The ESMO Magnitude of Clinical Benefit Scale

Lugano, 30 May 2015 --- ESMO, the European Society for Medical Oncology, has announced today the publication of the ESMO Magnitude of Clinical Benefit Scale (ESMO-MCBS)(1), a tool to assist oncology clinicians in evaluating the most effective anti-cancer medicines for their patients.

“While it is known that the value of any new treatment is determined by the magnitude of its clinical benefit against its cost, to date there has not been a standard tool for grading such magnitude,” says Nathan Cherny, Director of the Cancer Pain and Palliative Medicine Service, Department of Medical Oncology, Shaare Zedek Medical Center, Israel, who formulated the idea some years ago.

The ESMO-MCBS offers a rational, structured and consistent approach to ‘stratify’ a drug’s clinically meaningful benefit.

A manuscript describing the project and reporting the main results from a field testing of the scale conducted on 77 cancer medicines across 10 cancer types was published today in Annals of Oncology(2).

The ESMO-MCBS project is being presented today at the American Society of Clinical Oncology (ASCO) annual meeting in Chicago in an ASCO/ESMO joint session on ‘Global Perspective on Value’(3), and will show how the Scale can provide useful information when used in conjunction with the preliminary results of the European snapshot perception survey on anti-cancer medicine availability conducted last year.

“As the international organisation committed to the interest of the oncology community at large, we are concerned about some anti-cancer medicines approved by the European Medicines Agency (EMA) not being available or affordable to patients when prescribed,” says Rolf A. Stahel, ESMO President. “With the ESMO-MCBS, we aim to signal the drugs with a large magnitude of clinical benefit which should be endorsed across Europe for rapid patient access, especially when these medicines are recommended through evidence-based standards set forth in the internationally recognised ESMO Clinical Practice Guidelines.”

ESMO intends to apply the scale prospectively to new anti-cancer drugs that will be approved by the EMA. Drugs obtaining the highest scores on the Scale will be highlighted in the ESMO Clinical Practice Guidelines, with the hope that they will be rapidly made available by health authorities across the European Union.

The ESMO-MCBS can be used in a range of settings, e.g. in public policy decision-making, to develop and/or improve clinical guidelines, in day-to-day clinical situations.

The ESMO-MCBS incorporates a structured, rational and valid approach to data interpretation and analysis that reduces the tendency to have judgments affected by bias, uninformed and/or idiosyncratic data interpretation.

“In the absence of a standardised approach for grading the magnitude of clinical benefit, conclusions and recommendations derived from studies are often hotly disputed and very modest incremental advances have often been presented, discussed and promoted as major advances or ‘breakthroughs’,” says Elisabeth G.E. de Vries, Department of Medical Oncology, University Medical Center Groningen, University of Groningen, The Netherlands, Co-Chair of the ESMO-MCBS Task Force.

“Application of the Scale will reduce the likelihood that statements of clinical benefit will be distorted by either overestimation or overstatement on one extreme or nihilism at the other,” de Vries continues.

In due consideration of the profound differences between the curative and palliative settings the tool is presented in two parts:
Figure: Visualisation of ESMO-MCB scores for curative and non-curative setting (Source: Annals of Oncology)

“As part of ESMO’s ongoing work to integrate all aspects of oncology, we believe that a scale highlighting the most clinically effective new medicines plus a snapshot perception survey on the availability and affordability of existing medicines will provide useful insights for the oncology community to help move cancer treatment forward,” says Alexandru Eniu, Head of Day Hospital Unit, Cancer Institute Ion Chiricuta, Cluj-Napoca, Romania, ESMO Board member and Chair of the ESMO Emerging Countries Committee, co-project leader of the ESMO European Consortium Study on the Availability of Anti-Neoplastic Medicines.

Richard Sullivan, Kings Health Partners Integrated Cancer Centre, King’s College London, Institute of Cancer Policy, London, UK, comments: “The ESMO-MCBS is an important first step to the critical public policy issue of value in cancer care, helping to frame the appropriate use of limited public and personal resources to deliver cost effective and affordable cancer care.”

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Notes to Editors

References

1. A standardised, generic, validated approach to stratify the magnitude of clinical benefit that can be anticipated from anti-cancer therapies: The European Society for Medical Oncology Magnitude of Clinical Benefit Scale (ESMO-MCBS)
3. ASCO/European Society for Medical Oncology (ESMO) Joint Session: Global Perspective on Value Sat, May 30, 3:00 PM - 4:15 PM (local time): S100a

- A first-generation draft scale was developed and adapted through a “snowball” method based upon previous work of the ESMO-MCBS Task Force members who had independently developed preliminary models of clinical benefit grading.
- The first version of the ESMO-MCBS has been developed for solid cancers. The Scale is a dynamic tool, its criteria will be revised on a regular basis.
- The ESMO-MCBS can only be applied to comparative research outcomes; it is therefore not applicable when evidence of benefit derives from single arm studies. This limits its utility in the
uncommon situation in which registration is granted on the basis of outcomes reported from single arm studies.

- ESMO-MCBS scores for a specific therapy cannot be generalised to indications outside the confines of the context in which they have been evaluated. Consequently the ESMO-MCBS score for a particular medication or therapeutic approach may vary depending on the specifics of the indication and may vary between studies.

Members of the ESMO-MCBS Task Force

Nathan I Cherny, MBBS, FRACP, FRCP
Cancer Pain and Palliative Medicine Service, Department of Medical Oncology, Shaare Zedek Medical Center, Jerusalem, Israel

Richard Sullivan, MD, PhD
Kings Health Partners Integrated Cancer Centre, King’s College London, Institute of Cancer Policy, London, United Kingdom

Urania Dafni, ScD
Laboratory of Biostatistics, Division of Public Health, Department of Nursing, University of Athens, Greece.

J.Martijn Kerst, MD, PhD
Department of Medical Oncology Antoni van Leeuwenhoek Hospital, Netherlands Cancer Institute, Amsterdam, The Netherlands

Alberto Sobrero, MD, Department of Medical Oncology, IRCCS San Martino IST, Genova, Italy

Christoph Zielinski, MD
Division of Oncology, Medical University Vienna, Vienna, Austria.

Elisabeth G.E. de Vries, MD, PhD
Department of Medical Oncology, University Medical Center Groningen, University of Groningen, Groningen, The Netherlands

Martine J. Piccart, MD, PhD
Université Libre de Bruxelles, Jules Bordet Institute, Brussels, Belgium