News Release

August 25, 2017

Plasma fractionated preparations, KENKETSU NONTHRON® 500/1500 FOR INJECTION (Human antithrombin III agent) approved for additional indication of "Portal thrombosis" in Japan

Nihon Pharmaceutical Co., Ltd. (Headquarters: Tokyo: Hiroyuki Tsujiyama, "Nihon") announced today that Kenketsu Nonthron (human antithrombin III agent) has been approved for the additional indication of "portal thrombosis associated with antithrombin III reduction" in Japan.

While various causes of portal thrombosis are known, in particular, the patients with liver disorders such as liver cirrhosis are often associated with bleeding risks due to esophagus/gastric varices or portal hypertensive gastropathy as well as decrease of the platelets and coagulation factors. There is a need for a drug for portal thrombosis which is known to be associated with portal hypertensive gastropathy, has little risk of bleeding, and can expect recanalization of portal vein thrombus in a short period of time.

For this reason, we performed a clinical trial using Kenketsu Nonthron and compared with placebo, statistically significant improvement was observed in this drug, therefore "portal thrombosis associated with a decrease in antithrombin III" as the additional the indication was approved.

With the approval of this indication covering portal thrombosis expanding a new treatment option, Nihon strives to further contribute to the patients and medical professionals.

We will continue to contribute to the promotion of people's health through R & D, manufacturing and sales of superior pharmaceutical products and related medical products.

■ Approval for additional indication this time

【 INDICATION/EFFECTS 】: Portal thrombosis associated with decrease in

antithrombin III

【DOSAGE AND ADMINISTRATION】: If antithrombin III falls to less than 70% of normal, adults are usually administered with 1, 500 international unit (or 30 international unit / kg) of this drug for 5 days. When thrombolytic tendency is observed by administration of this drug, it is usually administered to the adult for 5 days of 5 times a day for a total of 1,500 international units per course (or 30 international unit / kg per course) of this drug.　If necessary, it can be repeated up to two courses.