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Eisai Co., Ltd.

ANTIEPILEPTIC DRUG FYCOMPA® REGULARLY AVAILABLE AGAIN IN GERMANY FROM DECEMBER FOLLOWING AGREEMENT WITH NATIONAL ASSOCIATION OF STATUTORY HEALTH INSURANCE FUNDS

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") has announced that its German sales company Eisai GmbH (Location: Frankfurt) and the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband) have agreed on a reimbursement price for Eisai's antiepileptic drug (AED) Fycompa® (perampanel). As of December 1, 2017, Fycompa will therefore once again be regularly available in Germany.

In the German Federal Joint Committee (G-BA)'s original assessment of Fycompa after its marketing authorization was granted, the additional benefit or innovative value (a prerequisite for insurance reimbursement pricing negotiations) of Fycompa was not, in Eisai's opinion, appropriately assessed by the G-BA. As a result, in 2013 Eisai withdrew Fycompa from commercial distribution in Germany and until March 2016 provided Fycompa free of charge through a patient access program in order to ensure that eligible German patients with epilepsy could continue to receive treatment. From April 2016 the product has been available in Germany through individual pharmacy importation process.
Fycompa was re-submitted in May 2014 to the G-BA for additional benefit assessment due to a change in the assessment process, but in November of the same year the G-BA determined once again that no additional benefit could be proven. In May 2017, new negotiations became possible due to a change in the law finally resulting in the pricing agreement with the GKV-Spitzenverband which is announced today.

Fycompa is a first-in-class AED discovered at Eisai's Tsukuba Research Laboratories. It is a highly selective, noncompetitive AMPA receptor antagonist that reduces neuronal hyperexcitation associated with seizures by targeting glutamate activity at postsynaptic AMPA receptors. In July 2012, marketing authorization was granted in Europe for Fycompa as an adjunctive treatment for partial onset seizures, with or without secondarily generalized seizures, in patients with epilepsy aged 12 years and older. In June 2015, marketing authorization was granted for Fycompa as an adjunctive treatment for primary generalized tonic-clonic seizures in adult and adolescent patients from 12 years of age with idiopathic generalized epilepsy.

Epilepsy is one of the most common neurological conditions in the world and over half a million people in Germany live with the condition. As approximately 30% of patients with epilepsy are unable to control their seizures with currently available AEDs,[1] this is a disease with significant unmet medical need, and innovative new medicines with new mechanisms of action are urgently required.

Through the recommencement of distribution of Fycompa to patients with epilepsy in Germany who are in urgent need of innovative new medicines based on the aforementioned agreement, Eisai is delighted to be able to contribute to many patients.

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[Notes to editors]

1. About Fycompa (perampanel)

Fycompa is a first-in-class AED discovered and developed by Eisai. With epileptic seizures being mediated by the neurotransmitter glutamate, the agent is a highly selective, noncompetitive AMPA receptor antagonist that reduces neuronal hyperexcitation associated with seizures by targeting glutamate activity at postsynaptic AMPA receptors. Fycompa is available in tablet form to be taken once daily orally at bedtime. In addition, a new oral suspension formulation has been approved and is being marketed in the United States.

Fycompa is currently approved in more than 55 countries and territories, including Japan, the United States, in Europe and Asia as an adjunctive treatment for partial-onset seizures (with or without secondarily generalized seizures) in patients with epilepsy 12 years of age and older.

In addition, Fycompa has been approved in more than 45 countries, including Japan, the United States, in Europe and Asia as an adjunctive therapy for primary generalized tonic-clonic (PGTC) seizures in patients with epilepsy 12 years of age and older. Furthermore, Fycompa is now indicated in the United States as a monotherapy use for the treatment of partial-onset seizures (with or without secondarily generalized seizures) in patients with epilepsy aged 12 and older. Meanwhile, Eisai is conducting respective global Phase III studies for the agent in pediatric patients with partial-onset seizures or PGTC seizures and in patients with seizures associated with Lennox-Gastaut syndrome. Additionally, a Phase III study as monotherapy for partial-onset seizures is being conducted in Japan.

2. About Additional Benefit Assessment Conducted by the German Federal Joint Committee (G-BA) and Statutory Health Insurance Reimbursement

In Germany, the enactment of the Act on the Reform of the Market for Medical Products (AMNOG) came into effect on January 2011. Under this amendment, all eligible new drugs launched on the German market must undergo an additional benefit assessment conducted by the G-BA, with subsequent price negotiations to be based on this assessment, and a reimbursement price to be agreed upon within one year from the drug's launch.

The G-BA routinely commissions the country's Institute for Quality and Efficiency in Health Care (IQWiG) to evaluate the clinical data demonstrating the drug’s additional benefit submitted by the pharmaceutical company (benefit dossier) to decide whether any additional benefit exists over a G-BA chosen comparator. The pharmaceutical company is next given an opportunity to comment on IQWiG's evaluation, after which the G-BA carries out its final decision whether or not to attest an additional benefit of the drug.

If an additional benefit is recognized by the G-BA, the drug proceeds to the price negotiation stage with the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband), and a reimbursement price has to be agreed upon based on, among other criteria, the assessment of the additional benefit as decided by the G-BA. On the other hand, if a drug was deemed to offer no recognized additional benefit or if the additional benefit could not be proven, the drug is generally designated either a reference price group, if available, or a reimbursement price based on the price of the most economical comparator used during the benefit assessment.

Based on the Act on Strengthening Pharmaceutical Supply in the Statutory Health Insurance (AM-VSG) that came into effect in May 2017, new negotiations with GKV-Spitzenverband can be initiated for products for which an additional benefit could not be proven.

1 “The Epilepsies and Seizures: Hope Through Research. What are the epilepsies?” National Institute of Neurological Disorders and Stroke, accessed November 7, 2017, http://www.ninds.nih.gov/disorders/epilepsy/detail_epilepsy.htm#230253109