

February 28, 2013

Dainippon Sumitomo Pharma Co., Ltd.

**Dainippon Sumitomo Pharma obtains approval for SUREPOST<sup>®</sup>, a rapid-acting insulin secretagogue, for the additional indications of combination therapy with biguanides and with thiazolidinediones**

Osaka, Japan, February 28, 2013 – Dainippon Sumitomo Pharma Co., Ltd. (DSP, Headquarters: Osaka, Japan; President: Masayo Tada) announces it obtained approval 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 indications of combination therapy with biguanides and combination therapy with thiazolidinediones in Japan as of February 28, 2012.

SUREPOST<sup>®</sup> is a rapid-acting insulin secretagogue that stimulates postprandial insulin secretion by acting on the sulfonylurea receptor in pancreatic beta cells, 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 the drug under the brand name 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 Phase 3 clinical studies in Japan involving patients with type 2 diabetes who showed insufficient glycemic control even with the administration of biguanide (metformin) or thiazolidinedione (pioglitazone), both of the SUREPOST<sup>®</sup> combination arms ameliorated postprandial blood glucose and showed a significant difference in the primary endpoint of lowering HbA1c levels compared to the placebo combination arm, demonstrating the safety and efficacy of the drug.

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 aiming to expand into additional indications.

(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<br>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<br>SUREPOST <sup>®</sup> tablet 0.5 mg: Each tablet contains 0.5 mg of repaglinide   |
| [Indication]                 | (Changes are underlined)<br>The reduction of postprandial blood glucose in patients with type 2 diabetes<br>SUREPOST <sup>®</sup> is to be used only when adequate effectiveness of either of the following treatments is not obtained:<br>(1) Diet and exercise alone or<br>(2) An alpha glucosidase inhibitor with diet and exercise<br><u>(3) Biguanides with diet and exercise</u><br><u>(4) Thiazolidinediones with diet and exercise</u> |
| 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.  |