



June 24, 2024

Distribution Discontinuation of HGF gene therapy product "Collategene®", following withdrawal of the manufacturing and marketing approval application

Mitsubishi Tanabe Pharma Corporation (Head Office: Chuo-ku, Osaka; Representative Director: Akihiro Tsujimura; hereinafter, "MTPC"), a member of the Mitsubishi Chemical Group, today announced the discontinuation of distribution of the HGF gene therapy product, Collategene® Intramuscular Injection 4 mg (hereinafter "Collategene®").

This decision was made to the withdrawal of the manufacturing and marketing approval application by the marketing authorization holder, AnGes Inc (Head Office: Ibaraki, Osaka, President: Ei Yamada, hereinafter, "AnGes").

Collategene_® distributed by MTPC since September 2019, was marketed based on the conditional and time-limited marketing approval by AnGes in Japan.

AnGes has drawn the manufacturing and marketing approval application that was to be refiled after the conditional and time-limited marketing approval. The expiration date of the current conditional and time-limited marketing approval is expired, and the distribution of Collategene® is also discontinued.

In response with this situation, MTPC conducts a market recall of Collategene® (Class II). However, the recall is not related to quality or safety, there is no risk of health damage arising from the event that caused this recall.

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