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Eisai disagrees with IQWiG on epileptic drug

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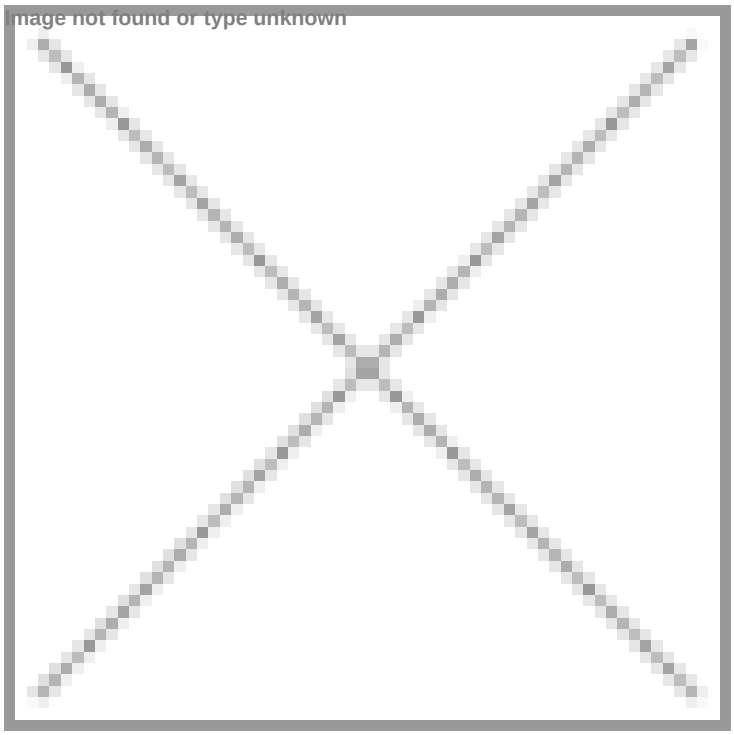
Eisai disagrees with German institute on antiepileptic drug



Singapore: Eisai has expressed strong disappointment with Institute for Quality and Efficiency in Health Care (IQWiG), Germany, in regards to their assessment of the additional benefit, of the new epilepsy treatment Fycompa (perampanel) compared to a treatment defined by Federal Joint Committee (G-BA). In the assessment report by IQWiG on Fycompa, published in G-BA website, the institute did not attest an additional benefit.

Comments on the report and its proposed conclusion can be submitted to the G-BA up until January 7, 2013. The G-BA will decide on the additional benefit in March 2013 after reviewing comments and the discussion from an oral hearing of experts end of January. The current IQWiG assessment has no implications on the reimbursement of perampanel or doctors' ability to prescribe this new partial epilepsy treatment.

It is reported that additional benefit is unproven based on methodological considerations. No statement was made regarding clinical efficacy and safety. Perampanel is the first in an entirely new class of treatment for uncontrolled partial epilepsy with a novel mechanism of action that is different from all other anti-epileptic drugs (AEDs). The company believes that, while discussing at length methodological aspects of analyses, IQWiG failed to adequately interpret the patient-relevant benefits and responsibly recognise the innovative nature of the new drug in a clinical setting with a high unmet need.

Perampanel is indicated as an adjunctive treatment for partial seizures (the most common form of epileptic seizures), with or without secondarily generalised seizures, in patients with epilepsy aged 12 years and older. It was first launched in Europe in

Germany and the UK in September 2012 and has been well received by both patients and doctors. It is the first and only licensed AED to selectively target AMPA receptors which play a critical role in causing seizures. It blocks the effects of glutamate, which can trigger and maintain seizures.

"We believe we provided compelling evidence of the additional benefit of perampanel based on the advice received by the G-BA. By taking a negative view, IQWiG ignores the therapeutic value that this first-in-class new AED brings to the real-life clinical setting. There still remains a very high need for new drugs to reduce seizures in patients with refractory partial epilepsy," points out Mr Franz Wetzel, Epilepsy Business Unit Director, Eisai Germany. "In addition, perampanel has the further benefit of convenient, once-daily dosing at bedtime and it is the only new-generation partial epilepsy treatment approved to treat adolescents with epilepsy from launch."