Table 1. GRADE Evidence Profile: In adults hospitalized with critical COVID-19, should vilobelimab compared to no vilobelimab be added to standard care?

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	vilobelimab	no vilobelimab	Relative (95% CI)	Absolute (95% CI)		
Mortality (follow-up: 28 days)												
2 (Vlaar 2020, Vlaar 2022)	randomized trials	not serious	not serious	not serious[a]	very serious[b,c]	none	56/192 (29.2%)	81/206 (39.3%)	**HR 0.73** (0.50 to 1.05)	**88 fewer per 1,000** (from 172 fewer to 15 more)	⨁⨁◯◯ Low	CRITICAL
Serious adverse events (follow-up: 21 days)												
2 (Vlaar 2020, Vlaar 2022)	randomized trials	not serious	not serious	not serious[a]	very serious[d]	none	112/190 (58.9%)	127/204 (62.3%)	**RR 0.95** (0.81 to 1.11)	**31 fewer per 1,000** (from 118 fewer to 68 more)	⨁⨁◯◯ Low	CRITICAL

CI: confidence interval; **HR**: hazard ratio; **RR:** risk ratio

Explanations

a. Not rated down for indirectness; however, clinical trials excluded immunocompromised persons and limited administration of study drug to participants receiving invasive mechanical ventilation within 48 hours before vilobelimab infusion.

b. Few events do not meet optimal information size and suggest fragility of the estimate.

c. 95% CI includes potential for reduction in mortality, as well as no meaningful difference with 1% mortality threshold.

d. 95% CI crosses multiple thresholds and cannot exclude the possibility of harm.