Regdanvimab for patients with mild-to-moderate COVID-19: a retrospective cohort study and subgroup analysis of patients with the Delta variant

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Supplementary Materials

Table S1. Number of patients eligible or ineligible for inclusion and receiving regdanvimab or SoC before and after 5 February, 2021 (date of conditional approval of regdanvimab in Korea); with reasons for exclusion shown.

	Before regdanvimab conditional approval (Sep 2020 – 4 Feb 2021)	After regdanvimab conditional approval (5 Feb 2021 – Oct 2021)	Total
Hospitalized patients with confirmed COVID-19	180	620	800
Excluded from the study, n	0	78	78
Mild COVID-19 without high-risk factors for progression	0	7	7
Administered Regdanvimab >7 days after symptom onset (regdanvimab cohort only)	N/A	4	4
Severe COVID-19	0	67	67
Eligible for study	180	542	722
Hospitalized patients in the regdanvimab cohort, n	N/A	438	438
Excluded from the study, n	N/A	20	20
Mild COVID-19 without high-risk factors for progression	N/A	7	7
Administered Regdanvimab >7 days after symptom onset (regdanvimab cohort only)	N/A	4	4
Severe COVID-19	N/A	9	9
Eligible for inclusion (regdanvimab cohort)	N/A	418	418

Hospitalized patients in the SoC cohort, n	180	182	362
Excluded from the study, n	0	58	58
Mild COVID-19 without high-risk factors for progression	0	0	0
Severe COVID-19	0	58	58
Eligible for inclusion (SoC cohort)	180	124	304

Data are n, unless otherwise specified.

COVID-19; coronavirus disease 2019; N/A, not applicable SoC, standard of care

Table S2. Proportion of unvaccinated patients who deteriorated to SpO_2 <90% in room air, required supplemental oxygen therapy above high flow, or experienced mortality due to COVID-19 up to Day 28 (primary efficacy endpoint), by cohort and Delta variant status

	Regdanvimab	SoC	% difference (95% CI) [P-value][a,b]
Unvaccinated cohort	12/297 (4.0)	30/275 (10.9)	−6.9 (−11.6, −2.0) [0.0020]
Delta variant subgroup	7/177 (4.0)	8/86 (9.3)	−5.3 (−13.9, 0.9) [0.0929]

Data are n (%), unless otherwise specified.

[a]Farrington and Manning method used to calculate the 95% exact CI for the proportion difference between regdanvimab and SoC cohort in each group.

[b]P-values were derived from Fisher exact test.

CI, confidence interval; COVID-19; coronavirus disease 2019; SoC, standard of care; SpO_2, peripheral oxygen

Table S3. Logistic regression model for the proportion of patients who deteriorated to SpO_2 <90% in room air, required supplemental oxygen therapy above high flow, or experienced mortality due to COVID-19 up to Day 28 (primary efficacy endpoint) in the delta variant vs non delta variant subgroups

		Logistic regression model[b]
	Regdanvimab	**Odds ratio (95% CI)** **[P-value][c]**
Delta variant	8/297 (2.7)	0.5327 (0.0789, 3.5962) [0.5181]
Non-delta variant or wild type[a]	3/35 (8.6)	

Data are n (%), unless otherwise specified.

[a]Patients with unknown variant data (n=86) may have included delta variant or others, so were excluded from this analysis.

[b]Logistic regression model with treatment as a fixed effect and age, BMI, at least one high risk factor and at least one COVID-19 vaccine as covariates.

[c]P-value is calculated on treatment effect from the logistic model.

Table S4. Secondary efficacy endpoints in unvaccinated individuals according to treatment and Delta variant status

	Overall regdanvimab n=297	**Overall SoC n=275**	**P-value[a]**	**Delta variant subgroup regdanvimab n=117**	**Delta variant subgroup SoC n=86**	**P-value[a]**
Patients with SpO_2 deterioration to <94% in room air, n (%)	24 (8.1)	85 (30.9)	<0.0001	11 (6.2)	11 (12.8)	0.0708
Patients with SpO_2 deterioration to <90% in room air, n (%)	4 (1.3)	24 (8.7)	<0.0001	2 (1.1)	4 (4.7)	0.0915[b]
Patients requiring low-flow oxygen therapy, n (%)	70 (23.6)	126 (45.8)	<0.0001	44 (24.9)	28 (32.6)	0.1890
Patients requiring high-flow oxygen therapy, n (%)	9 (3.0)	13 (4.7)	0.2917	5 (2.8)	6 (7.0)	0.1850[b]
Patients requiring mechanical ventilation, n (%)	0	0	NA	0	0	NA
Duration of hospitalization due to COVID-19, mean (SD), days	10.30 (3.07)	12.01 (4.71)	<0.0001	9.77 (2.46)	8.49 (4.19)	0.0114

Patients discharged, n (%) Up to Day 14	273 (91.9)	206 (74.9)	<0.0001	168 (94.9)	74 (86.0)	0.0128
Patients receiving other therapies, n (%) Remdesivir	48 (16.2)	106 (38.5)	<0.0001	34 (19.2)	25 (29.1)	0.0721
Patients with all-cause mortality, n (%)	0	1 (0.4)	0.4808[b]	0	1 (1.2)	0.3270[b]

[a]P-value is derived from Student t-test for continuous variables and chi-squared test or Fisher exact test for categorical variables.

[b]P-value derived from Fisher exact test; chi-squared test may not be valid because 25% or 50% of the cells have expected counts <5.

COVID-19, coronavirus disease 2019; SD, standard deviation; SoC, standard of care; NA, not applicable; SpO_2, peripheral oxygen saturation.