July 30, 2020

Sumitomo Dainippon Pharma Co., Ltd.

Sumitomo Dainippon Pharma Submits New Drug Application for Approval of Manufacturing and Marketing for Imeglimin Hydrochloride for the Treatment of Type 2 Diabetes in Japan

Sumitomo Dainippon Pharma Co., Ltd. (Head Office: Osaka, Japan; Representative Director, President and CEO: Hiroshi Nomura) announced that it submitted today a new drug application for approval of manufacturing and marketing for imeglimin hydrochloride (generic name) in Japan for the treatment of type 2 diabetes.

Demonstrating a novel mechanism of action (MOA) that targets mitochondrial bioenergetics, this compound is expected to improve insulin secretory disorder and insulin sensitivity, both of which are key causes of type 2 diabetes.

This application involves the data of three Phase 3 studies (TIMES1, TIMES2, TIMES3) targeting patients with type 2 diabetes. These studies have confirmed the efficacy, safety, and tolerability of imeglimin in monotherapy, as well as in combination therapy with an approved oral hypoglycemic agent or an insulin formulation for Japanese patients with type 2 diabetes.

Sumitomo Dainippon Pharma provides multiple therapeutic agents for type 2 diabetes with different MOAs. This regulatory approval allows us to offer yet another treatment option, thus making greater contributions to the treatment of type 2 diabetes in Japan.

<Reference information>

About Imeglimin Hydrochloride

Imeglimin is a new chemical substance classified as a tetrahydrotriazine compound, and the first clinical candidate in its chemical class. Imeglimin has a unique mechanism of action (MOA) that targets mitochondrial bioenergetics and acts on all three key organs that play a critical role in the treatment of type 2 diabetes: the pancreas, muscles, and the liver. It is thought that imeglimin demonstrates glucose lowering benefits by increasing insulin secretion in response to glucose, improving insulin sensitivity, and suppressing gluconeogenesis. Imeglimin has the potential to prevent endothelial and diastolic dysfunction, which can provide protective effects against the micro- and macro-vascular defects induced by diabetes, and has the potential for a protective effect on beta-cell survival and function. This unique MOA also offers the potential opportunity for imeglimin to be a candidate for the treatment of type 2 diabetes in almost all stages of the current anti-diabetic treatment paradigm, including monotherapy or as an add-on to other glucose lowering therapies.

Sumitomo Dainippon Pharma introduced imeglimin from Poxel SA, a biopharmaceutical

company listed on the Euronext Paris in October 2017, for the development and commercialization of imeglimin in Japan, China, South Korea, Taiwan, and nine other Southeast Asian countries.

Meanwhile, Metavant Sciences Ltd., a subsidiary of Roivant Sciences Ltd. with whom Sumitomo Dainippon Pharma signed a strategic alliance, is planning a Phase 3 program of imeglimin in the U.S. and Europe.

About the TIMES Program

TIMES (**T**rials of **Im**eglimin for **E**fficacy and **S**afety), the Phase 3 program for imeglimin for the treatment of type 2 diabetes in Japan, consists of three pivotal trials involving over 1,100 patients, out of which the non-control individuals were administered the dose of 1,000mg twice daily. Preliminary results of the three trials were announced in press releases dated April. 4, 2019 (TIMES1), December 20, 2019 (TIMES2), and June 25, 2019 (TIMES3).

- TIMES1: A Phase 3, 24-week, double-blind, placebo-controlled, randomized, monotherapy trial that assessed the efficacy, safety, and tolerability of imeglimin in Japanese patients with type 2 diabetes
- TIMES2: A Phase 3, 52-week, open-label, parallel-group trial that assessed the long-term safety and efficacy of imeglimin in Japanese patients with type 2 diabetes. In this trial, imeglimin was administered orally as combination therapy with approved hypoglycemic agents, including a DPP-4 inhibitor, an SGLT2 inhibitor, a biguanide, a sulphonylurea, a glinide, an alpha-glucosidase inhibitor, a thiazolidine, and a GLP1 receptor agonist or as monotherapy.
- TIMES3: A Phase 3, 16-week, double-blind, placebo-controlled, randomized trial with a 36-week open-label extension period that evaluated the efficacy and safety of imeglimin in combination with insulin in Japanese patients with type 2 diabetes and Japanese patients with type 2 diabetes on insulin therapy with inadequate glycemic control.

Contact
Corporate Communications
Sumitomo Dainippon Pharma Co., Ltd.
TEL: +81-6-6203-1407 (Osaka); +81-3-5159-3300 (Tokyo)