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Veklury® (remdesivir) Use of COVID-19 Vaccines

This document is in response to your request for information regarding Veklury® (remdesivir [RDV]) and the use of COVID-19 vaccines. This response was developed according to principles of evidence-based medicine and contains data from prospective and retrospective studies (N≥200).

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The full indication, important safety information, and boxed warnings are available at: www.gilead.com/-/media/files/pdfs/medicines/covid-19/veklury/veklury_pi.

Summary

Product Labeling[1]

Subjects in RDV clinical trials NIAID ACTT-1, GS-US-540-5773 (SIMPLE severe), GS-US-540-5774 (SIMPLE moderate), GS-US-540-9012 (PINETREE), and GS-US-540--5823 (CARAVAN) were unvaccinated for COVID-19.

Study GS-US-540-5912 evaluated RDV 200 mg once daily for 1 day followed by RDV 100 mg once daily for 4 days (for a total of up to 5 days of IV administered therapy) in 243 hospitalized adult subjects with confirmed COVID-19 and renal impairment. Thirty-one subjects (13%) had received a COVID-19 vaccine.

Available Data on RDV and the Use of COVID-19 Vaccines

In a retrospective cohort study in Singapore that assessed RDV use and chronic complications, there was no significant difference in the risk of developing new, long-term diagnoses of cardiovascular, neurological, respiratory, and autoimmune sequelae across vaccination subgroups up to 300 days post COVID-19 hospitalization.[2]

In a case-control study using data from the Kaiser Permanente integrated healthcare system, the number of COVID vaccinations was inversely associated with the development of long COVID, and RDV treatment for acute COVID-19 was associated with decreased odds of developing long COVID.[3]

In a retrospective cohort study in Korea that evaluated early RDV treatment, having received >3 doses of COVID-19 vaccine was not significantly associated with all-cause mortality within 28 days of COVID-19 diagnosis, but it was significantly associated with reduced odds of requiring supplemental O_2 in univariable and multivariable analyses.[4]

Available Data on RDV and the Use of COVID-19 Vaccines

Retrospective Cohort Study in Singapore[2]

Study design and vaccination status

A retrospective cohort study was conducted using data from the national COVID-19 testing registry of Singapore to evaluate the impact of RDV on the risk of developing long-term diagnoses of cardiovascular, neurological, respiratory, and autoimmune sequelae or symptoms up to 300 days post COVID-19 hospitalization. Adult patients hospitalized with COVID-19 between September 2021 and July 2023 who did not die on admission, had complete sociodemographic data, had ≥1 indication for RDV, and were not reinfected within 300 days of hospitalization were included in the analysis (RDV, n=11,353; control, n=18,822). Covariates included COVID-19 vaccination status, which was stratified by unboosted (0–2 vaccine doses) and boosted (≥3 vaccine doses, with the third dose 6–9 months after the second dose) status. Vaccination statuses are presented below (Table 1).

Table 1. Baseline Vaccination Status in the RDV and Control Cohorts (Wee et al)[2]

Parameter, n (%)		RDV (n=11,353)	Control (n=18,822)	*P*-Value
Vaccination status	Unvaccinated/partially vaccinated	1875 (16.5)	1486 (7.9)	0.27
	Fully vaccinated	3056 (26.9)	5507 (29.3)	0.05
	Boosted	4963 (43.7)	9826 (52.2)	0.17
	Doubly boosted	1459 (12.9)	2003 (10.6)	0.07
Time since last vaccination dose, d	<120	3169 (27.9)	6048 (32.1)	0.09
	120–300	2879 (25.4)	5220 (27.7)	0.05
	181–240	1571 (13.8)	2683 (14.3)	0.01
	241–360	1586 (14)	2616 (13.9)	0
	>360	849 (7.5)	1334 (7.1)	0.02

Results

There was no significant difference in the risk of developing new, long-term diagnoses (ie, cardiovascular, neurological, respiratory, and autoimmune system involvement) between treatment groups and across vaccination subgroups up to 300 days post COVID-19 hospitalization (Table 2).

Table 2. Risk of New, Long-Term Diagnoses in RDV-Treated and Control Cohorts by Vaccination Status (Wee et al)[2]

Outcome, n/N (%)		RDV (n=11,353)	Control (n=18,822)	aHR (95% CI)
Any long-term diagnosis	Unboosted vaccine	276/2331 (11.84)	394/3537 (11.14)	0.93 (0.77–1.12)
	Boosted vaccine	502/2558 (19.62)	830/5399 (15.37)	1.17 (1.03–1.33)
Any major cardiovascular or cerebrovascular AE[a]	Unboosted vaccine	161/3980 (4.05)	202/5812 (3.48)	0.99 (0.77–1.27)
	Boosted vaccine	307/5140 (5.97)	418/9809 (4.26)	1.18 (1–1.39)

Abbreviations: AE=adverse event; aHR=adjusted hazard ratio.
[a]Defined as the first incidence of heart failure, myocardial infarction, stroke, sudden cardiac death, or ventricular arrhythmia.

Kaiser Permanente Case-Control Study in the US[3]

Study design and vaccination status

A case-control study was conducted using data from the Kaiser Permanente Southern California integrated healthcare system to assess the relationship between the number of COVID-19 vaccinations received prior to acute COVID-19 infection, as well as treatment for acute COVID-19, with the incidence of long COVID-19, defined as symptoms present ≥6 months post infection. Adults with a documented COVID-19 infection from October 2020 to November 2022 were included in the analysis, which assessed the effect of RDV treatment on long COVID outcomes; patients with a history of myalgic encephalomyelitis/chronic fatigue syndrome or fibromyalgia were excluded from the analysis. Patients with long COVID were less likely to have been treated with RDV (Table 3).

Table 3. Baseline Vaccination and RDV Treatment Status in Patients in the Long COVID and Control Groups (Liu et al)[3]

Parameter, n (%)		Control (n=13,160)	Long COVID (n=2632)	*P*-Value
Number of COVID-19 vaccination doses received	0	8961 (68.1)	1875 (71.2)	0.03
	1	2351 (17.9)	426 (16.2)	
	2	1524 (11.6)	278 (10.6)	
	3	305 (2.3)	51 (1.9)	
	4	19 (0.1)	2 (0.1)	
RDV treatment	No	12,845 (97.6)	2611 (99.2)	<0.01
	Yes	315 (2.4)	21 (0.8)	

Results

Compared with no COVID vaccination, the number of COVID vaccinations was inversely associated with long COVID. Treatment with RDV at the time of acute COVID-19 infection was associated with decreased odds of developing long COVID (Table 4).

Table 4. Association of the Number of Vaccination Doses and RDV Treatment With Long COVID (Liu et al)[3]

Variable		aOR (95% CI)
Number of COVID-19 vaccination doses received, n	0	1
	1	0.84 (0.73–0.97)
	2	0.79 (0.65–0.96)
	3	0.68 (0.46–1.01)
	4	0.31 (0.06–1.58)
RDV treatment[a]		0.31 (0.19–0.49)

Abbreviation: aOR=adjusted odds ratio.
[a]Compared with patients who did not receive RDV treatment.

Retrospective Cohort Study in Korea[4]

Study design and vaccination status

A retrospective cohort study investigated the effects of early RDV administration vs no RDV in patients hospitalized with the Omicron variant of COVID-19 in Korea (N=286) between February 2022 and February 2023. Adults who had symptom onset within 7 days of RDV

administration and had ≥1 risk factor for severe disease were included in the analysis; exclusion criteria included the need for supplemental O_2 or hospitalization in the intensive care unit at the time of diagnosis. Patients in the RDV group received 200 mg on Day 1 and 100 mg on Days 2 and 3. The primary and secondary outcomes were all-cause mortality and the need for supplemental O_2, respectively, within 28 days of COVID-19 diagnosis. Overall, 75.2% of patients (early RDV, n=57/85 [67.1%]; control, 155/197 [78.7%]; *P*=0.038) had received ≥3 COVID-19 vaccination doses.

Results

Between the RDV and control groups, there were no significant differences in all-cause mortality (3.4% and 6.1%, respectively; *P*=0.556) or the need for supplemental O_2 within 28 days (15.9% and 14.6%; *P*=0.783). By Cox regression analysis, having received >3 doses of COVID-19 vaccine was not significantly associated with all-cause mortality within 28 days of COVID-19 diagnosis (HR, 0.368; 95% CI: 0.133–1.014; *P*=0.053). However, having received >3 doses of COVID-19 vaccine was significantly associated with a reduced odds of requiring supplemental O_2 by univariable analysis (OR, 0.417; 95% CI: 0.21–0.829; *P*=0.013) and multivariable analysis (OR, 0.412; 95% CI: 0.202–0.839; *P*=0.015).

References

1. Veklury. Gilead Sciences Inc. Veklury® (remdesivir) for injection, for intravenous use. VEKLURY® (remdesivir) injection, for intravenous use. U.S. Prescribing Information. Foster City, CA.
2. Wee LE, Lim JT, Tay AT, et al. Remdesivir and risk of long-term multi-systemic sequelae following COVID-19 hospitalization. *Clin Microbiol Infect.* 2025;31(10):1704-1712.
3. Liu C, Liu C, Yan R, et al. Association of COVID vaccinations and treatments with long COVID beyond 6 months: a case-control study on the adult population in a large integrated healthcare system in the United States from 2020 to 2023. *Prev Med Rep.* 2025;57:103188.
4. La YJ, Oh WS, Kim C, Lim MN, Jeon YD. Clinical outcomes of early remdesivir administration in hospitalized patients at high risk for severe COVID-19 during the Omicron wave. *BMC Infect Dis.* 2025;25(1):167.

Abbreviations

ACTT=Adaptive COVID-19 Treatment Trial
CARAVAN=Clinical Administration of RDV After COVID-19 Diagnosis in Children
HR=hazard ratio
O_2=oxygen
OR=odds ratio
RDV=remdesivir

Product Label

For the full indication, important safety information, and boxed warning(s), please refer to the Veklury US Prescribing Information available at: www.gilead.com/-/media/files/pdfs/medicines/covid-19/veklury/veklury_pi.

Follow Up

For any additional questions, please contact Gilead Medical Information at:

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