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Veklury® (remdesivir) Use in Immunocompromised Patients

This document is in response to your request for information regarding the use of Veklury® (remdesivir [RDV]) in immunocompromised patients. This response was developed according to principles of evidence-based medicine and contains information from phase 3 clinical studies (N≥500), and real-world, retrospective studies (N≥8000).

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Summary

Clinical Data: RDV Use in Immunocompromised Patients

Currently, there are no clinical trial data available on the use of RDV in immunocompromised patients. Although some clinical trials, such as ACTT-1 and PINETREE, included some immunocompromised participants, efficacy and safety results were not reported for these participants.[1,2]

Retrospective Data: RDV Use in Immunocompromised Patients

In a retrospective observational cohort study of immunocompromised patients hospitalized with COVID-19, treatment with RDV (n=39,315) was associated with lower 14- and 28-day in-hospital mortality compared with no treatment with RDV (n=53,471), with consistent benefits across subgroups stratified by age, variant era, and severity of immunosuppression.[3]

In a retrospective, PS-matched analysis of the Premier Healthcare Database, immunocompromised patients hospitalized with COVID-19 (n=11,404) between December 2021–December 2024 who received RDV had lower unadjusted and adjusted all-cause mortality rates at Days 14 and 28 than those who did not receive RDV, regardless of supplemental O_2 requirements or underlying immunocompromising condition.[4] In an earlier subgroup analysis of immunocompromised patients hospitalized with COVID-19 between December 2021–February 2024, patients treated with RDV (n=18,542) had a lower risk of COVID-19-related readmission within 30 days of index hospitalization than patients who did not receive RDV (n=14,775; OR, 0.86; 95% CI: 0.8–0.92; *P*<0.0001).[5]

Clinical Data: RDV Use in Immunocompromised Patients

National Institute of Allergy and Infectious Diseases Sponsored Study: ACTT-1

A phase 3, randomized, adaptive, double-blind, placebo-controlled, multicenter study evaluated the safety and efficacy of RDV (n=541) compared with placebo (n=521) in hospitalized adult participants diagnosed with COVID-19 with evidence of lower respiratory tract infection.[6] Immune system disorder (definition not provided) was noted as a comorbidity in 32 (6%) and 41 (8%) participants in the RDV and placebo groups, respectively. Efficacy and safety results were not provided for this subset of participants.[1]

RDV IV Outpatient Study: PINETREE

A phase 3, randomized, double-blind, placebo-controlled, multicenter study evaluated the safety and efficacy of a 3-day course of RDV (n=279) or placebo (n=283) administered IV in an outpatient setting in nonhospitalized participants with baseline characteristics that increased their risk for COVID-19 disease progression. Risk factors for progression included immunocompromised status, defined as having undergone an SOT, a blood transplant, or a bone marrow transplant; immune deficiencies; HIV with a low CD4 cell count or not currently receiving HIV treatment; long-term use of corticosteroids; or use of immune-weakening medications.[2,7]

Overall, 14 participants (5%) in the RDV group and 9 participants (3.2%) in the placebo group were immunocompromised; 12 (4.3%) and 18 (6.4%) participants in the RDV and placebo groups, respectively, had cancer.[2] Efficacy and safety results were not provided for these participants.

Retrospective Data: RDV Use in Immunocompromised Patients

Retrospective, Observational Cohort Study Using HealthVerity Data[3]

Study design and demographics

A retrospective, observational cohort study evaluated in-hospital mortality at Days 14 and 28 in immunocompromised patients hospitalized with COVID-19 between May 2020 and December 2023. Immunocompromised states included HIV/AIDS, hematologic and solid malignancies, organ transplant, and rheumatologic or inflammatory conditions. Outcomes in patients who initiated RDV within 2 days of admission (n=39,315) were compared with those who did not receive RDV during the 28-Day follow-up period (n=53,471).

Analyses were conducted in subgroups stratified by age (12–64 years: early RDV, n=13,227 compared with no RDV, n=17,266; age ≥65 years: early RDV, n=26,088 compared with no RDV, n=36,205), variant era (Pre-Delta: early RDV, n=16,246 compared with no RDV, n=24,288; Delta: early RDV, n=7,701 compared with no RDV, n=6,573; Omicron: early RDV,

n=15,368 compared with no RDV, n=22,610), and severity of immunosuppression (mild or moderate/severe). Select baseline demographics and characteristics in patients stratified by severity of immunosuppression are included in Table 1 below.

Table 1. Baseline Demographics and Disease Characteristics by Severity of Immunosuppression (Berry et al)[3]

Key Demographics and Characteristics		Severity of Immunosuppression			
		Mild		Moderate/Severe	
		Early RDV (n=32,344)	No RDV (n=44,650)	Early RDV (n=6971)	No RDV (n=8821)
Age, median (Q1, Q3), years		71 (61, 80)	73 (62, 82)	67 (58, 76)	68 (57, 77)
Female, n (%)		16,205 (50)	23,135 (52)	3549 (51)	4602 (52)
Immunosupressive condition, n (%)	Solid malignancy	20,000 (62)	26,736 (60)	4506 (65)	5525 (63)
	Rheumatologic or inflammatory condition	14,134 (44)	20,742 (46)	2570 (37)	3628 (41)
	Other	2564 (8)	4124 (9)	1366 (20)	1863 (21)
	Organ transplant	1122 (3)	1623 (4)	1091 (16)	1296 (15)
	Hematologic malignancy	1122 (3)	1406 (3)	991 (14)	1100 (12)
	HIV/AIDS	246 (1)	339 (1)	364 (5)	513 (6)
Comorbidities, n (%)	CVD	24,694 (76)	35,752 (80)	5732 (82)	7453 (84)
	Chronic lung disease	14,324 (44)	109,807 (44)	4273 (61)	5192 (59)
	Diabetes type 1/2	13,189 (41)	19,924 (45)	3043 (44)	4015 (46)
	Cancer[a]	10,121 (31)	14,110 (32)	3367 (48)	4091 (46)
	CKD	7486 (23)	14,054 (31)	2109 (30)	3336 (38)
	Obesity	10,515 (33)	13,541 (30)	2561 (37)	3277 (37)
Baseline medication, n (%)	Glucocorticoid	20,462 (63)	15,082 (34)	3857 (55)	2986 (34)
	Oral antiviral	1 (<1)	29 (<1)	1 (<1)	4 (<1)
Supplemental O_2 support, n (%)	NSO	22,812 (71)	34,210 (77)	4591 (66)	6307 (71)
	Low-flow O_2	5040 (16)	5201 (12)	1283 (18)	1306 (15)
	High-flow O_2	3195 (10)	3638 (8)	778 (11)	800 (9)
	IMV/ECMO	1297 (4)	1601 (4)	319 (5)	408 (5)

Abbreviations: CKD=chronic kidney disease.
[a]Excluding nonmelanoma skin cancer.

Results

In the overall population and across subgroups stratified by age, variant era, and severity of immunosuppression, participants who received early treatment with RDV had reduced cumulative incidences of in-hospital mortality at Day 14 and Day 18 compared with participants who did not receive treatment with RDV (Table 2).

Table 2. Cumulative Incidence of In-Hospital Mortality Overall and by Subgroup (Berry et al)[3]

Subgroup		In-Hospital Mortality, %			
		Day 14		Day 28	
		Early RDV	No RDV	Early RDV	No RDV
Overall		9.22	11.84	13.66	16.56
Age, years	12–64	3.89	5.58	7.13	9.41
	≥65	11.78	14.96	16.79	20.11

Subgroup		In-Hospital Mortality, %			
		Day 14		Day 28	
		Early RDV	No RDV	Early RDV	No RDV
Variant era	Pre-Delta	10.07	13.5	15.23	18.98
	Delta	11.13	13.7	17.87	20.01
	Omicron	7.62	9.38	10.37	12.68
Severity of immunosuppression	Mild	9.06	11.6	13.44	16.21
	Moderate/severe	9.96	13.13	14.6	18.52

In the overall immunocompromised population, early treatment with RDV was associated with lower RR of death and absolute reductions in mortality at Day 14 and Day 28 versus no RDV; results were consistent across subgroups stratified by age, variant era, and severity of immunosuppression (Table 3).

Table 3. RRs and Risk Differences of In-Hospital Mortality Overall and by Subgroup (Berry et al)[3]

Subgroup		Day 14, (95% CI)		Day 28, (95% CI)	
		RR	Risk Difference	RR	Risk Difference
Overall		0.78 (0.75–0.81)	-2.61 (-3.06 to -2.17)	0.82 (0.8–0.85)	-2.9 (-3.39 to -2.41)
Age, years	12–64	0.7 (0.63–0.77)	-1.69 (-2.18 to -1.19)	0.76 (0.7–0.82)	-2.28 (-2.9 to -1.66)
	≥65	0.79 (0.75–0.83)	-3.18 (-3.81 to -2.56)	0.83 (0.8–0.87)	-3.32 (-3.99 to -2.65)
Variant era	Pre-Delta	0.75 (0.71–0.79)	-3.44 (-4.06 to -2.81)	0.8 (0.77–0.84)	-3.75 (-4.51 to -2.99)
	Delta	0.81 (0.74–0.89)	-2.57 (-3.72 to -1.42)	0.89 (0.83–0.96)	-2.14 (-3.46 to -0.83)
	Omicron	0.81 (0.76–0.87)	-1.76 (-2.33 to -1.19)	0.82 (0.77–0.87)	-2.31 (-2.95 to -1.66)
Severity of immunosuppression	Mild	0.78 (0.75–0.82)	-2.54 (-3.01 to -2.08)	0.83 (0.8–0.86)	-2.77 (-3.3 to -2.23)
	Moderate/severe	0.76 (0.69–0.83)	-3.18 (-4.24 to -2.11)	0.79 (0.74–0.84)	-3.93 (-5.07 to -2.78)

Note: An RR <1 and a risk difference <0 favored early RDV treatment.

Additional safety outcomes were not reported.

Premier Healthcare Database: PS-Matched Cohort Study

Study design and demographics

A retrospective, comparative effectiveness cohort study analyzed data from the Premier Healthcare Database to evaluate all-cause in-hospital mortality in immunocompromised patients who received RDV treatment within 2 days of hospital admission compared with patients who received no RDV treatment during hospitalization. Data from adult patients with a primary discharge diagnosis of COVID-19 between December 2021 and December 2024 and who had underlying immunocompromising conditions (including solid tumors, hematologic malignancies, transplants, primary immunodeficiencies, HIV, immunosuppressive drug use, bone marrow failure syndromes, and related disorders) were included in the analysis.[4]

The primary outcome was 14- and 28-Day all-cause inpatient mortality, and patients were followed from hospital Day 3. Predefined subgroup analyses were conducted in patients with cancer (including hematologic malignancies), hematologic malignancies alone, and solid organ or stem cell transplantation. Exploratory analyses were also conducted in patients with lymphoma, multiple myeloma, and SOT or HSCT. Patients were further stratified by requirement or non-requirement of supplemental O_2 support.[4]

The duration of RDV use and the number of RDV doses received was not reported. Overall, 11,404 patients who received RDV within the first 2 days of hospitalization were PS-matched 1:1 with 11,404 patients who did not receive RDV during hospitalization (Table 4). The absolute standardized difference for baseline covariates between the RDV and no-RDV groups was <0.15.[4]

Table 4. Baseline Demographics and Disease Characteristics (Kalil et al)[8]

Key Demographics and Characteristics		RDV (n=11,404)	No RDV (n=11,404)
Age, n (%)	18–49 years	538 (4.7)	538 (4.7)
	50–64 years	2043 (17.9)	2043 (17.9)
	≥65 years	8823 (77.4)	8823 (77.4)
Omicron period, n (%)	Early (December 2021–December 2022)	7259 (63.7)	7259 (63.7)
	Late (January 2023–December 2024)	4145 (36.3)	4145 (36.3)
Comorbidities, n (%)	CVD	10,323 (90.5)	10,286 (90.2)
	Cancer	4841 (42.5)	4873 (42.7)
	Chronic pulmonary disease	4599 (40.3)	4576 (40.1)
	Diabetes mellitus	4369 (38.3)	4353 (38.2)
	Renal disease	4227 (37.1)	4246 (37.2)
	Obesity	2780 (24.4)	2819 (24.7)
Immunocompromising condition, n (%)	Moderate/severe primary immunodeficiencies	3144 (27.6)	3113 (27.3)
	Hematologic malignancies	1832 (16.1)	1776 (15.6)
	Bone marrow failure/aplastic anemia	1675 (14.7)	1646 (14.4)
	SOT and HSCT recipients	827 (7.3)	833 (7.3)
	Leukemia	724 (6.3)	667 (5.8)
	Lymphoma	619 (5.4)	608 (5.3)
	Toxic effects of antineoplastics	574 (5)	583 (5.1)
	Multiple myeloma	386 (3.4)	384 (3.4)
	Asplenia	223 (2)	235 (2.1)
	HIV	156 (1.4)	180 (1.6)
Immunosuppressive medications, n (%)		3962 (34.7)	3957 (34.7)
Other treatments at baseline, n (%)	Corticosteroids	8995 (78.9)	8967 (78.6)
	Anticoagulants	8195 (71.9)	8207 (72)
	Baricitinib	425 (3.7)	416 (3.6)
	Tocilizumab	267 (2.3)	250 (2.2)
	Oral antivirals	38 (0.3)	37 (0.3)
	Convalescent plasma	6 (0.1)	5 (0)
Supplemental O_2 requirement, n (%)	NSO	6212 (54.5)	6216 (54.5)
	Low-flow O_2	3357 (29.4)	3357 (29.4)
	High-flow O_2/non-invasive ventilation	1656 (14.5)	1656 (14.5)
	IMV/ECMO	179 (1.6)	179 (1.6

Results

The unadjusted all-cause mortality rates in the PS-matched cohort at 14 and 28 days were numerically lower in the overall Omicron RDV group than in the no RDV group (Table 5). In addition, lower unadjusted mortality rates were observed with RDV regardless of supplemental O_2 requirement compared with the no RDV cohort.[4]

Table 5. Unadjusted 14- and 28-Day Mortality by Cohort Overall and by Baseline Supplemental O_2 Need (Kalil et al)[8]

O_2 Status	14-Day Mortality		28-Day Mortality	
	RDV	No RDV	RDV	No RDV
Overall, n (%)	**1030 (9)**	**1330 (11.7)**	**1406 (12.3)**	**1706 (15)**
No supplemental O_2, n/N (%)	361/6212 (5.8)	457/6212 (7.4)	480/6212 (7.7)	570/6212 (9.2)
Any supplemental O_2, n/N (%)	669/5192 (12.9)	873/5192 (16.8)	926/5192 (17.8)	1136/5192 (21.9)

After adjusting for differences in baseline and clinical covariates, mortality risk was significantly lower at Days 14 and 28 in patients who received RDV than in those who did not, regardless of supplemental O_2 use (Table 6).[4]

Table 6. Adjusted 14- and 28-Day Mortality Overall and by Supplemental O_2 Need (Kalil et al)[4]

O_2 Status	aHR[a] (95% CI); *P*-Value	
	14-Day Mortality	28-Day Mortality
Overall	**0.75 (0.69–0.82); <0.0001**	**0.8 (0.74–0.86); <0.0001**
No supplemental O_2	0.77 (0.66–0.89); 0.0004	0.81 (0.71–0.92); 0.0017
Any supplemental O_2	0.75 (0.68–0.82); <0.0001	0.79 (0.73–0.86); <0.0001

[a]aHR values <1 favor RDV treatment, whereas values >1 favor no RDV treatment.
Note: Findings by early and late Omicron periods were consistent with the results for the entire Omicron period.

RDV was associated with significantly lower mortality at Days 14 and 28 across several prespecified immunocompromising conditions (Table 7**Error! Reference source not found.**).[4]

Table 7. Adjusted 14- and 28-Day Mortality in Select Underlying Immunocompromising Conditions (Kalil et al)[4]

Immunocompromising Condition	aHR[a] (95% CI); *P*-Value	
	14-Day Mortality	28-Day Mortality
Cancer	0.74 (0.68–0.81); <0.0001	0.76 (0.71–0.83); <0.0001
Hematologic malignancy	0.67 (0.57–0.79); <0.0001	0.69 (0.6–0.8); <0.0001
Leukemia	0.61 (0.48–0.78); <0.0001	0.67 (0.54–0.83); 0.0003
Lymphoma	0.88 (0.67–1.16); 0.3794	0.84 (0.67–1.05); 0.1303
Multiple myeloma	0.46 (0.31–0.69); 0.0002	0.47 (0.33–0.67); <0.001
SOT and HSCT recipients	0.66 (0.47–0.92); 0.0156	0.66 (0.51–0.86); 0.0023

[a]aHR values <1 favor RDV treatment, whereas values >1 favor no RDV treatment.

Additional safety outcomes were not reported.

Immunocompromised patient subgroup analysis: COVID-19–related readmission

An earlier analysis of data from the Premier Healthcare Database evaluated the association between RDV treatment and COVID-19–related readmission within 30 days of index

hospitalization among patients admitted for COVID-19 between December 2021 and February 2024. One of the subgroup analyses included patients with immunocompromised conditions, and they were further categorized according to the need for supplemental O_2.[5] Among those in the immunocompromised subgroup (RDV, n=18,542; no RDV, n=14,775), after inverse probability of treatment weighting, 70% were ≥65 years of age, ~79% received corticosteroids, ~50% did not require supplemental O_2 during their initial admission, and ~40% had cancer.[5,9]

At readmission, the mean ± SD length of stay was 8.9±13.2 days and the all-cause in-hospital mortality rate was 26%; 55% received corticosteroid monotherapy, 12% received RDV + corticosteroids, 5% received RDV + corticosteroids + baricitinib/tocilizumab, 3% received RDV + corticosteroids/baricitinib/tocilizumab, and 1% received RDV monotherapy. There was a 14% lower risk of COVID-19–related readmission with RDV than without RDV (5.3% compared with 6.2%; OR, 0.86; 95% CI: 0.8–0.92; *P*<0.0001). Regardless of the need for supplemental O_2, similar outcomes were noted for RDV compared with no RDV: no supplemental O_2, 4.9% compared with 5.9% (OR, 0.82; 95% CI: 0.75–0.91); supplemental O_2, 5.8% compared with 6.5% (OR, 0.89; 95% CI: 0.81–0.97).[5]

References

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Abbreviations

ACTT-1=Adaptive COVID-19 Treatment Trial-1
aHR=adjusted hazard ratio
CD4=cluster of differentiation 4
CVD=cardiovascular disease
ECMO=extracorporeal membrane oxygenation
HSCT=hematopoietic stem cell transplantation
IMV=invasive mechanical ventilation
NSO=no supplemental oxygen
O_2=oxygen
OR=odds ratio
PS=propensity score
RDV=remdesivir
RR=relative risk
SOT=solid organ transplantation

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.

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