MedicalXpress

# Apalutamide in prostate cancer: indication of considerable added benefit

May 7 2019

Do adult men with non-metastatic castration-resistant prostate cancer who have a high risk of developing metastases benefit from treatment with apalutamide—or would they do better to simply continue their conventional androgen deprivation therapy? The German Institute for Quality and Efficiency in Health Care (IQWiG) addressed this question in an early benefit assessment. Analysis of the data from the ongoing randomized controlled trial SPARTAN resulted in an indication of a considerable added benefit of the new drug.

Clear advantages are particularly shown for one important patient-relevant outcome: symptomatic progression. This outcome consisting of several components was carefully recorded in the study—albeit on the basis of a definition that impedes quantification of the advantage: Patients who had decided against a new systemic anticancer treatment despite corresponding symptoms might have been uncovered by the statistics, since only cases in which such treatment was actually started were recorded. Within the framework of this definition, symptomatic progression occurred about twice as often in the comparator arm of the study than in the apalutamide arm.

## Clearly patient-relevant

"In the past, we have often criticised the way in which progression was defined and recorded in oncological studies", says Stefan Lange, Deputy Director of IQWiG. "The study authors took a completely different

approach here: Instead of recording mere measurements, for instance, tumour growth by x millimetres, pathological fractures and compressions of the spinal cord as well as symptoms requiring surgical intervention, new systemic anticancer treatment or radiation therapy were determined. This is definitely patient-relevant."

Some side effects occurred clearly more often under apalutamide than in the comparator arm of the study. However, these disadvantages do not outweigh the advantage recorded for symptomatic progression.

## 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.11681.html

Provided by Institute for Quality and Efficiency in Health Care