Ajinomoto Pharmaceuticals Co., Ltd. (President, Takashi Nagamachi; Headquarters, Tokyo, Japan) today announced that the Phase 2a results of an oral α4 integrin antagonist, development code AJM300, in patients with ulcerative colitis were presented in the Joint Presidential Plenary Session at Digestive Disease Week 2014 held May 3 – 6 in Chicago, IL, USA.

In inflammatory bowel disease including ulcerative colitis, excessive infiltration of lymphocytes into the inflamed lesion is known to be associated with the disease progression. AJM300 has a new mode of action that prevents the adhesion and invasion of lymphocytes mainly to the inflamed lesion. With the mode of action completely different from any conventional therapy and the oral availability, AJM300 is expected to be an additional treatment option for patients to increase quality of life.

Dr. Mamoru Watanabe, Professor of Gastroenterology and Hepatology, Tokyo Medical and Dental University, who is the presenter of the above, says, “The clinical study data suggests that AJM300 can be a promising new treatment option for patients with ulcerative colitis who are not satisfied with current conventional therapies.” He also says, “AJM300 has an advantage of orally available medicine. I look forward to the day when a Japan-origin new drug contributes to treatment of inflammatory bowel disease in the world.”
AJM300, an Oral α4 Integrin Antagonist, for Active Ulcerative Colitis:
a Multicenter, Randomized, Double-Blind, Placebo-Controlled Phase 2a Study.

<table>
<thead>
<tr>
<th>Purpose</th>
<th>The purpose of the present study was to investigate for efficacy and safety of AJM300 orally administered 3 times a day at 960mg/dose for 8 weeks in patients with active ulcerative colitis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study design</td>
<td>A multicenter, randomized, double-blind, placebo-controlled, parallel group phase 2a clinical study</td>
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<tr>
<td>Patients</td>
<td>Patients with moderately active ulcerative colitis who had inadequate response or intolerance to 5-aminosalicylic acid preparations or steroids, or who were not able to continue treatment with such agents due to side effects (n=102)</td>
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<tr>
<td>Primary endpoint</td>
<td>Improvement rate at 8 weeks</td>
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</table>
| Results | • The clinical response rates at week 8 (primary endpoint) were 62.7% in AJM300 group and 25.5% in placebo group. There were statistically significant improvements (p=0.0002).  
• The clinical remission rates at 8 weeks (secondary endpoint) were 23.5% in AJM300 group and 3.9% in placebo group (p=0.0099). The mucosal healing rates were 58.8% in AJM300 group and 29.4% in placebo group (p=0.0014). There were statistically significant improvements in AJM300 group, respectively.  
• AJM300 was well tolerated. No severe adverse events or no severe infections were observed. Abnormalities in laboratory test results tended to be increased in AJM300 group, but all the changes were mild and the symptoms ameliorated without any additional treatments. |

Ajinomoto Pharmaceuticals Co., Ltd. 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.

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