Dainippon Sumitomo Pharma submits an application for partial change of the approved indication to “Type 2 Diabetes” for SUREPOST®, a rapid-acting insulin secretagogue

Dainippon Sumitomo Pharma Co., Ltd. (“DSP”) (Head Office: Osaka, Japan; President: Masayo Tada) announces that it submitted an 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 in Japan as of December 25, 2013.

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 90 countries around the world, under the brand name "Prandin®" in the United States and "NovoNorm®" in European countries. In Japan, DSP took over development of the drug from Novo Nordisk A/S in 2004 and received manufacturing and marketing approval for SUREPOST® as monotherapy as well as in combination with alpha-glucosidase inhibitors in January 2011. After the initial launch in May 2011, SUREPOST® was approved for the additional indications of combination therapy with biguanides and with thiazolidinediones in February 2013.

The long-term combination administration studies DSP recently conducted involving patients with type 2 diabetes who had shown insufficient glycemic control even with the administration of DPP-4 inhibitor in addition to diet and exercise confirmed that combined use of SUREPOST® is both effective (significant improvements in postprandial hyperglycemia and HbA1c levels) and safe. The long-term studies encompassed all the oral hypoglycemic agent families currently approved in Japan (with the exception of sulfonylurea (“SU”)) and showed the efficacy and safety of the treatment. Because the results satisfied the MHLW Guideline for Clinical Evaluation of Oral Hypoglycemic Agents, DSP today filed an application for partial change of the approval for manufacture and marketing with respect to the indication to “Type 2 Diabetes.” When approved, SUREPOST® may be used for combination therapy with any oral hypoglycemic agents except for SU.

DSP hopes that expanded indication for SUREPOST® tablets will offer broader therapeutic options for patients with type 2 diabetes, allowing us to further contribute to the treatment of type 2 diabetes.
A profile of SUREPOST® tablets is shown in the next page as reference information.

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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]  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 and 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]  Dainippon Sumitomo Pharma Co., Ltd.