EVALUATION FORM 2A
For therapies that are not likely to be curative with primary endpoint of OS

If median OS with the standard treatment is ≥12 - <24 months

GRADE 4
HR ≤0.70 AND gain ≥5 months
Increase in 3-year survival alone ≥10% (if >20% patients have reached 3 years OS)

GRADE 3
HR ≤0.70 AND gain ≥3 - <5 months

GRADE 2
HR ≤0.70 AND gain ≥1.5 - <3 months
HR >0.70 - 0.75 AND gain ≥1.5 months

GRADE 1
HR >0.75 OR gain <1.5 months

Preliminary magnitude of clinical benefit grade (highest grade scored)

4 3 2 1

HR, hazard ratio; OS, overall survival
Quality of Life assessment

Does secondary endpoint quality of life show improvement or delayed deterioration in quality of life

Adjustments

01. Upgrade 1 level if improved quality of life and/or less grade 3-4 toxicities impacting daily well-being are shown

02. If there is a long-term plateau in the survival curve, and OS advantage continues to be observed at 5 years, also score according to form 1a (treatments with curative potential) and present both scores i.e. A/4

Final adjusted magnitude of clinical benefit grade

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<tr>
<th>Grade</th>
<th>5</th>
<th>4</th>
<th>3</th>
<th>2</th>
<th>1</th>
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Non-curative setting grading 5 and 4 indicates a substantial magnitude of clinical benefit

OS, overall survival.