Sipuleucel-T in prostate cancer: Indication of added benefit

March 20 2015

Sipuleucel-T (trade name Provenge) has been approved since September 2014 for men with metastatic prostate cancer who have few or no symptoms and do not yet require chemotherapy. In the dossier assessment conducted by the German Institute for Quality and Efficiency in Health Care (IQWiG) in January 2015, no added benefit could be derived for sipuleucel-T.

In an addendum, the Institute now examined information subsequently submitted by the manufacturer in the commenting procedure: According to the findings, there is an indication of added benefit; however, the extent is non-quantifiable.

Mortality: data in the dossier incomplete and not interpretable

Treatment switching occurred in all three approval studies comparing sipuleucel-T with placebo, which were presented in the dossier by the manufacturer: More than two thirds of the patients in the placebo group started treatment with sipuleucel-T on progression of their disease. In both study arms, patients received chemotherapy with docetaxel on progression. The proportion of patients who received docetaxel and the time point of this treatment differed, however, and the respective information provided in the dossier was incomplete.

The study results on overall survival in the dossier could therefore not be

interpreted in a meaningful way: Docetaxel has a positive effect on survival. If, for example, it is given at an earlier time point in the sipuleucel-T arm than in the control arm, lower mortality cannot be explained solely by the effect of sipuleucel-T. Then there is a risk of overestimating the effect of sipuleucel-T.

Additional analyses showed advantage in mortality

The manufacturer presented further data and sensitivity analyses on overall survival with its comment. This now led to a consistent picture in comparison with the primary analysis of the data in the dossier: According to this, the lower mortality in the sipuleucel-T arms cannot be explained solely by differences in the administration of docetaxel after progression.

However, the advantages in overall survival are accompanied by negative effects in the form of side effects: Fever, headache and chills were more frequent in patients in the sipuleucel-T arm. However, these side effects were non-serious and mainly occurred only directly after the administration of sipuleucel-T. IQWiG therefore did not downgrade the positive effect regarding mortality. The conclusion of the addendum for sipuleucel-T is therefore an indication of an added benefit with the extent "non-quantifiable".

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 G-BA. After publication of the manufacturer's dossier and the IQWiG dossier assessment, the manufacturer submitted additional information in the commenting procedure. The G-BA subsequently commissioned IQWiG to assess the

data subsequently submitted. IQWiG now presents this assessment in the form of an addendum. The G-BA makes a final decision on the extent of added benefit.

More information: www.iqwig.de/download/A15-08_A …-38_Sipuleucel-T.pdf

Provided by Institute for Quality and Efficiency in Health Care

Citation: Sipuleucel-T in prostate cancer: Indication of added benefit (2015, March 20) retrieved 6 May 2024 from https://medicalxpress.com/news/2015-03-sipuleucel-t-prostate-cancer-indication-added.html

This document is subject to copyright. Apart from any fair dealing for the purpose of private study or research, no part may be reproduced without the written permission. The content is provided for information purposes only.