

Nintedanib in lung cancer: Added benefit depends on disease severity

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Since November 2014 nintedanib (trade name: Vargatef) has been approved in combination with docetaxel for the treatment of adults with advanced non-small cell lung cancer (NSCLC) of the glandular tissue (adenocarcinoma) who have already received chemotherapy. The German Institute for Quality and Efficiency in Health Care (IQWiG) examined in a dossier assessment whether this new drug offers an added benefit over the appropriate comparator therapy.

According to the findings, there is an indication of a minor added benefit of nintedanib in combination with [docetaxel](#) in patients without [brain metastases](#). However, in patients with brain metastases, the new drug has more disadvantages than chemotherapy with docetaxel alone. This results in a hint of a lesser benefit of nintedanib with the extent "considerable".

Findings from the only study are biased: at most indications can be derived

In its dossier the drug manufacturer compares treatment comprising nintedanib plus docetaxel with treatment comprising placebo plus docetaxel. As the treatment period in the nintedanib arm was longer than in the placebo arm (median: 4.3 versus 3 months), the observation periods for the study arms differed. Except for overall survival, the results are therefore uncertain for all outcomes.

In principle, at most an indication of an added benefit can be derived from the results of the only study included in the manufacturer dossier. As the analysis of the data shows, the advantages or disadvantages of nintedanib in combination with docetaxel primarily depend on whether patients already had brain metastases at the start of the study or not.

Patients without brain metastases live longer

Patients without brain metastases who received nintedanib in combination with docetaxel lived longer than study participants who were only treated with docetaxel (median: 13.5 versus 10.3 months). This results in an indication of a minor added benefit of nintedanib.

Although diarrhoea was more frequent in patients receiving nintedanib, this disadvantage does not challenge the survival advantage. Therefore, overall an indication remains of a minor added benefit for patients without brain metastases.

More symptoms in patients with brain metastases

If patients who already had brain metastases at the start of the study were treated with nintedanib, loss of appetite occurred more often and the symptoms nausea and vomiting, as well as diarrhoea, worsened during treatment. These disadvantages result in a hint of a lesser benefit of nintedanib in [patients](#) with brain metastases.

G-BA decides on the extent of added benefit

This 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 G-BA. After publication of the dossier assessment, the G-BA conducts a commenting procedure and makes a

final decision on the extent of added benefit.

An overview of the results of IQWiG's benefit assessment is given by a German-language executive summary. In addition, the website "<http://www.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 "<http://www.informedhealthonline.org>). If you would like to be informed when these documents are available, please send an e-mail to "info@iqwig.de.

The G-BA website contains both general English-language information on the benefit assessment of new drugs pursuant to §35a Social Code Book (SGB) V and specific German-language information on the assessment of nintedanib.

More information: www.iqwig.de/download/A15-01_N...ertung-35a-SGB-V.pdf

Provided by Institute for Quality and Efficiency in Health Care

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