Expansion of Indication for Autologous Cultured Epidermis “JACE”:
Dystrophic and Junctional Epidermolysis Bullosa

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Japan Tissue Engineering Co., Ltd. (a Fujifilm subsidiary; President: Ken-ichiro Hata, “J-TEC”, hereafter) has received a supplemental approval from Japan's Ministry of Health, Labour and Welfare (MHLW) dated December 28, 2018, to include dystrophic and junctional epidermolysis bullosa, which is designated as an orphan disease, to the indications for the autologous cultured epidermis “JACE”.

J-TEC obtained marketing approval for “JACE” in Japan as Japan’s first regenerative medical product indicated for severe burns in 2007, and it has been covered by the national health insurance since 2009. Also, at the end of September 2016, JACE received a supplemental approval for the additional indication for giant congenital melanocytic nevus treatment, which is also designated as an orphan disease.

Aiming to expand the indications for JACE, J-TEC submitted the application to add dystrophic and junctional epidermolysis bullosa in March 2018.

Given this approval, we provide a new treatment option for patients with dystrophic and junctional epidermolysis bullosa.

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