Fingolimod: 'Hint' of advantages in a small group of patients

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The immunosuppressive drug fingolimod (trade name: Gilenya) is approved for the treatment of highly-active relapsing-remitting multiple sclerosis (RRMS) in adults. In an early benefit assessment pursuant to "Act on the Reform of the Market for Medicinal Products" (AMNOG), the German Institute for Quality and Efficiency in Health Care (IQWiG) assessed whether fingolimod offers an added benefit compared with the present standard therapy.

According to the findings of the assessment, patients with a rapidly progressive and severe course of disease who take fingolimod experience fewer flu-like symptoms. Under consideration of this advantage on the one hand and the uncertain evidence base on the other, IQWIG has concluded that the data provide a "hint" of a minor added benefit of fingolimod for this group of patients.

Due to a lack of evaluable data, an added benefit is not proven for two further groups of patients.

Separate assessment in three groups of patients

According to the different areas of application, IQWiG performed separate assessments of the drug in three groups of patients. Fingolimod was compared with glatiramer acetate in patients with highly active RRMS who had not responded to a complete and appropriate (usually at least one-year) cycle with beta-interferon (IFN-?).

In patients with highly active RRMS who had not received sufficient IFN-? therapy and in those with rapidly progressive severe RRMS, fingolimod was in each case compared with IFN-? 1a.

Evaluable data only for one group of patients

One relevant study was available for the early benefit assessment, an approval study on fingolimod (TRANSFORMS), which compared treatment with fingolimod versus IFN ? 1a in adults with RRMS. However, the study only provided data for one of the three patient groups specified by the Federal Joint Committee (G-BA), namely for those with rapidly progressive severe RRMS.

The manufacturer dossier did not contain evaluable data for a benefit assessment in the other two groups, that is, patients with highly active RRMS who had already received a complete pre-treatment with IFN-? and patients with RRMS who had not received sufficient pre-treatment with IFN-?. An added benefit of fingolimod is therefore not proven for these therapeutic indications.

Fewer flu-like symptoms in some patients

The study results in patients with rapidly progressive severe RRMS did not indicate significant differences between treatment groups for the outcomes "relapse", "progression of disability" and "health-related quality of life". No data were reported for the outcomes "fatigue" and "activities of daily living" for this patient group, even though such data were collected in the study. Likewise, no significant difference was shown between treatment groups regarding the overall rate of side effects (adverse events), serious adverse events, and study discontinuations due to adverse events.

However, for the outcome "frequency of flu-like symptoms" the data provided an indication of less harm: patients treated with fingolimod experienced fewer such symptoms.

Only "hint" of added benefit due to inadequate data

It should be noted that conclusions on the group of patients with rapidly progressive severe RRMS are somewhat uncertain. For example, according to the approval status, this patient group is defined by several disease criteria, but the study participants

for whom the manufacturer had presented data did not fulfil all of these criteria and can only be identified indirectly as a patient group in the study pool.

Under consideration of this uncertain evidence base on the one hand and the potential advantage on the other, in summary IQWiG concludes that there is a "hint" of a minor added benefit of fingolimod in patients with rapidly progressive severe RRMS treated with fingolimod compared with those treated with beta-interferon.

G-BA decides on the extent of added benefit

The procedure for inferring the overall conclusion on the extent of added benefit is a proposal from IQWiG. The G-BA, which has opened a formal commenting procedure, decides on the extent of added benefit.

The following extract provides an overview of the results of the benefit assessment performed by IQWiG. The website gesundheitsinformation.de, which is issued by IQWiG, provides easily understandable brief information.

The G-BA website contains both general information on benefit assessments pursuant to §35a Social Code Book V and specific information on the assessment of fingolimod.

Provided by Institute for Quality and Efficiency in Health Care

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