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Ajinomoto Pharmaceuticals Co., Ltd.

**PIIa Clinical Study Results of AJM300 in Ulcerative Colitis**

- Oral α4 integrin inhibitor was demonstrated to be effective in treatment of inflammatory bowel disease for the first time in the world -

Ajinomoto Pharmaceuticals Co., Ltd. (“Ajinomoto Pharmaceuticals”) (President, Takashi Nagamachi; Headquarters, Chuo-ku, Tokyo) has obtained the results of PIIa clinical study of α4 integrin inhibitor, development code “AJM300”, in patients with ulcerative colitis. AJM300 is the investigational new drug for inflammatory bowel disease treatment agent that Ajinomoto Pharmaceuticals originally created.

The number of patients suffering from ulcerative colitis is reported to be about 130,000 in Japan. The cause of disease remains unknown, and there exists merely limited agents for treatment at the present. In inflammatory bowel diseases like ulcerative colitis, excessive infiltration of lymphocytes into the inflamed site is considered to associate with the disease progression. AJM300 has a new action mechanism that prevents mainly adhesion and infiltration of lymphocytes into the inflamed site. With the action mechanism completely different from existing agents, AJM300 is expected to widen the range of choices of treatment for patients to improve quality of life.

This clinical study is a randomized double-blind comparative study* for patients with moderately active ulcerative colitis who were not effectively cured with 5-aminosalicylic acid preparations or steroids, or who were not able to receive treatment due to side effects of the treatments. The study was conducted with 102 patients in 42 sites located in Japan with the primary endpoint of clinical response rate at 8 week post-administration in remission for the purpose of induction to
remission. The study demonstrated that the clinical response rate were significantly high in the AJM300 treatment group as compared to the placebo* group. The levels of side effects were mild in all the observed cases.

While antibody preparations (injections) are drawing attention in the disease area, AJM300 is Ajinomoto Pharmaceutical's originally developed agent of new action mechanism with the advantage that is orally available. With the results of clinical study, Ajinomoto Pharmaceuticals expects that AJM300 can be a new choice in treatment of ulcerative colitis.

Ajinomoto Pharmaceuticals accelerates the clinical study in Japan and simultaneously promotes out-licensing outside Japan aiming to develop a Japan-made new globally-available agent.

Ajinomoto Pharmaceuticals aims to be a “specialty pharmaceutical company in the gastrointestinal disease area”. Ajinomoto Pharmaceuticals is committed to a healthier and better quality of life of each individual patient through practice of “For Your Quality Of Life” to realize wishes of patients and medical practitioners.

*Randomized double-blind comparative study / Placebo

Randomized double-blind comparative study is a method of study to objectively evaluate the efficacy of medicine. In the study, neither investigators nor patients know which the patient take, a placebo (a mimic preparation that looks like a true medicine but contains no active ingredient) or the true medicine.

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