First feasibility study of the ESMO-MCBS scale in rare tumor entities

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The results of the first study analysing the application of the ESMO-Magnitude of Clinical Benefit Scale (ESMO-MCBS) in a real-life context for rare tumour entities, were announced today at the ESMO 2016 Congress in Copenhagen.

The ESMO-MCBS is a new tool to quantify the clinical benefit of a certain drug for the treatment of cancer and its application in daily clinical practice. It was first evaluated on common tumour entities by one of Europe's largest cancer centres, the Medical University of Vienna (MUV), which also conducted this new study.

Dr Barbara Kiesewetter at MUV states, "We assessed data on neuroendocrine tumors (NET), glioblastoma, sarcomas, thyroid, pancreatic, ovarian, head/neck and urothelial cancers. Data was analysed in a three-step approach: we collected data on regimens in daily use at the MUV, then analysed the data with the ESMO-MCBS as our second step and finally we evaluated and discussed the data in terms of clinical feasibility and practicability in daily practice." "We noted a phenomenon whereby the ESMO-MCBS particularly highlights the clinical benefit to be expected of new immunomodulatory drugs. This was also observed in our field testing on common tumour entities and may help us to implement these treatments in daily practice in the near future. We are particularly excited that new data on check point inhibitors for rare entities is due to be available soon. For example, in head and neck cancers, the CHECKMATE141 data currently scores for an ESMO-MCBS score of 3 (field testing) based on available results2 but might

improve to an even stronger recommendation with more mature survival data," she continued.

"The practicability of applying the ESMO-MCBS is somewhat limited for very rare tumours, for example sarcoma and glioblastoma, due to a lack of randomized data. However, the ESMO-MCBS was applicable in most situations where controlled trials were available such as the data on salvage treatment with pazopanib for soft tissue sarcoma achieving a score of 3 based on a significant progression free survival (PFS) gain of 3 months in comparison to 1.6 months in the placebo arm. "For sarcomas, practicability of ESMO-MCBS was limited due to a lack of trials in many indications. However, the ESMO-MCBS was useful whenever randomized data were available. For example, the ESMO-MCBS score of 4 clearly underlines the clinical benefit achieved by adding dacarbazine to gemcitabine in pre-treated soft tissue sarcoma. This is in line with our clinical experience and supports further use of the ESMO Magnitude of Clinical Benefit Scale," Kiesewetter explained.

The ESMO-MCBS has been designed to assess the therapeutic benefit of drugs registered for the treatment of cancer. It considers the predefined primary and secondary study endpoints: overall survival and progression-free survival in terms of absolute gain and lower end of the 95% confidence interval of the corresponding hazard ratio and quality of life or toxicity respectively. Data of the new treatment is then analysed with respect to the duration of response or survival in the control arm, which has to be entered in corresponding forms and results in a clinical benefit ranking.

"We found that the ESMO-MCBS is a helpful tool for clinical practice in rare tumours, as well as for common tumour entities, if randomized data is available. It supports treatment decisions based on the expected clinical benefit. It is very simple to use and we feel that it is going to prove to be a very important tool for daily clinical practice based on our

study results. Clinicians can go back to the data when considering new treatments and use the ESMO-MCBS online to analyse what can be expected from a new approach," concluded Dr Kiesewetter.

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