

# **Dacomitinib in advanced lung cancer: Disadvantages outweigh survival advantage**

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Since its approval in April 2019, dacomitinib has been available for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor

receptor (EGFR)-activating mutations. The German Institute for Quality and Efficiency in Health Care (IQWiG) now examined in an early benefit assessment whether this drug offers an added benefit for patients in comparison with the appropriate comparator therapy. The result: While overall survival is longer under dacomitinib treatment, side effects, including severe events, are more frequent. Also, the patients' symptoms worsen earlier and more often than under the comparator treatment, and their health-related quality of life is worse. Overall, an added benefit in comparison with the appropriate comparator therapy is therefore not proven.

## **Only data on one of two research questions**

The Federal Joint Committee (G-BA) distinguished between two research questions based on the mutation status in the EGFR gene of the tumour cells, since the effectiveness of the treatment options depends on the exact structure of this receptor. For the EGFR mutations "L858R" or "Del19", the appropriate comparator therapy was another drug of the same substance class, i.e. afatinib, gefitinib or erlotinib. Patients with other activating mutations were to be treated individually depending on the type of mutation in the comparator arm.

The drug manufacturer did not present [study data](#) on this second research question in its dossier, so that an added benefit of dacomitinib is not proven for this reason alone. For the first research question, there are data from the unblinded randomized controlled trial ARCHER 1050, in which patients—predominantly Asians—were treated with either dacomitinib or gefitinib.

## **Patients reported numerous disadvantages**

With about 34 months, the median survival time in the dacomitinib arm

of the study was just over seven months longer than in the gefitinib arm (just under 27 months). In addition, there were isolated advantages regarding certain side effects. However, this was offset by a large number of disadvantages: Numerous side effects, particularly including severe side effects, were more common under dacomitinib. Patient-reported symptoms worsened more frequently and also earlier. Deterioration of health-related quality of life was also more pronounced than under gefitinib.

"Particularly the deterioration in quality of life is remarkable; data are rarely as clear as they are here," says Thomas Kaiser, Head of IQWiG's Drug Assessment Department. "The patients found their global health status, their role functioning, their cognitive functioning and their social functioning to be more impaired than under gefitinib." Overall, the negative effects outweigh the positive effect on [overall survival](#). An added benefit of dacomitinib in comparison with the appropriate comparator therapy is therefore not proven.

Provided by Institute for Quality and Efficiency in Health Care

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