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(Code:4560 TSE First Section)

**On the start of phase 1 for KRP-104, therapeutic agent for diabetes, in USA**

KYORIN Pharmaceutical Co., Ltd. (Ikuo Ogihara, President) filed an IND application (Investigational New Drug Application) for Phase I Clinical Study (Ph 1; Phase 1) on an anti-diabetic agent, KRP-104, that we have newly discovered with the FDA and has initiated administration of KRP-104 to healthy subjects in the United States in this month. The clinical trial on KRP – 104 is the first project for which KYORIN Pharmaceutical Co., Ltd. has filed an IND application with the FDA independently.

KYORIN has been engaged in a collaborative development of KRP – 104 with ActivX Biosciences since 2002, and this project has made it possible to conduct the search for the lead compound as rapidly as we had hoped. This drug is a DPP-IV inhibitor, which shows effect of enhancing insulin secretion and consequently shows glucose-lowering effect by inhibiting the decomposition of insulin secretion hormone. It has a novel mechanism of enhancing insulin secretion during the post-prandial hyperglycemic stage making it a promising candidate for use alone or in combination with other anti-diabetic agents with a reduced risk of hypoglycemia.

Following the Kyorin MIC '09 midterm management plan, our corporation intends to adopt a drug discovery business model that focuses capital investment on drug discovery and the derivation of products in the late stage of development as goals and aspires to be “a distinguished and integrated healthcare company with the core business in global drug discovery research based on reliability.” As a concrete approach to achieving these goals, we have established a clinical operation office at our affiliate company, ActivX Biosciences, which serves as a base of clinical research in order to plan and control the implementation of overseas clinical trials. Based on this, we will endeavor to implement global drug discovery research and development and expedite Proof of Concept (POC; proof of Concept). The launch of the U.S. clinical trial at this time is a part of the reinforcement of our global drug discovery research, and we will try to conduct speedy clinical trials through POC.

**Reference materials**

What is DPP-IV (Dipeptidyl – Peptidase IV) inhibitor?

It is well known that oral administration of glucose induces higher insulin secretion than intravenous administration. A gastrointestinal hormone secreted from the gastrointestinal tract, so-called incretin, is involved in this reaction. GLP – 1 (Glucagon – like peptide – 1), one of incretins, has the effect of stimulating insulin secretion with blood glucose concentration-dependent manner. DPP-IV is an enzyme that hydrolyzes and inactivates GLP – 1. Due to DPPIV being inhibited by DPP-IV inhibitor, GLP – 1 activity in the blood is maintained and insulin secretion is enhanced. DPP-IV inhibitor has effect of enhancing insulin secretion, which is dependent on blood glucose concentration and different from other existing anti-diabetic agents, making it a promising diabetes medication with less hypoglycemia risk.

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