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Shire Korea gets approval for hemophilia A treatment

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Adynovate is an injectable therapy that has the same ingredient as Shire's Advate, which is the country's most commonly used hemophilia A treatment.

Shire Korea, the local branch of the global biotech pharmaceutical Shire, has received the approval from the Ministry of Food and Drug Safety for Adynovate, its long-lasting factor VIII gene recombinant hemophilia A treatment.

Hemophilia A, also called factor VIII deficiency, is a genetic disorder caused by a lack of a clotting protein called factor VIII. The Korea Hemophilia Foundation estimated more than 1,600 hemophilia A patients in Korea in 2016.

Adynovate is an injectable therapy that has the same ingredient as Shire's Advate, which is the country's most commonly used hemophilia A treatment. Adynovate is an innovative treatment that improves patient convenience by reducing the dosage to twice a week while maintaining the efficacy and safety of Advate.

The ministry's approval is based on Adynovate's multi-center, open-label, phase 2 and phase 3 trials conducted in more than 20 countries, including Korea. Studies showed that patients who got injected with Adynovate twice a week had a 95 percent reduction in overall annual bleeding rate (ABR) as opposed to those who used the treatment only upon bleeding or surgery. Around 40 percent of patients who used Adynovate for routine preventive therapy also did not experience bleeding.