Darolutamide in prostate cancer: Indication of considerable added benefit

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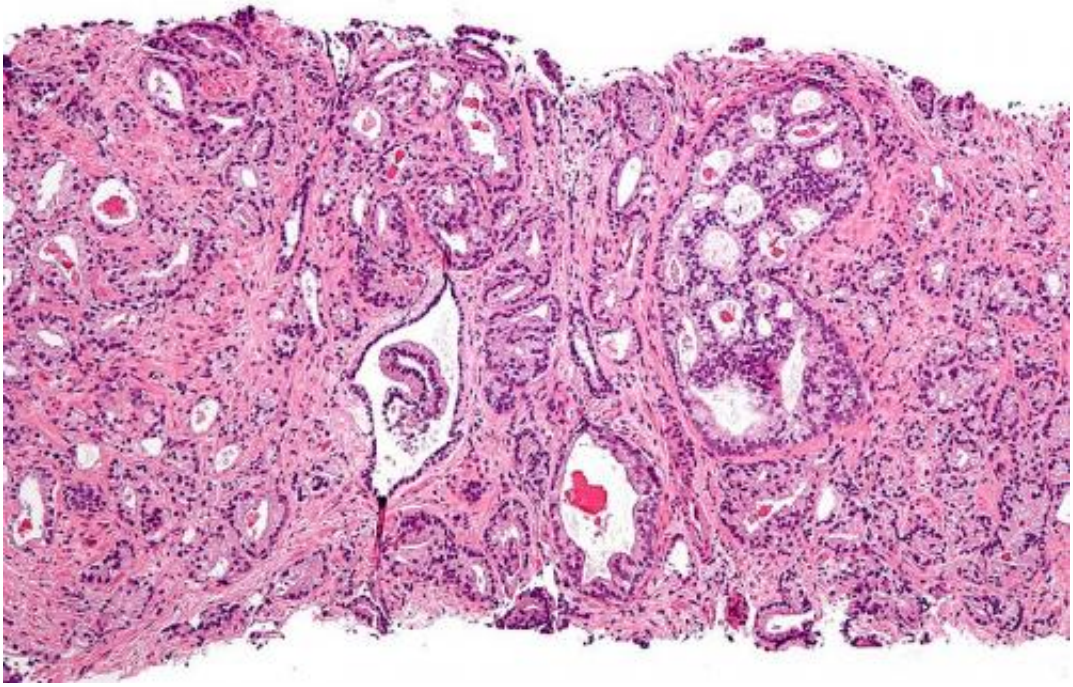

Micrograph showing prostatic acinar adenocarcinoma (the most common form of prostate cancer) Credit: Wikipedia, CC BY-SA 3.0

Up to now, adult men with non-metastatic castration-resistant prostate cancer (nmCRPC) at high risk of developing metastatic disease usually continued their conventional androgen deprivation therapy (ADT) while the cancer was observed for the occurrence of metastases (so-called watchful waiting). The German Institute for Quality and Efficiency in Health Care (IQWiG) now examined in an early benefit assessment

whether adding the drug darolutamide offers an added benefit for patients in comparison with the appropriate comparator therapy.

Since the advantages in overall survival, symptoms and late complications, as well as in health-related quality of life are not accompanied by disadvantages, there is an indication of considerable added benefit.

Study is ongoing

The early benefit assessment was based on data from the ongoing randomized trial ARAMIS, which compares darolutamide in combination with ADT with placebo treatment in combination with ADT. The study included adult men with high-risk nmCRPC who either had had both testes removed or who continued their drug ADT in addition to the study medication (darolutamide or placebo).

The study was double-blind until metastases or unacceptable toxicity occurred. After unblinding, the patients could choose to continue their darolutamide plus ADT treatment or receive darolutamide instead of placebo. There were no restrictions regarding other subsequent therapies.

In the benefit assessment, the first of two data cut-offs was used for all outcomes except overall survival, as analyses were not available for all included outcomes at the second data cut-off. Besides, the follow-up observation in the study is systematically shortened for all outcomes except overall survival. In addition, a number of patients (which was unequal in the two study arms) had discontinued treatment already at the first data cut-off; and many patients switched from the placebo plus ADT arm to the darolutamide plus ADT arm after the first data cut-off.

Patients live longer and have fewer symptoms

The certainty of results was rated as high for overall survival and as low for all other outcomes. Consequently, there is an indication of considerable added benefit in the outcome category of mortality, but no more than hints in the other outcome categories: The added benefit is considerable to major for morbidity (symptoms and late complications), and minor for health-related quality of life. In the category of side effects, there is no hint of lesser or greater harm from the new drug.

In the overall consideration, there is therefore an indication of considerable added benefit of darolutamide plus ADT versus watchful waiting while maintaining ongoing conventional ADT.

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.

More information: www.iqwig.de/en/projects-resul … de-book-v.13138.html

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