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SNDA FOR A FAST-ACTING POSTPRANDIAL HYPOGLICEMIC AGENT *FASTIC®* TABLET / *STARSIS®* TABLET FOR COMBINATION THERAPY WITH BIGUANIDE WAS APPROVED

November 14, 2007 - Tokyo - Ajinomoto Co., Inc. (Headquarters: Tokyo, President & CEO: Norio Yamaguchi) and Astellas Pharma Inc. (Headquarters: Tokyo, President & CEO: Masafumi Nogimori) announced today that a supplemental New Drug Application for *FASTIC®* Tablet / *STARSIS®* Tablet (generic name: nateglinide[*1]), a fast-acting postprandial hypoglycemic agent, jointly developed by two companies for the indication of combination therapy with biguanide agents[*2] has been approved.

Nateglinide, an amino acid derivative, is an oral hypoglycemic agent having the insulin secreting action with a quick onset and short duration. After the launch in August 1999, nateglinide has been used in monotherapy or in combination with alpha-glucosidase inhibitors for treatment of diabetes, indicated for "improvement of postprandial blood glucose changes in patients with non-insulin-dependent diabetes." The two companies conducted clinical trials in Japanese patients for the combination therapy with biguanide agents and obtained an approval for the indication.

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

The combination therapy of nateglinide that suppresses elevation of postprandial blood glucose levels and biguanide agents that improve insulin resistance has already been proved to be effective and safe overseas outside Japan. This approval will certainly provide a new choice of effective therapeutic method for type 2 (non-insulin-dependent) diabetic patients in Japan.

***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 Ildong Pharmaceutical Co., Ltd. (Headquarters: Seoul, South Korea) is the licensee in the territory of South Korea. This agent has been approved and marketed in 89 countries and regions as a diabetic agent.

***2 About biguanide agents :**

Biguanide agents are oral hypoglycemic agents that improve insulin resistance by the main action mechanism of hepatic glucose production inhibition, of which metformin hydrochloride and buformin hydrochloride have been available in Japanese market. Effectiveness of combination therapies of diabetic agents having different mechanisms and characters are recognized. Outside Japan, especially in Europe and the US, the combination therapy of nateglinide and biguanide agents has been approved and widely prescribed; however, there was no clinical data available with Japanese patients up to the present.

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