News release

Kyowa Kirin Initiated Phase 3 Clinical Study of KW-3357 for the Treatment of Preeclampsia

Tokyo, Japan, November 20th, 2019 --- Kyowa Kirin Co., Ltd. (TSE: 4151, President and CEO: Masashi Miyamoto, "Kyowa Kirin") announces today that a phase 3 clinical study of KW-3357 (Generic name: Antithrombin Gamma (Genetical Recombination), Product Name: ACOALAN®) was started in Japan for the treatment of early onset severe preeclampsia.

The Phase 3 study is a multi-centered, randomized, placebo-controlled, double-blind trial conducted in Japan to access efficacy and safety of KW-3357 for patients with early onset severe preeclampsia.

“Severe preeclampsia can result in both acute and long-term complications for both the mother and her newborn, however, currently there are no effective treatments for the pregnant without termination.” said Mitsuo Satoh, Ph.D., Executive Officer, Vice President, Head of R&D Division of Kyowa Kirin. “We’ll keep working on the study to explore the possibility of KW-3357 for patients with preeclampsia.”

KW-3357 is an antithrombin (AT) drug created through the technology of recombinant DNA and sugar-chain control, which is a recombinant AT preparation with the same amino acid sequence and the same type of sugar chain structure as human natural AT. AT inhibits blood coagulation by forming a complex with the coagulation factor of proteolytic enzyme. In Japan, KW-3357 has been approved for the treatments of thrombophilia due to congenital AT deficiency (CAD) and disseminated intravascular coagulation (DIC) since July, 2015 and commercialized under the brand name of ACOALAN®.

Kyowa Kirin and the Japan Blood Products Organization (head office: Tokyo, Japan, President and representative director: Takahide Ishikawa, "JB") have signed an outsourcing agreement concerning sales of ACOALAN® in Japan. Under the agreement, JB is responsible for the commercial activity and information providing to medical institutions.

The Kyowa Kirin Group companies strive to contribute to the health and well-being of people around the world by creating new value through the pursuit of advances in life sciences and technologies.

<Summary of the Study>

Target Disease	Early onset severe preeclampsia
Phase	Phase 3
Study Design	Multi-centered, randomized, placebo-controlled, double-blind
Group	KW-3357, Placebo
Primary Endpoint	Days of maintaining pregnancy
Enrollment	180
Country/Region	Japan

About Antithrombin (AT)

AT is a single chain glycoprotein with a molecular weight of about 60,000 produced by liver and vascular endothelial cell. AT binds to procoagulant serine proteases such as thrombin and Factor Xa and inhibits their procoagulant activities.

About Preeclampsia

Preeclampsia is gestational hypertension accompanied by one or more of the following new-onset conditions at or after 20 weeks' gestation: Proteinuria, Other maternal organ dysfunction, Uteroplacental dysfunction.
Severe preeclampsia can result in both acute and long-term complications for both the pregnant and her newborn. Maternal complications of severe preeclampsia include pulmonary edema, myocardial infarction, stroke, acute respiratory distress syndrome, coagulopathy, severe renal failure, and retinal injury. These complications are more likely to occur in the presence of preexistent medical disorders and with acute maternal organ dysfunction related to preeclampsia. Fetal and newborn complications of severe preeclampsia result from exposure to uteroplacental insufficiency or from preterm birth, or both.