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Veklury® (remdesivir) Use in Treatment-Experienced Patients

This document is in response to your request for information regarding the use of Veklury® (remdesivir [RDV]) for the treatment of COVID-19 in patients who were previously treated with other therapies for COVID-19.

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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

Available Data on the Use of RDV in Treatment-Experienced Patients

In a retrospective cohort study that analyzed the frequency of retreatment and/or prolonged treatment with RDV after an initial course of RDV, of the 1067 patients who met inclusion criteria, 27 patients (2.5%) received retreatment and/or prolonged treatment. Eight of the 27 patients had received other treatments for COVID-19 prior to courses of RDV; their clinical courses are summarized in Table 2.[1]

Available Data on the Use of RDV in Treatment-Experienced Patients

Retrospective, Real-World Cohort Study in Japan

Study design and demographics[1]

A nationwide claims-based cohort study in Japan retrospectively analyzed data from hospitalized patients with COVID-19 to determine the frequency of retreatment and prolonged treatment after an initial course of RDV. Eligible patients within the database were ≥18 years of age (the database primarily included patients aged <75 years), had been diagnosed with COVID-19 between July 1, 2022, and June 2, 2023 (dominant variant: Omicron BA.5), and had received ≥1 course of RDV for ≥5 days. The primary outcome was the rate of retreatment (defined as a second course of antiviral treatment that was initiated within 90 days after completion of the first RDV course) and/or prolonged antiviral treatment (defined as >10 days of RDV). RDV treatment courses that were completed within 10 days were counted as a single course. Study investigators analyzed the use of immunosuppressive drugs prior to RDV, which included the following: corticosteroids (equivalent to 20 mg/day of prednisolone for >21 days). CNI, MMF, TNF inhibitors, and antimetabolites within the previous 90 days; and anti-CD20 and anti-CD19 Abs; bendamustine; and CAR-T therapy within the past year.

Overall, 1067 patients met inclusion criteria; overall, 65% of patients were male, 39% received steroid therapy for COVID-19, 4.1% received baricitinib, and 1.8% received tocilizumab, 39% required supplemental O_2 therapy within the first 10 days of COVID-19 infection, and 3.6% required admission to the ICU. Rates of underlying conditions were generally similar between cohorts, which included the 27 who received retreatment and/or prolonged treatment and the 1040 who did not (Table 1).

Table 1. Baseline Demographics and Disease Characteristics (Yamamoto et al)[1]

Key Demographics and Characteristics		Retreatment and/or Prolonged Treatment (n=27)	No Retreatment or Prolonged Treatment (n=1040)	RR (95% CI); *P*-Value
Age	Median (IQR), years	57 (50–64)	55 (45–62)	–
	≥65 years, n	6	197	1.2 (0.5–3); 0.62
Male, n		21	671	1.9 (0.8–4.7); 0.22
Characteristics during initial COVID-19 infection, n	Steroid for COVID-19	15	399	2 (0.9–4.2); 0.08
	Tocilizumab	1	18	2.1 (0.3–14.8); 0.39
	Baricitinib	0	44	0; 0.62
	ICU admission	1	37	1.4 (0.1–7.5); 1
O_2 supplementation during initial COVID-19 infection, n	Within first 10 days of infection	8	407	0.7 (0.3–1.5); 0.42
	Face mask or NC only	6	334	0.6 (0.2–1.5); 0.4
	High-flow NC	2	31	2.5 (0.6–10.1); 0.2
	NIPPV	0	2	0; 1
	Mechanical ventilation	1	47	0.8 (0.1–5.9); 1
Recent concomitant immunosuppressant medications, n	Anti-CD20 Ab[a]	12	22	24.3 (12.3–47.9); <0.0001
	Corticosteroids[b,c]	6	22	10.6 (4.6–24.2); <0.0001
	Bendamustine[a]	3	11	9.4 (3.2–27.6); 0.004
	CNI[b]	3	66	1.8 (0.6–5.9); 0.25
	MMF[b]	2	36	2.2 (0.5–8.8); 0.25
	Chemotherapy for solid organ tumors	1	24	1.6 (0.2–11.4); 0.48
	Antimetabolite[b]	1	14	2.6 (0.4–18.6); 0.32
	TNF inhibitor[b]	0	6	0; 1
	Anti-CD19 mAb[a]	0	1	0; 1
	CAR-T[a]	0	1	0; 1
Immunocompromised conditions, n	Hypoglobulinemia	5	10	15.9 (7–36.4); <0.0001
	SOT recipient	2	31	2.5 (0.6–10.1); 0.2
	Allo-HSCT recipient	2	20	3.8 (1–15.1); 0.1
	AIDS	1	0	41 (28.1–59.9); 0.03

Abbreviations: Allo=allogeneic; NC=nasal cannula; NIPPV=non-invasive positive pressure ventilation; RR=risk ratio; SOT=solid organ transplant.
[a]Within the previous year.
[b]Within the previous 90 days.
[c]Equivalent to 20 mg/day of prednisolone for >21 days.

Results

Of the 27 patients (2.5%) who met the primary endpoint, 25 received retreatment (median [range]: 1 [1–6] courses), 4 received prolonged treatment, including 2 who received both retreatment and prolonged treatment. The median (IQR) duration of time from initial RDV treatment to retreatment was 21 (15–39) days, and 74.1% (20/27) received retreatment with RDV within 30 days of initiation of the initial course. The clinical courses of the 8 patients who received retreatment and/or prolonged treatment with RDV after other COVID-19 treatments are summarized in Table 2. Of these patients, 4 had previously received anti-CD20 Abs and required supplemental O_2 therapy during retreatment or prolonged treatment.[1]

Table 2. Clinical Courses of Patients Who Received RDV Treatment After Other Antivirals in the Retreatment or Prolonged Treatment Cohort (Yamamoto et al)[2,3]

Pt	Age; Sex; Underlying Conditions Associated With Immunosuppression; O_2 Required[a]	Treatment Order	Day[b]	Radiologic Signs of Pneumonia; Symptoms	COVID-19 Severity	Antiviral Therapy Modality	Treatment Regimen and Duration	Treatment Outcome
1	53 y; female; AIHA, ITP, AHA, HGG, CS, IS; O_2 required	1	0	Newly developed; fever, cough, dyspnea	Severe	Neutralizing mAb	Sotrovimab × 1 dose	Failure
		2	10	Persistent; worsening fever, dyspnea	Severe	MonoTx	RDV × 5 d	Failure
		3	32	Recurrent; persistent cough, dyspnea	Severe	MonoTx	RDV × 10 d	Failure
		4	72	Recurrent; persistent cough, dyspnea	Moderate	MonoTx	NMV/r × 5 d	Failure
		5	93	Persistent; persistent dyspnea	Moderate	MonoTx	MOL × 5 d	Failure
		6	107	Persistent; persistent dyspnea	Moderate	Sequential	MOL × 5 d; RDV × 10 d; MOL × 5 d; NMV/r × 5 d	Success
4	32 y; male; AML, HGG, HSCT, GVHD, CS, IS; O_2 required	1	0	None; fever	Mild	MonoTx	MOL × 5 d	Failure
		2	9	Newly developed[c]; recurrent fever, cough, rhinorrhea	Severe	MonoTx	RDV × 5 d	Success
5	65 y; male; ML, RTX	1	0	Newly developed; fever, cough	Moderate	MonoTx	RDV × 5 d	Failure
		2	25	Recurrent; recurrent fever, cough	Moderate	MonoTx	MOL × 5 d	Failure
		3	80	Recurrent[d]; recurrent fever, cough, new onset dyspnea	Severe	Sequential	RDV × 5 d; NMV/r × 5 d	Failure
		4	121	Recurrent[d]; recurrent fever, cough, dyspnea	Severe	Sequential and combination	RDV + NMV/r × 5 d; RDV + ESV × 5 d; NMV/r × 5 d	Success
8	63 y; female; Good syndrome, HGG; O_2 required	1	0	Newly developed[c]; fever, cough	Moderate	MonoTx	MOL × 5 d	Failure
		2	14	Recurrent[d]; recurrent fever, cough	Moderate	MonoTx	RDV × 5 d	Failure
		3	28	Recurrent[d]; recurrent fever	Moderate	Sequential	MOL × 5 d; NMV/r × 5 d	Success

Pt	Age; Sex; Underlying Conditions Associated With Immunosuppression; O_2 Required[a]	Treatment Order	Day[b]	Radiologic Signs of Pneumonia; Symptoms	COVID-19 Severity	Antiviral Therapy Modality	Treatment Regimen and Duration	Treatment Outcome
9	60 y; male; ML, HGG, RTX, CAR-T, HSCT	1	0	None; fever, cough, rhinorrhea	Mild	MonoTx	RDV × 5 d	Failure
		2	173[e]	Newly developed; persistent/worsening fever, cough, dyspnea	Moderate	MonoTx	MOL × 5 d	Failure
		3	209	Persistent and worsening[c]; persistent/worsening fever, cough, dyspnea	Severe	MonoTx	RDV × 10 d	Failure
		4	234	Recurrent[c]; recurrent fever	Moderate	Sequential	NMV/r × 5 d; ESV × 5 d; NMV/r × 5 d	Success
11	72 y; male; ML, RTX	1	0	None; fever, cough	Mild	MonoTx	RDV × 3 d	Failure
		2	11	Newly developed; recurrent fever, dyspnea	Severe	MonoTx	MOL × 5 d	Failure
		3	19	None; recurrent fever	Mild	MonoTx	RDV × 5 d	Success
15	75 y; male; ML, HGG, RTX, HSCT; O_2 required	1	0	None; fever, cough, sore throat	Mild	MonoTx	MOL × 5 d	Failure
		2	18	Newly developed; recurrent fever, persistent/worsening cough	Severe	MonoTx	RDV × 5 d	Success
21	56 y; male; MM, HGG, HSCT; O_2 required	1	0	None; fever, cough	Mild	MonoTx	MOL × 5 d	Failure
		2	8	None; persistent fever, cough	Mild	MonoTx	MOL × 5 d	Failure
		3	14	Newly developed; worsening fever, cough, new onset dyspnea	Severe	MonoTx	RDV × 10 d	Success

Abbreviations: AHA=acquired hemophilia A; AIHA=autoimmune hemolytic anemia; AML=acute myeloid leukemia; CS=corticosteroid use; ESV=ensitrelvir; GVHD=graft-vs-host disease; HGG=hypogammaglobulinemia; IS=immunosuppressant use; ITP=immune thrombocytopenia; ML=malignant lymphoma; MM=multiple myeloma; MOL=molnupiravir; monoTx=monotherapy; NMV/r=nirmatrelvir/ritonavir; Pt=patient; RTX=rituximab within 1 year.

[a]O_2 supplementation was recorded at the time of the first use at retreatment or prolonged antiviral therapy, not with each antiviral treatment course.

[b]Day 0=start date of first treatment to retreatment.

[c]Pneumonia not cured by antibiotics.

[d]Pneumonia not cured by corticosteroids.

[e]Though tumor-related fever was thought to be the cause of the low-grade fever and rhinorrhea, the patient developed a cough and dyspnea, and ground-glass opacities were noted on CT scan. On Day 173 a rapid antigen test was positive for COVID-19, which pointed to a differential diagnosis of either persistent or recurrent COVID-19 infection.

Note: Those noted as having CAR-T had the treatment within 1 year, those having RTX had the treatment within 1 year, and those noted as having HSCT had the treatment within 2 years.

Literature Search

A literature search was conducted in Ovid MEDLINE and Embase databases for studies published up to February 4, 2026, using the search terms of Veklury, remdesivir, retreatment, rechallenge, treatment experienced, prior COVID-19 treatment, and related search terms.

References

1. Yamamoto S, Ikeuchi K, Saito M, et al. Retreatment or prolonged antiviral therapy in severe acute respiratory syndrome Coronavirus-2 infection among immunocompromised patients during 2022-2023: A nationwide claims-based cohort study in Japan. *J Infect Chemother.* 2025;31(11):102830.
2. Yamamoto S, Ikeuchi K, Saito M, et al. Retreatment or prolonged antiviral therapy in severe acute respiratory syndrome Coronavirus-2 infection among immunocompromised patients during 2022-2023: A nationwide claims-based cohort study in Japan [Supplementary Material]. *J Infect Chemother.* 2025.
3. Yamamoto S, Ikeuchi K, Saito M, et al. Retreatment or prolonged antiviral therapy in severe acute respiratory syndrome Coronavirus-2 infection among immunocompromised patients during 2022-2023: A nationwide claims-based cohort study in Japan [Supplementary Material MMC2]. *J Infect Chemother.* 2025.

Abbreviations

Abs=antibodies
CAR-T=chimeric antigen receptor T-cell therapy
CD=cluster of differentiation
CNI=calcineurin inhibitors
HSCT=hematopoietic stem cell transplantation
ICU=intensive care unit
MMF=mycophenolate mofetil
O_2=oxygen
RDV=remdesivir
TNF=tumor necrosis factor

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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