SCOTTISH MEDICINES CONSORTIUM APPROVES AMPA RECEPTOR ANTAGONIST FYCOMPA® AS ANTIEPILEPTIC TREATMENT UNDER NATIONAL HEALTH SERVICE SCOTLAND

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, “Eisai”) announced today that Scotland’s health technology assessment (HTA) body, the Scottish Medicines Consortium (SMC), has approved Eisai’s AMPA receptor antagonist Fycompa® (perampanel) as a second-line adjunctive treatment in patients with refractory partial-onset epilepsy under National Health Service Scotland (NHS Scotland). The SMC approval of perampanel is the drug’s first HTA worldwide.

SMC assessed perampanel from an efficacy, safety and health economics perspective based on three submitted placebo-controlled double-blind studies, based on a comparative health economic analysis that took into account overall costs (including drug costs, inpatient visits, A&E services, outpatient and GP visits) compared with existing antiepileptic drugs. SMC evaluated that perampanel was superior to placebo in terms of seizure control. Furthermore, perampanel was evaluated to be a cost-effective

Eisai will continue to make further contributions to address the diversified needs of, and increase the benefits provided to, epilepsy patients and their families.

[Please refer to the following notes for further information on SMC and perampanel Phase III studies.]

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[Notes to editors]

1. About the Scottish Medicines Consortium (SMC)

The Scottish Medicines Consortium (SMC) is an independent body that carries out assessments on the status of all newly licensed medicines, all new formulations of existing medicines and new indications for established products regarding their health benefits and price justification as an advisory board to the National Health Service Scotland (NHS Scotland) about whether or not a newly licensed drug should be accepted for use under Scotland's national health insurance. SMC is made up of lead clinicians, pharmacists and health economists together with representatives of health boards, the pharmaceutical industry and the public.

2. About perampanel Phase III Studies

The clinical development plan for perampanel consisted of three global Phase III studies (Studies 306, 305 and 304) in which a total of 1,480 epilepsy patients with partial-onset seizures ages 12 years and older participated. The key goal of Study 306 was to identify the minimal effective dose and included four treatment arms (placebo, 2 mg, 4 mg, and 8 mg). Studies 304 and 305 included three arms (placebo, 8 mg, and 12 mg) and were to evaluate a more extended dose range.

The studies were similar in design: global, randomized, double-blind, placebo-controlled, dose-escalation, parallel-group studies. The primary and secondary endpoints were the same in all the studies: percentage change in seizure frequency, 50% responder rate, percentage reduction of complex partial plus secondarily generalized seizures, and evaluation for dose response. The primary endpoint for the EMA is 50% responder rate and the FDA is median percent change in seizure frequency.

Results of the studies are as follows.

1) Study 306

- The 50% responder rates compared to placebo for the ITT (intention-to-treat) population were:
  2 mg = 20.6% ($p = 0.4863$), 4 mg = 28.5% ($p = 0.0132$), 8 mg = 34.9% ($p = 0.0003$) versus 17.9% with placebo.
- The median percent change in seizure frequency for the ITT population were:
  2 mg = -13.6% ($p = 0.4197$), 4 mg = -23.3% ($p = 0.0026$), 8 mg = -30.8% ($p < 0.0001$) versus -10.7% with placebo
- The most frequent treatment-emergent adverse events were dizziness, headache and somnolence.

2) Study 305

- The 50% responder rates compared to placebo for the ITT population were:
  8 mg = 33.3% ($p = 0.0018$), 12 mg = 33.9%