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Veklury® (remdesivir) Real-World Mortality Data

This document is in response to your request for information regarding Veklury® (remdesivir [RDV]) and real-world mortality data. This response was developed according to principles of evidence-based medicine and only contains data from large, retrospective real-world studies (N≥50,000) that were published in peer-reviewed journals and included patients infected with COVID-19 from the Omicron-predominant variant of concern (VOC) period to present.

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Summary

Real-World Data on RDV Use and Mortality

A retrospective, comparative effectiveness cohort study analyzed data from the Premier Healthcare Database during the Omicron VOC (December 2021–December 2024) to assess all-cause in-hospital 14- and 28-day mortality rates in patients who received RDV treatment within 2 days of hospital admission vs patients who received no RDV treatment during hospitalization. Cohorts of patients aged ≥18 years, aged ≥65 years, with COVID-19 pneumonia, and with COPD were assessed. Patients were further categorized by whether they did or did not require supplemental O_2 support.[1]

- A total of 72,397 adult patients who received RDV within the first 2 days of hospitalization (aged ≥65 years, n=52,140; COVID-19 pneumonia, n=44,754; COPD, n=20,408) were 1:1 PS-matched to patients who did not receive RDV during hospitalization.
- The 14- and 28-day mortality rates, when adjusted for differences in baseline and clinical covariates, were significantly lower among patients who received RDV compared with those who did not receive RDV; these results were consistent across all cohorts and regardless of supplemental O_2 requirement (each, $P<0.05$).

A sequential target trial emulation using N3C data evaluated the association between RDV initiation and 60-day mortality in adults hospitalized with COVID-19 between May 2020 and July 2024. RDV initiation was categorized as early (Days 1–3 of hospitalization) or delayed (Days 4–7). Patients were stratified by disease severity based on oxygen support requirements: NSO, NISO, and IMV/ECMO. A total of 53,449 RDV initiators were 1:1 PS-matched to 53,449 non-initiators; 47,989 and 5460 PS-matched pairs were included in the early and delayed initiation cohorts, respectively.[2]

- In the overall pooled analysis, RDV initiation was associated with a statistically significant reduction in mortality relative to non-initiation in the NSO and NISO subgroups, but in not the IVM/ECMO subgroup.

- Early RDV initiation was associated with a statistically significant reduction in 60-day mortality in the NSO and NISO subgroups, but not in the IVM/ECMO subgroup. In contrast, delayed initiation was not associated with a statistically significant difference in mortality between initiators and non-initiators in any subgroup.

Real-World Data on RDV Use and Mortality

Premier Healthcare Database: PS-Matched Cohort Study

Study design and demographics[1]

A retrospective, comparative effectiveness cohort study analyzed data from the Premier Healthcare Database to assess all-cause in-hospital mortality in patients who received RDV treatment within 2 days of hospital admission vs patients who received no RDV treatment during hospitalization. Data from adult patients with a primary discharge diagnosis of COVID-19 that was also present on admission during the early Omicron period (December 2021–December 2022) or late Omicron period (January 2023–December 2024) were included in the analysis. Exclusion criteria included the following: pregnancy, incomplete data, death or discharge within 2 days of admission, transfer to or from another hospital, transfer from hospice, admission to the hospital for an elective procedure, use of ECMO at admission, or initiation of RDV >2 days after hospital admission. Patients in the RDV cohort received ≥1 dose of RDV during the first 2 days of admission, whereas those in the non-RDV cohort did not receive RDV during their hospitalization.

The primary outcome was 14- and 28-day all-cause inpatient mortality (defined as a discharge status of “expired” or “hospice”). Cohorts of patients aged ≥18 years, aged ≥65 years (overall, aged 65–75 years, 75–84 years, and ≥85 years), and with COVID-19 pneumonia were analyzed; patients were further categorized by requirement of NSO support and requirement of supplemental O_2 support.

Table 1. Premier Healthcare Database: Baseline Demographics and Disease Characteristics of PS-Matched Cohort[1]

Key Demographics and Characteristics		RDV (n=72,397)	No RDV (n=72,397)
Age, n (%)	18–49 years	5237 (7.2)	5237 (7.2)
	50–64 years	13,414 (18.5)	13,414 (18.5)
	≥65 years	53,746 (74.2)	53,746 (74.2)
Female, n (%)		37,347 (51.6)	37,419 (51.7)
Race, White/Black/Asian/other, %		76.9/14/2/7.1	76.7/14.2/2/7.1
Ethnicity, Hispanic/Non-Hispanic/unknown, %		8.1/85.1/6.9	8.3/84.9/6.8
Omicron period, %	Early	64.8	64.8
	Late	35.2	35.2
Baseline comorbidities, %	Cardiovascular disease	89	88.9
	Diabetes mellitus	39.9	39.8
	COPD	37.3	37.1
	Renal disease	31.7	32.1
	Obesity	27.8	27.7
	Immunocompromising condition	17.2	17.2
	Cancer	7.3	7.2

Key Demographics and Characteristics		RDV (n=72,397)	No RDV (n=72,397)
Other treatments at baseline, %	Corticosteroids	76.7	76.6
	Anticoagulants	75.9	75.8
	Baricitinib	5.4	5.5
	Tocilizumab	2.7	2.6
	Oral antivirals	0.4	0.4
Baseline O_2 requirements, n (%)	NSO	36,361 (50.2)	36,361 (50.2)
	Low-flow O_2	22,498 (31.1)	22,498 (31.1)
	High-flow O_2/non-invasive ventilation	11,717 (16.2)	11,717 (16.2)
	IMV/ECMO	1821 (2.5)	1821 (2.5)

Results

The unadjusted all-cause mortality rates at 14 and 28 days were numerically lower in the overall Omicron RDV group than in the no-RDV group (Table 2).[3]

Table 2. Premier Healthcare Database: Unadjusted 14- and 28-Day Mortality Rates by Cohort for the Entire Omicron Period, Overall and by O_2 Requirement[3]

Cohort	O_2 Requirement	14-Day Mortality, %		28-Day Mortality, %	
		RDV	No RDV	RDV	No RDV
Adults	**Overall**	**6.7**	**8.5**	**8.9**	**10.7**
	NSO	4.2	5.3	5.4	6.5
	Supplemental O_2	8.8	12.5	11.7	16
Age ≥65 years	**Overall**	**8.1**	**10.1**	**10.3**	**12.4**
	NSO	5.1	6.5	6.4	7.8
	Supplemental O_2	10.7	14.9	13.7	18.5
COVID-19 pneumonia	**Overall**	**8.3**	**11.6**	**11.2**	**15**
	NSO	5.4	7.5	7.1	9.5
	Supplemental O_2	10	14.6	13.6	19.1
COPD	**Overall**	**7.1**	**9.6**	**9.1**	**12**
	NSO	4.5	5.9	5.8	7.2
	Supplemental O_2	8.4	12	10.7	15.2

After adjusting for differences in baseline and clinical covariates, mortality risk was significantly lower at Day 14 and Day 28 in patients who received RDV than in those who did not, across all cohorts and regardless of supplemental O_2 use (Table 3). Mortality rate estimates were adjusted in a Cox proportional hazards model according to month of admission and time-varied treatments coadministered at baseline (eg, baricitinib, tocilizumab, and oral antivirals).[1]

Table 3. Premier Healthcare Database: Adjusted 14- and 28-Day Mortality by Cohort for the Entire Omicron Period[1]

Cohort	O_2 Status	14-Day Mortality, aHR (95% CI)[a]	28-Day Mortality, aHR (95% CI)[a]
Adults	**Overall**	**0.76 (0.73–0.79)**	**0.78 (0.75–0.81)**
	NSO	0.75 (0.7–0.81)	0.78 (0.73–0.83)
	Supplemental O_2	0.76 (0.72–0.8)	0.78 (0.75–0.82)
Age ≥65 years[b]	**Overall**	**0.74 (0.71–0.78)**	**0.77 (0.74–0.81)**
	NSO	0.79 (0.73–0.84)	0.8 (0.75–0.86)
	Supplemental O_2	0.72 (0.68–0.76)	0.76 (0.72–0.8)
COVID-19 pneumonia	**Overall**	**0.76 (0.73–0.8)**	**0.79 (0.76–0.83)**
	NSO	0.77 (0.71–0.83)	0.8 (0.74–0.86)
	Supplemental O_2	0.76 (0.72–0.8)	0.79 (0.75–0.83)

Cohort	O_2 Status	14-Day Mortality, aHR (95% CI)[a]	28-Day Mortality, aHR (95% CI)[a]
COPD	**Overall**	**0.75 (0.7–0.8)**	**0.76 (0.71–0.81)**
	NSO	0.77 (0.67–0.88)	0.81 (0.71–0.91)
	Supplemental O_2	0.74 (0.68–0.8)	0.74 (0.69–0.8)

[a]*P*<0.05 for comparisons of RDV treatment vs no RDV treatment at 14- and 28-days.
[b]Results by age subcategory (65–74 years, 75–84 years, and ≥85 years) were consistent with the results reported here for the overall group aged ≥65 years.
Note: Findings by early and late Omicron periods were consistent with the results for the entire Omicron period.

Sensitivity analyses performed using inverse probability of treatment weighting that compared RDV initiation within the first 2 days of hospital admission vs no RDV initiation in the first 2 days were consistent with the overall results.[1]

Additional safety outcomes were not reported.

Target Trial Emulation Using the N3C Database: PS-Matched Cohort Study of Early vs Delayed RDV Treatment[2]

Study design and demographics

A sequential target trial emulation using the N3C database evaluated whether the timing of RDV initiation impacted 60-day mortality in adults hospitalized with COVID-19 between May 2020 and July 2024. RDV initiation was categorized as follows: early, within Days 1 to 3 of hospitalization; delayed, Days 4 to 7 of hospitalization. Patients were stratified by disease severity according to O_2 support requirement: NSO, NISO, and IMV/ECMO. Exclusion criteria included death or discharge within 24 hours of baseline, prior RDV use, incomplete baseline or follow-up data, and undergoing renal replacement therapy. Patients were followed from baseline for up to 60 days or until the primary outcome of death, whichever occurred first.

A total of 53,449 RDV initiators were 1:1 PS-matched to 53,449 non-initiators; 47,989 and 5460 PS-matched pairs were included in the early and delayed initiation cohorts, respectively (Table 4). Baseline comorbidities (eg, cardiovascular-related conditions, diabetes, obesity, chronic lung disease, cancer, and COVID-19 pneumonia) and concomitant treatments (eg, corticosteroids, anticoagulants, immunosuppressants, and other antiviral agents) were well balanced between RDV initiators and non-initiators. The absolute standardized mean difference for baseline covariates was <0.1.

Table 4. N3C Database: Baseline Demographics and Disease Characteristics and O_2 Status by Early vs Delayed Initiation in PS-Matched Cohorts[2]

Key Demographics and Characteristics	RDV Initiators (n=53,449)	Non-Initiators (n=53,449)
Age at admission, mean ± SD, years	67.91±16.22	68.07±16.22
Female, n (%)	26,655 (49.87)	26,608 (49.78)
Race, White/Black/Asian/Native Hawaiian and Pacific Islander/American Indian and Alaska native, %	64.2/17.9/3.2/ 0.8/0.8	63.8/18.5/3/ 0.7/0.8
Ethnicity, Hispanic or Latino, %	9.6	9.7

Key Demographics and Characteristics		RDV Initiators (n=53,449)	Non-Initiators (n=53,449)
Baseline O_2 requirements, n	NSO	31,167	31,167
	Early/delayed RDV initiation	27,216/3951	N/A
	NISO	19,992	19,992
	Early/delayed RDV initiation	18,598/1394	N/A
	IMV/ECMO	2290	2290
	Early/delayed RDV initiation	2175/115	N/A

Results

In the overall pooled analysis, RDV initiation was associated with a statistically significant reduction in mortality relative to non-initiation in the NSO and NISO subgroups, but not in the IMV/ECMO subgroup (Table 5). Similarly, early RDV initiation was associated with a statistically significant reduction in 60-day mortality in the NSO and NISO subgroups, but not in the IMV/ECMO subgroup. In contrast, delayed initiation was not associated with a statistically significant difference in mortality between initiators and non-initiators in any subgroup.

Table 5. N3C Database: Adjusted 60-Day Mortality by Clinical Severity[2]

Cohort	Treatment Initiation	RDV Initiators Deaths, n/N (%)	Non-Initiators Deaths, n/N (%)	60-Day Mortality, HR (95% CI)
NSO	**Overall**	**3650/31,167 (11.7)**	**4005/31,167 (12.9)**	**0.9 (0.86–0.94)[a]**
	Early RDV initiation	3010/27,216 (11.1)	3345/27,216 (12.3)	0.89 (0.84–0.95)[a]
	Delayed RDV initiation	640/3951 (16.2)	660/3951 (16.7)	0.96 (0.85–1.08)
NISO	**Overall**	**3134/19,992 (15.7)**	**3330/19,992 (16.7)**	**0.93 (0.89–0.98)[a]**
	Early RDV initiation	2825/18,598 (15.2)	3061/18,598 (16.5)	0.91 (0.84–0.99)[a]
	Delayed RDV initiation	309/1394 (22.2)	269/1394 (19.3)	1.17 (0.98–1.4)
IMV/ ECMO	**Overall**	**1087/2290 (47.5)**	**1093/2290 (47.7)**	**0.96 (0.89–1.05)**
	Early RDV initiation	1029/2175 (47.3)	1039/2175 (47.8)	0.96 (0.85–1.09)
	Delayed RDV initiation	58/115 (50.4)	54/115 (47)	1.07 (0.72–1.57)

Abbreviation:HR=hazard ratio.
[a]Statistically significant for comparison between RDV initiators and non-initiators.
Note: Early=initiated RDV Days 1 to 3 of hospitalization; delayed=initiated RDV between Days 4–7; overall=all RDV initiated across Days 1–7.

Sensitivity analyses and an analysis of 30-day mortality were consistent with the main findings.

Additional safety outcomes were not reported.

References

1. Loubet P, Chandak A, Spivey S, et al. Real-world effectiveness of early remdesivir in reducing mortality among vulnerable patients hospitalized for COVID-19: Evidence for clinical pharmacists and inpatient care providers. *Am J Health Syst Pharm.* 2026;83(Supplement_3):S2915-S2930.
2. Makkar SR, Hansen K, Hotaling N, Toler A, Sidky H. Effect of Early and Delayed Treatment With Remdesivir on Mortality in Patients Hospitalized With COVID-19. *Open Forum Infect Dis.* 2025;12(2):ofae740.
3. Loubet P, Chandak A, Spivey S, et al. Real-world effectiveness of early remdesivir in reducing mortality among vulnerable patients hospitalized for COVID-19: Evidence for clinical pharmacists and inpatient care providers [Supplement]. *Am J Health Syst Pharm.* 2026;83(Supplement_3):1-72.

Abbreviations

aHR=adjusted hazard ratio
COPD=chronic obstructive pulmonary disease
ECMO=extracorporeal membrane oxygenation
IMV=invasive mechanical ventilation
N3C=National COVID Cohort Collaborative
NSO=no supplemental oxygen
NISO=noninvasive supplemental oxygenation
O_2=oxygen
PS=propensity score
RDV=remdesivir
VOC=variant of concern

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

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