ESMO-MCBS

ESMO-Magnitude of Clinical Benefit Scale

EVALUATION FORM 1B - ESMO-MCBS v2.0

Single arm de-escalation studies in the adjuvant setting

Name of study:					
Study medicine:		**Indication:**			
First author:		**Year:**		**Journal:**	
Name of evaluator:					

GRADE A	Multicentre trial with observed DFS or mature OS are within 2% of the pre-specified target DFS or OS (at pre-specified relevant time point, derived from the standard of care)	☐
GRADE B	Single-centre trial with observed DFS or mature OS are within 2% of the pre-specified target DFS or OS (at pre-specified relevant time point, derived from the standard of care)	☐
GRADE C	Trial with observed DFS or mature OS within more than 2% but less than 5% of the pre-specified target DFS or OS (at pre-specified relevant time point, derived from the standard of care)	☐

Mark with √ if relevant

Preliminary magnitude of clinical benefit score	**A**	**B**	**C**
	☐	☐	☐

DFS, disease-free survival; ESMO-MCBS, European Society For Medical Oncology-Magnitude of Clinical Benefit Scale; OS, overall survival.

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TOXICITY ANNOTATION

Acute Transient Toxicity (AT)

Is the new treatment associated with:

Grade ≥3 adverse events impacting well-being in >30% of patients ☐

Premature discontinuation of therapy due to adverse events in >10% of patients ☐

Hospitalisation for adverse events in >10% of patients ☐

Mark with √ if relevant

Persistent Toxicity (PT)

Is the new treatment associated with:

Chronic neuropathy in >20% of the patients* ☐

Other grade ≥3 chronic toxicity adversely impacting well-being in >20% of patients ☐

*All adjuvant and curative therapies incorporating full dose taxanes and/or >3 months oxaliplatin will be annotated PT on the basis of accumulated evidence of persistent neuropathy.

Mark with √ if relevant

Magnitude of clinical benefit score with toxicity annotation	**A**	**B**	**C**
	☐	☐	☐
	(AT) ☐ (PT) ☐	(AT) ☐ (PT) ☐	(AT) ☐ (PT) ☐

Note: Highest magnitude clinical benefit grade that can be achieved in form 1b is grade A and the lowest is C.

Curative setting grading - A and B indicate a substantial magnitude of clinical benefit.

AT, acute toxicity; PT, persistent toxicity.