Dainippon Sumitomo Pharma Co., Ltd.

## Oral hypoglycemic drug METGLUCO® obtained a manufacturing and marketing approval

Dainippon Sumitomo Pharma Co., Ltd. (DSP, Headquarters: Osaka, Japan; President: Masayo Tada) announced that it has obtained a manufacturing and marketing approval for "METGLUCO® tablet 250mg" (generic name: metformin hydrochloride), an oral hypoglycemic drug, in Japan as of January 20, 2010 from the Ministry of Health, Labor and Welfare.

METGLUCO® 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 the stimulation of insulin secretion.

In 1961, DSP developed and launched "MELBIN® tablet" containing metformin hydrochloride for the first time in Japan.

Metformin drugs have been widely used as the first choice for treatment of type 2 diabetes in Europe and the U.S. In order to have metformin employed for the appropriate indication and dose, and to have it supplied for medical practice as soon as possible, in 2003 DSP licensed-in Glucophage® (namely METGLUCO® in Japan) which has already been approved for manufacturing and marketing in more than 100 countries, complete with an abundance of clinical and non-clinical evidence, from Merck Santé s.a.s. (France). DSP conducted clinical trials using this drug in Japan and applied for manufacturing approval of this drug as Japanese brand name METGLUCO® tablet 250mg.

METGLUCO® 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® represents a breakthrough in the diabetes therapy as the existing metformin drugs only allow daily dosages of maximum 750 mg. METGLUCO® may be taken not only after meals, but just before meals as well.

DSP plans to sell METGLUCO® after it is listed in the national health insurance drug

price listing, and expects that the launch of METGLUCO® will provide a new choice of treatment for type 2 diabetic patients and contribute to furthering the therapy for type 2 diabetes.

Merck Santé s.a.s. is part of Merck Serono Division. Merck Serono is a Divison for innovative prescription pharmaceuticals of Merck KGaA, Darmstadt, Germany.

<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

(2) use of sulfonylurea drugs in addition to diet

therapy / exercise therapy

[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

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