EISAI RECEIVES APPROVAL FOR INDICATION EXPANSION OF PROTON PUMP INHIBITOR PARIET® FOR USE IN PREVENTION OF RECURRENT GASTRIC OR DUODENAL ULCER CAUSED BY LOW-DOSE ASPIRIN THERAPY AND ADDITIONAL 5 MG TABLET FORMULATION IN JAPAN

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, “Eisai”) announced today that it has received approval of a new indication for proton pump inhibitor Pariet® Tablets 10 mg (rabeprazole sodium, “Pariet”) in Japan for use in the prevention of recurrent gastric or duodenal ulcers caused bd ( )Tja4e6Cl8eub(( )Tj

Media Inquiries:
Public Relations Department,
Eisai Co., Ltd.
+81-(0)3-3817-5120

[Notes to editors]

1. About Pariet®

Pariet is a proton pump inhibitor (PPI) that was discovered and developed by Eisai. First launched in Japan in 1997, it is approved in more than 100 countries and territories worldwide. In Japan, Pariet is available in 10 mg and 20 mg

3. About the Phase II/III ClinicalStudy (Study 308 / Study 309)

1) Study 308

Study design:	A multicenter, randomized, parallel-group, double-blind comparative trial of Pariet vs. teprenone
Study population:	Patients with a history of gastric or duodenal ulcer receiving long administration of low-dose aspirin, 472 subjects
Primary objective:	To evaluate the effect of preventing recurrence of gastric or duodenal ulcers by administering Pariet and examine the superiority of Pariet over Teprenone.
Treatment administered:	Treatment with either Pariet 5 mg once daily, Pariet 10 mg once daily, or teprenone 50 mg three times daily
Duration of treatment:	24 weeks
Primary endpoint:	Cumulative recurrence rate of gastric or duodenal ulcers

2) Study 309

Study design:	A multicenter, randomized, parallel-group, open-label trial of long term treatment with Pariet
Study population:	Patients confirmed to have no recurrence of gastric or duodenal ulcer at the end of 24 weeks of treatment in Study 308 and agree to transfer to Study 309, 328 subjects
Primary objective:	Evaluate the safety and efficacy of Pariet administered adjunctively long-term with low-dose aspirin
Treatment administered:	Treatment with Pariet 5 mg or 10 mg once daily (patients who were in the Pariet treatment arm in Study 308 continued with the same dosage, patients who were in the comparator treatment arm were given either Pariet 5 mg or Pariet 10 mg
Duration of treatment:	28-52 weeks (maximum 76 weeks including Study 308)
Primary endpoint:	Long-term safety