

April 17, 2012

Dainippon Sumitomo Pharma Co., Ltd.

**Dainippon Sumitomo Pharma submits an application for SUREPOST<sup>®</sup>, a rapid-acting insulin secretagogue, for the additional indication of combination therapy with thiazolidinediones and with biguanides**

Dainippon Sumitomo Pharma Co., Ltd. (DSP, Headquarters: Osaka, Japan; President: Masayo Tada) announces it submitted an application for “SUREPOST<sup>®</sup> tablet 0.25 mg” and “SUREPOST<sup>®</sup> tablet 0.5 mg” (generic name: repaglinide), a rapid-acting insulin secretagogue, for the additional indication of combination therapy with thiazolidinediones and with biguanides in Japan as of April 17, 2012.

SUREPOST<sup>®</sup> is a rapid-acting insulin secretagogue that stimulates the postprandial insulin secretion rapidly, thereby ameliorating postprandial blood glucose and lowering HbA1c in type 2 diabetes patients.

Repaglinide is approved and marketed in over 90 countries worldwide, under the brand name “Prandin<sup>®</sup>” in the United States and “NovoNorm<sup>®</sup>” in European countries. In Japan, DSP took over development of the drug from Novo Nordisk A/S and continued clinical studies, then in January 2011 received manufacturing and marketing approval for SUREPOST<sup>®</sup> as monotherapy as well as in combination with alpha-glucosidase inhibitors. SUREPOST<sup>®</sup> was launched by DSP in May 2011.

In the Japanese Phase 3 clinical studies involving patients with type 2 diabetes who showed insufficient glycemic control even with the administration of thiazolidinedione or biguanide in addition to diet and exercise, both of the SUREPOST<sup>®</sup> combination arms showed a significant difference in the primary endpoint of lowering HbA1c levels compared to the placebo combination arm. Based on the results of these Phase 3 studies, we submitted an application for the additional indication. In addition, the results of the studies will be presented at the 55th Annual Meeting of the Japan Diabetes Society to be held from May 17, 2012.

DSP hopes that additional indication for SUREPOST<sup>®</sup> tablets will expand therapeutic options for patients with type 2 diabetes, allowing us to further contribute to the treatment of type 2 diabetes. Furthermore, DSP is conducting Phase 3 clinical studies in Japan for combination therapy with SUREPOST<sup>®</sup> tablets and DPP-4 inhibitors.

(The profile of SUREPOST<sup>®</sup> tablets is attached)

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<Reference>

## Profile of "SUREPOST<sup>®</sup>"

[Brand Name]	SUREPOST <sup>®</sup> tablet 0.25 mg SUREPOST <sup>®</sup> tablet 0.5 mg
[Generic Name]	repaglinide
[Content / Description]	SUREPOST <sup>®</sup> tablet 0.25 mg: Each tablet contains 0.25 mg of repaglinide SUREPOST <sup>®</sup> tablet 0.5 mg: Each tablet contains 0.5 mg of repaglinide
[Indication]	The reduction of postprandial blood glucose in patients with type 2 diabetes SUREPOST <sup>®</sup> 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
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.