Nivolumab in advanced lung cancer: Indication of major added benefit

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Nivolumab has been approved since April 2016 as a checkpoint inhibitor for the treatment of adults with locally advanced or metastatic nonsquamous non-small-cell lung cancer (NSCLC) who have already undergone chemotherapy. In an early benefit assessment, the German Institute for Quality and Efficiency in Health Care (IQWiG) has now examined whether in these patients this monoclonal antibody offers advantages over the appropriate comparator therapy.

According to the findings, there is an indication of a major added benefit of nivolumab over docetaxel. An added benefit over the appropriate comparator therapy (best supportive care) is not proven in patients for whom treatment with docetaxel or similar drugs is not indicated.

Approval study stopped early due to survival advantage

The Federal Joint Committee (G-BA) specified docetaxel, pemetrexed or - depending on the mutation status - gefitinib, erlotinib or crizotinib as the appropriate comparator therapy. Patients for whom these drugs are not indicated were to be treated in the control arm with best supportive care instead, that is, treatment tailored to the individual patient's needs in order to alleviate pain and improve quality of life. The manufacturer did not present data on this second research question.

For the first research question, the manufacturer cited the approval study CA209-057, in which nivolumab was compared with docetaxel. After an interim analysis, all patients in the docetaxel arm were offered the option of further treatment with nivolumab, as the new drug showed clear advantages for overall survival. However, only PD-L1-positive patients had a statistically significant survival advantage. In contrast, an added benefit for overall survival is not proven in patients with a negative PD-L1 status.

Also advantages for side effects

Nivolumab also has advantages over docetaxel with regard to several outcomes from the category "side effects" (severe and serious adverse events, discontinuation due to adverse events, alopecia, and blood and lymphatic system disorders).

Overall, for patients who can be treated with docetaxel and similar drugs the data provide an indication of a major added benefit of nivolumab over the appropriate comparator therapy. Due to a lack of data, an added benefit is not proven for patients for whom such drugs are not indicated.

G-BA decides on the extent of added benefit

The dossier assessment is part of the early benefit assessment according to the Act on the Reform of the Market for Medicinal Products (AMNOG) supervised by the Federal Joint Committee (G-BA). After publication of the dossier assessment, the G-BA conducts a commenting procedure and makes a final decision on the extent of the added benefit.

An overview of the results of IQWiG's benefit assessment is given by a German-language executive summary. In addition, the Website gesundheitsinformation.de, published by IQWiG, provides easily

understandable German-language information.

More English-language information will be available soon (Sections 2.1 to 2.6 of the dossier assessment as well as subsequently published health information on informedhealth.org).

More information: www.iqwig.de/download/A16-25_N … ertung-35a-SGB-V.pdf

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