences this year to strengthen their potential.

URL: https://www.osaka-med.ac.jp/en/

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## About Fukui Tateami Co., Ltd.

Fukui Tateami is a warp knitted fabric manufacturing company located in Fukui, Japan, with 90 employees and more. Our products encompass a wide spectrum of applications, such as fashionable apparel, active sportswear, automotive interiors, industrial materials, household textiles. With over 75 years of extensive experience and advanced technology, Fukui Tateami has entered the medical field. It posted sales of JPY3.4 billion (USD 31 million) and total assets of JPY 3.0 billion (USD 27 million) in the fiscal year ending March 31, 2019.

Please visit http://www.fukutate.co.jp/en

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## **About the Teijin Group**

Teijin (TSE: 3401) is a technology-driven global group offering advanced solutions in the fields of environmental value; safety, security and disaster mitigation; and demographic change and increased health consciousness. Originally established as Japan's first rayon manufacturer in 1918, Teijin has evolved into a unique enterprise encompassing three core business domains: high-performance materials including aramid, carbon fibers and composites, and also resin and plastic processing, films, polyester fibers and products converting; healthcare including pharmaceuticals and home healthcare

equipment for bone/joint, respiratory and cardiovascular/metabolic diseases, nursing care and pre-symptomatic healthcare; and IT including B2B solutions for medical, corporate and public systems as well as packaged software and B2C online services for digital entertainment. Deeply committed to its stakeholders, as expressed in the brand statement "Human Chemistry, Human Solutions," Teijin aims to be a company that supports the society of the future. The group comprises more than 170 companies and employs some 20,000 people across 20 countries worldwide. Teijin posted consolidated sales of JPY 853.7 billion (USD 8.0 billion) and total assets of JPY 1,004.2 billion (USD 9.4 billion) in the fiscal year that ended on March 31, 2020.

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