Table 18. GRADE evidence profile, Recommendation 17

**Question:** Casirivimab/imdevimab compared to no casirivimab/imdevimab for ambulatory persons with mild to moderate COVID-19 at high risk of progression to severe disease

*Last updated 6/16/2021; last reviewed 9/19/2021*

<table>
<thead>
<tr>
<th>Certainty assessment</th>
<th>No of patients</th>
<th>Effect</th>
<th>Certainty</th>
<th>Importance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<tr>
<td><strong>All-cause mortality (1,200 mg) (follow up: 29 days)</strong></td>
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<tr>
<td>1 ¹ randomized trials</td>
<td>not serious a</td>
<td>not serious</td>
<td>very serious b,c</td>
<td>none</td>
</tr>
<tr>
<td><strong>COVID-19 related hospitalizations (1,200 mg) (follow up: 29 days)</strong></td>
<td></td>
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<td></td>
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<tr>
<td>1 ¹ randomized trials</td>
<td>not serious a</td>
<td>not serious</td>
<td>not serious e</td>
<td>serious b</td>
</tr>
<tr>
<td><strong>Serious adverse events (all doses) (follow up: 29 days)</strong></td>
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<td></td>
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<tr>
<td>1 ¹ randomized trials</td>
<td>not serious a</td>
<td>not serious</td>
<td>not serious</td>
<td>serious b</td>
</tr>
</tbody>
</table>

**GRADE Working Group grades of evidence**

- **High certainty:** We are very confident that the true effect lies close to that of the estimate of the effect.
- **Moderate certainty:** We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
- **Low certainty:** Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.
- **Very low certainty:** We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect.

**Risk of bias:** Study limitations
- **Inconsistency:** Unexplained heterogeneity across study findings
- **Indirectness:** Applicability or generalizability to the research question
- **Imprecision:** The confidence in the estimate of an effect to support a particular decision
- **Publication bias:** Selective publication of studies

**CI:** Confidence interval; **RR:** Risk ratio

**Explanations**

- a. Differential post randomization event exclusions (1040 participants) in the original phase (participants without risk factors) is unknown. Publication did not provide an intention to treat analysis. Not rated down for risk of bias as the data in this evidence profile is limited to the amended phase 1,200 mg dose only and not the entire data set (1,200 mg is the currently recommended dose). However, sensitivity analysis of the entire data set showed similar results: for hospitalizations 23/2091 vs 59/1341; RR 0.25 (95% CI 0.16, 0.4); deaths: 2/2091 vs 3/1341; RR 0.43 (95% CI 0.08, 2.3).
- b. Small number of events; fragility present.
c. 95% CI cannot exclude no difference or increased mortality.

d. As the RR 95% CI is wide due to sparse data, absolute risk difference recalculated independently and not based on RR.

e. COVID-19 related hospitalizations is a surrogate for ICU admission, mechanical ventilation and death. Not rated down.

f. Disclaimer: Provisional evidence rating based on preliminary evidence from non-peer reviewed publication.

Reference