

For Immediate Release

April 22, 2010

## Dainippon Sumitomo Pharma Co., Ltd.

## Launch of oral hypoglycemic drug METGLUCO®

Dainippon Sumitomo Pharma Co., Ltd. ("DSP" Headquarters: Osaka, Japan; President: Masayo Tada) launches "METGLUCO<sup>®</sup> tablet 250mg" (generic name: metformin hydrochloride), an oral hypoglycemic drug, in Japan as from May 10, 2010.

METGLUCO<sup>®</sup> is a biguanide oral hypoglycemic drug, showing blood-glucose lowering effect by way of inhibitory action against hepatic glyconeogenesis, stimulatory action for glucose uptake in the peripheral tissue and inhibitory action against intestinal glucose absorption, without stimulation of insulin secretion. Metformin drugs have been widely used as the first choice for treatment of type 2 diabetes in Europe and the U.S and are strongly supported by international guidelines for this use. However, the indications and dosages for Metformin drugs are different in Japan, Europe and the United States of America.

Already in 1961, DSP developed and launched "MELBIN<sup>®</sup> tablet" containing metformin hydrochloride for the first time in Japan. Re-examining properness of the indication and dose of metformin drugs for Japanese patients and intending to supply drugs as soon as possible, in 2003 DSP licensed-in from Merck Santé s.a.s. (France)<sup>1</sup> Glucophage<sup>®</sup> (namely METGLUCO<sup>®</sup> in Japan) which had already been approved in manufacturing and marketing in more than 100 countries, supported by an abundance of clinical and non-clinical evidences. DSP conducted clinical trials on this drug in Japan and obtained a manufacturing and marketing approval of this drug under the Japanese brand name "METGLUCO<sup>®</sup> tablet 250mg".

<sup>&</sup>lt;sup>1</sup> Merck Santé s.a.s. is a subsidiary of Merck KGaA, Darmstadt, Germany, operating within the Merck Serono division

METGLUCO<sup>®</sup> can be prescribed as a monotherapy, dosed at 750-1500 mg as the daily maintenance dosage or 2250 mg as the highest daily dosage. Thus METGLUCO<sup>®</sup> represents a breakthrough in the diabetes therapy as the existing metformin drugs only allow daily dosages of maximum 750 mg. METGLUCO<sup>®</sup> may be taken not only after meals but also just before meals.

DSP emphasizes promotion of appropriate use of  $METGLUCO^{\$}$  as well as of "MELBIN<sup>®</sup> in order to contribute to furthering awareness for type 2 diabetes therapy.

[An outline of "METGLUCO® is given in "Reference"]

## <Reference>

## Profile of "METGLUCO®"

[Brand Name]	METOGLUCO® tablet 250 mg
[Generic Name]	Metformin hydrochloride
[Content / Description]	One tablet contains 250 mg of metformin hydrochloride
[Indication]	Type 2 diabetes
	To be administered only when adequate effectiveness
	of either of the following treatments is not obtained:
	(1) solely diet therapy / exercise therapy
	<ul><li>(2) use of sulfonylurea drugs in addition to diet therapy / exercise therapy</li></ul>
[Dose and Administration]	Start with the usual adult dosage of 500 mg of
	metformin hydrochloride per day; determine the
	usual maintenance dosage of 750 mg – 1500 mg per
	day while observing its effect; keep the highest
	dosage at 2250 mg maximum per day while there
	may be a rise or fall in dosage depending on patient's
	symptoms.
	The daily dose is divided into two to three portions
	for oral administration either just before or after a
	meal.
[Characteristics]	1. "METGLUCO $^{\textcircled{R}}$ is the only metformin drug
	approved in Japan with the usual maintenance
	dosage of 1500 mg / day (maintenance dosage:
	750 - 1500 mg).
	2. It lowers blood-glucose by way of inhibitory
	action against hepatic glyconeogenesis,
	stimulatory action for glucose uptake in skeletal
	muscle and adipose tissue and inhibitory action
	against intestinal glucose absorption, without
	stimulation of insulin secretion.
	3. As a result of a long-term administration study
	(54  weeks) which was conducted on type $2$

diabetes patients who were not sufficiently

	controlled by diet therapy / exercise therapy (over
	12 weeks), a continuous lowering of blood-glucose
	was observed in the case of administration of
	1500 mg / day (an analysis by the mode dosage
	during the study period).
	There was no difference in blood-glucose lowering
	effect depending on the degree of fatness.
[Manufacturer and Distributor]	Dainippon Sumitomo Pharma Co., Ltd.
[Day of Approval]	January 20, 2010
[Day of NIH price listing]	April 16, 2010
[List price]	9.9 yen / one 250 mg tablet
[Packages]	[PTP] 100 tablets (10 tablets x 10), 1000 tablets (10
	tablets x 100)
	[Unset] 500 tablets