Sumitomo Dainippon Pharma

News Release

November 18, 2014

Sumitomo Dainippon Pharma Co., Ltd.

Sumitomo Dainippon Pharma obtains Approval in Japan for Partial Change of the Approved Indication to "Type 2 Diabetes" for SUREPOST®, a Rapid-acting Insulin Secretagogue

Sumitomo Dainippon Pharma Co., Ltd. (Head Office : Osaka, Japan; President: Masayo Tada) announced today that its application for partial change of the approved indication to "Type 2 Diabetes" for its "SUREPOST® tablet 0.25mg" and "SUREPOST® tablet 0.5mg" (generic name: repaglinide), a rapid-acting insulin secretagogue, was approved in Japan as of November 18, 2014. SUREPOST® can now be used for combination therapy with any oral hypoglycemic agents with the exception of SU (sulfonylurea) and any insulin formulations.

SUREPOST® is a rapid-acting insulin secretagogue that stimulates the postprandial insulin secretion rapidly, thereby ameliorating postprandial blood glucose and lowering HbA1c in patients with type 2 diabetes. Repaglinide is approved and marketed in over 100 countries in America, Europe and other parts of the world. In Japan, Sumitomo Dainippon Pharma launched SUREPOST® as monotherapy as well as in combination with alpha-glucosidase inhibitors in May 2011. Then in February 2013, SUREPOST® was approved for the additional indications of combination therapy with biguanides and with thiazolidinediones.

In compliance with the July 2010 Ministry of Health, Labour and Welfare Guideline for Clinical Evaluation of Oral Hypoglycemic Agents*, Sumitomo Dainippon Pharma conducted long-term studies in Japan on combined use of SUREPOST® with DPP-4 inhibitors which had not yet been approved. The studies confirmed both long-term effectiveness (significant improvements in postprandial hyperglycemia and HbA1c levels) and safety of such combined therapy. Based on the results of the studies and in accordance with the MHLW Guideline, Sumitomo Dainippon Pharma filed an application for partial change of the approval to the indication to "Type 2 Diabetes" in December 2013, which application was approved this month.

Sumitomo Dainippon Pharma hopes that the expanded indication for SUREPOST® tablets will offer broader therapeutic options for patients with type 2 diabetes, allowing the Company to further contribute to the treatment of type 2 diabetes.

*Guideline for Clinical Evaluation of Oral Hypoglycemic Agents:
The guideline released by the Ministry of Health, Labour and Welfare in July 2010 which provides for the standard procedures to be followed in the planning, conduct and evaluation of clinical studies on oral hypoglycemic agents (OHAs) for new drug application. When the investigational drug is confirmed to be useful in the clinical studies conducted based on the Guideline, the appropriate description of the indication is "type 2 diabetes."

<Reference information>

Profile of "SUREPOST®"

[Brand Name] SUREPOST® tablet 0.25mg
SUREPOST® tablet 0.5mg

[Generic Name] repaglinide

[Content/Description] SUREPOST® tablet 0.25mg: Each tablet contains 0.25mg of repaglinide
SUREPOST® tablet 0.5mg: Each tablet contains 0.5mg of repaglinide

[Indication]

Current	Previous
Type 2 diabetes	The reduction of postprandial blood glucose in patients with type 2 diabetes SUREPOST® is to be used only when adequate effectiveness of either of the following treatments is not obtained: (1) Diet and exercise alone, or (2) An alpha glucosidase inhibitor with diet and exercise, or (3) Biguanides with diet and exercise, or (4) thiazolidinediones with diet and exercise.

[Dose/Administration] The usual adult dose starts at 0.25mg 3 times daily taken orally immediately before meals. A maintenance dose is usually from 0.25 to 0.5mg taken one time, to be increased or decreased as required. In addition, it is possible to increase a one-time dose up to 1mg.

[Manufacturer and Distributor] Sumitomo Dainippon Pharma Co., Ltd.

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