Citation

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On the different assessments of ESMO and IQWiG on pembrolizumab/'Keytruda'

Highest possible ESMO value vs. no added benefit

In the cover interview with 'Monitor Versorgungsforschung' (02/25), Dr Thomas Kaiser, Director of IQWiG, briefly discussed the benefit assessment of the active substance pembrolizumab and the MSD drug 'Keytruda' (1): In response to the question 'How is it that IQWiG sees a lower benefit in an assessment, while the ESMO, a European specialist society, sees the highest possible assessment?' (2), Kaiser replied as follows: 'In the ESMO assessment, only the observed benefit in terms of recurrence plays a role.' In its benefit assessment (3), IQWiG also described the advantage of the active substance for recurrences, but weighted it differently from the ESMO (4). In this interview, MVF promised to investigate this considerable contradiction in the interpretation of evidence.

>> According to Kaiser, it makes sense to look at 'not just 30 per cent of the evidence', because 100 per cent of the evidence should always be taken into account if it is already available. Furthermore, a weighing up of the pros and cons is not visible in the ESMO assessment, although life-threatening side effects or even side effects associated with hospitalisation have occurred in some cases. In addition, the recurrences achieved were offset by a high proportion of severe and very severe side effects.

The interview statement by the head of IQWiG that the ESMO only looked at 30 per cent of the evidence and did not take adverse events into account at all when weighing up the evidence is something that market access experts interviewed by MVF on this issue find quite interesting. The reason: In the ESMO assessment, under the item 'Adjustments-Toxicity Comment' (marked red in the figure), it is clear that this point was taken into account and certainly played a role in the assessment. However, this fact did not lead to such a devaluation as with IQWiG, as the major advantages in recurrences in a curative setting are so important for the professional association. IQWiG's benefit assessment (3) states: 'On the positive effects side, there is only an indication of a minor additional benefit for the recurrence endpoint. In contrast, for numerous outcomes in the adverse events category, there are indications of greater harm of varying, in some cases considerable, extent. Even taking into account the fact that the treatment is limited to 1 year, these negative effects, some of which are considerable, clearly outweigh the small positive effect clearly. '

IQWiG's conclusion: 'There is no indication of an additional benefit of pembrolizumab for overall survival compared to waiting and observing; an additional benefit is therefore not proven.'

Prof Bernhard Wörmann, MD, argued almost the opposite in the oral opinion procedure at the G-BA (5). The medical director of the German Society for Haematology and Medical Oncology (DGHO) stated the following: 'In the ESMO Magnitude of Clinical Benefit Scale, this pembrolizumab indication receives an A.' This is the highest possible rating for a curative therapy and reflects what he and his colleagues would see from a clinical perspective: 'This has become a new standard. If patients like this survive disease-free at a significant rate after two and three years, that's the greatest thing we can achieve in this situation.' In the MVF interview on the following pages, Wörmann places this statement in a wider context by raising fundamental questions about the methodology and prioritisation of therapy parameters.. <<

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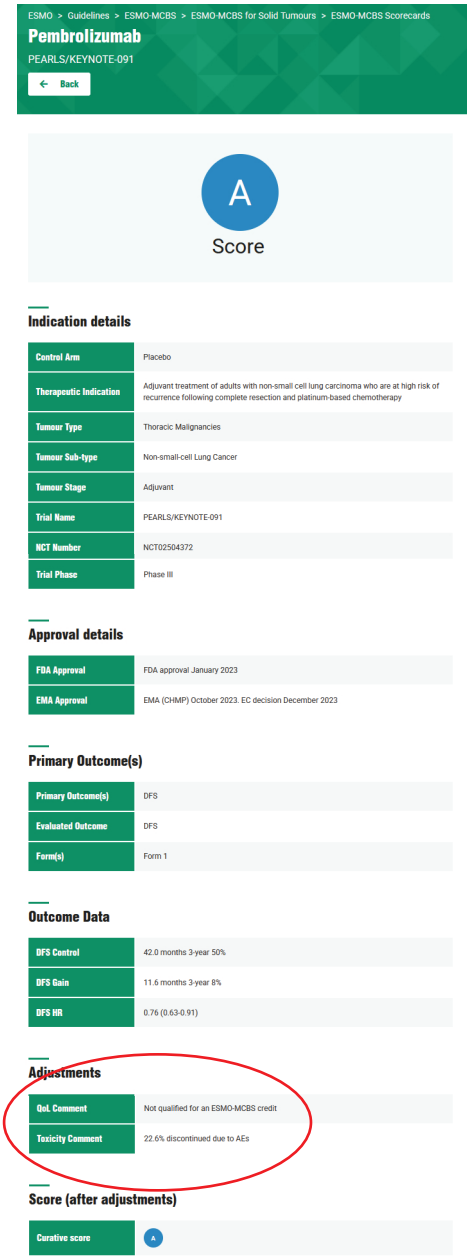


Fig. 1: ESMO-MCBS scorecard for pembrolizumab. Source: ESMO (4).

Literature:
1: https://www.g-ba.de/bewertungsverfahren/nutzenbewertung/1026/
2: https://www.monitor-versorgungsforschung.de/abstract/staerkerer-fokus-auf-die-methoden-der-studiendurchfuehrung/
3: https://www.g-ba.de/downloads/92-975-7660/2024-05-01_Nutzenbewertung-IQWIG_Pembrolizumab_D-1058.pdf
4: https://www.esmo.org/guidelines/esmo-mcbs/esmo-mcbs-for-solid-tumours/esmo-mcbs-scorecards/scorecard-373-1
5: https://www.g-ba.de/downloads/91-1031-1026/2024-09-09_Wortprotokoll_Pembrolizumab_D-1058.pdf