# NEW INDICATION FOR FAST-ACTING POSTPRANDIAL HYPOGLICEMIC AGENT FASTIC® TABLET / STARSIS® TABLET

#### WAS APPROVED FOR COMBINATION THERAPY WITH THIAZOLIDINES

December 24, 2008 - Tokyo - Ajinomoto Co., Inc. (Headquarters: Tokyo, President & CEO: Norio Yamaguchi) and Astellas Pharma Inc. (Headquarters: Tokyo, President & CEO: Masafumi Nogimori) announced today that an additional indication for *FASTIC®* Tablet / *STARSIS®* Tablet (generic name: nateglinide\*1), a fast-acting postprandial hypoglycemic agent, jointly developed by the two companies for use in combination therapy with thiazolidines\*2 has been approved on December 22.

Nateglinide, an amino acid derivative, is an oral hypoglycemic agent that has insulin secretion enhancing effect with quick onset and short duration. Since the launch in August 1999, nateglinide has been used in monotherapy or in combination with alpha-glucosidase inhibitors or biguanides for treatment of diabetes, indicated for "improvement of postprandial blood glucose changes in patients with type 2 (non-insulin-dependent) diabetes." The two companies conducted clinical trials in Japanese patients for the combination therapy with thiazolidines and obtained the approval for the indication.

Ajinomoto Co., Inc. has sold nateglinide in Japan through Daiichi Sankyo Co., Ltd. (Headquarters: Tokyo) under the brand names of *FASTIC®* Tablet 30 and *FASTIC®* Tablet 90, and Astellas Pharma Inc. has sold the same under the brand names of *STARSIS®* Tablet 30 mg and *STARSIS®* Tablet 90 mg.

The newly approved combination therapy between nateglinide that suppresses elevation of postprandial blood glucose levels and thiazolidines that improve insulin resistance has already been proven to be effective and safe in the United States. Through this approval, nateglinide will certainly provide a new choice of effective therapeutic methods for type 2 diabetic patients in Japan\*3.

## \*1 About nateglinide:

Nateglinide is licensed by Ajinomoto Co., Inc. to Novartis Pharma AG (Headquarters: Basel, Switzerland) worldwide except for Japan and South Korea, and to Ildong Pharmaceutical Co., Ltd. (Headquarters: Seoul, South Korea) for South Korea. This agent has been approved and marketed in 78 countries and regions as an anti-diabetic agent.

#### \*2 About thiazolidines:

Thiazolidines are oral hypoglycemic agents that decrease blood glucose levels by accelerating intake of glucose mainly into peripheral (musculoskeletal and fatty) tissues as well as by suppressing gluconeogenesis in the liver through increase of insulin action. In Japan, pioglitazone hydrochloride is available in the market.

## \*3 Nateglinide-thiazolidine combination:

Like combination between nateglinide and thiazolidines, combination therapies of anti-diabetic agents that have different action mechanisms and effects are recognized to be effective. There was no clinical data available with Japanese patients up to now while the combination between nateglinide and thiazolidine has been approved and widely prescribed in the United States.

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