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Veklury® (remdesivir) Use in RDV 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 RDV.

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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; 12 of these patients received retreatment and/or prolonged treatment with RDV for COVID-19, and their clinical courses are summarized in the results section below.[1]

Available Data on RDV Use 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, including 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 the inclusion criteria; 65% of patients were male, 39% received steroid therapy for COVID-19, 4.1% received baricitinib, 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 comprised the 27 patients who received retreatment and/or prolonged treatment and the 1040 patients 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; 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), and 4 received prolonged treatment, including 2 who received both retreatment and prolonged treatment. The median (IQR) 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 12 patients who received retreatment and/or prolonged treatment with RDV after prior exposure to RDV are summarized in Table 2. Of these, 2 patients (Patients 12 and 16) had prior anti-CD20 Ab exposure and required supplemental oxygen during retreatment and/or prolonged treatment (Table 2).[2,3]

Table 2. Clinical Courses of Patients Who Received RDV Treatment After Prior RDV Exposure 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	Combination (sequential)	MOL × 5 d→ RDV × 10 d→ MOL × 5 d→ NMV/r × 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[c]; recurrent fever, cough, new onset dyspnea	Severe	Combination (sequential)	RDV × 5 d→ NMV/r × 5 d	Failure
		4	121	Recurrent[c]; recurrent fever, cough, dyspnea	Severe	Combination (concurrent sequential)	RDV + NMV/r × 5 d→ RDV + ESV × 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[d]	Newly developed; persistent/worsening fever, cough, dyspnea	Moderate	MonoTx	MOL × 5 d	Failure
		3	209	Persistent and worsening[e]; persistent/worsening fever, cough, dyspnea	Severe	MonoTx	RDV × 10 d	Failure
		4	234	Recurrent[e]; recurrent fever	Moderate	Combination (sequential)	NMV/r × 5 d→ ESV × 5 d→ NMV/r × 5 d	Success
11	72 y, male; ML, RTX	1	0	None; fever, cough, sputum, sore throat	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
12	61 y, male; ML, RTX, CS; O_2 required	1	0	None; low-grade fever, cough, sore throat, rhinorrhea	Mild	MonoTx	RDV × 3 d	Failure
		2	6[f]	None, persistent low-grade fever, cough, rhinorrhea	Mild	MonoTx	RDV × 5 d	Success
13	84 y, female; ML, RTX	1	0	Newly developed[e]; fever, cough, dyspnea, sputum	Severe	MonoTx	RDV × 10 d	Failure
		2	14	Recurrent; recurrent fever	Severe	Combination (concurrent)	RDV × 10 d + NMV/r × 5 d	Success
14	74 y, male; ML, RTX	1	0	Newly developed; fever, cough, dyspnea, sputum	Critical	MonoTx	RDV x 10 d	Failure
		2	15	Worsening; recurrent fever, cough, dyspnea, sputum	Severe	Combination (concurrent)	RDV × 10 d + NMV/r x 5 d	Success
16	70 y, male; ML, RTX; O_2 required	1	0	None; fever, cough, sore throat	Mild	MonoTx	RDV × 5 d	Failure
		2	12	None; persistent fever, cough	Mild	Combination (concurrent)	RDV × 10 d + NMV/r × 5 d	Success
18	56 y, male; ML, RTX, CS, IS	1	0	Newly developed; fever, dyspnea	Severe	MonoTx	RDV × 5 d	Failure
		2	15	Persistent; recurrent fever	Moderate	Combination (sequential)	RDV × 10 d→ MOL × 5 d	Success
20	41 y, male;	1	0	None; fever, cough, sputum	Mild	MonoTx	RDV × 5 d	Failure

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
	ML, RTX	2	16	None; recurrent fever, rhinorrhea, sore throat	Mild	MonoTx	RDV × 10 d	Success
22	76 y, male; GPA, RTX	1	0	Newly developed; fever, cough, dyspnea	Severe	MonoTx	RDV × 5 d	Failure
		2	73	Persistent and worsening;[c] recurrent fever, persistent and worsening dyspnea	Critical	Combination (sequential)	RDV × 10 d→ NMV/r → MOL × 5 d	Success
23	64 y, male; ML, HGG, EPC; O_2 required	1	0	Newly developed; fever	Severe	MonoTx	RDV × 10 d	Failure
		2	20	Recurrent; recurrent fever, onset of cough, dyspnea	Severe	Combination (sequential)	RDV × 10 d→ NMV/r × 5 d	Success

Abbreviations: AHA=acquired hemophilia A; AIHA=autoimmune hemolytic anemia; CS=corticosteroid use; ESV=ensitrelvir; GPA=granulomatosis with polyangiitis; HGG=hypogammaglobulinemia; IS=immunosuppressant use; ITP=immune thrombocytopenia; ML=malignant lymphoma; monoTx=monotherapy; Pt=patient.

[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 initial treatment.

[c]Pneumonia not cured by corticosteroids.

[d]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, suggesting a differential diagnosis of either persistent or recurrent COVID-19 infection.

[e]Pneumonia not cured by antimicrobials.

[f]The patient had persistent low-grade fever, cough, and rhinorrhea without improvement following the initial 3-day RDV course. A day 6 PCR showed a low cycle threshold value of 14.1, which was consistent with persistent COVID-19.

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

Case Reports

There are limitations in the interpretation of case reports. Case reports cannot be generalized. Unlike in controlled clinical trials, causality cannot be inferred based on uncontrolled observational data. Additionally, incidence or prevalence cannot be estimated due to the lack of a representative population sample. Other limitations of case reports include the retrospective design and publication bias.[4]

Repeated RDV treatment administered concomitantly with convalescent plasma in a CD20+-depleted patient[5]

A 53-year-old female with follicular lymphoma who had been previously treated with the CD20+ cell Ab obinutuzumab (last dose of 1000 mg IV was infused in January 2020) presented with COVID-19 symptoms on March 23, 2020. The patient was admitted, discharged, and readmitted to the hospital several times and was readmitted on Day 54 due to worsened dyspnea, anemia, diarrhea, fever, hypotension, and blood and stool samples positive for SARS-CoV-2. On Day 63, she began 10 days of RDV treatment (200 mg IV loading dose on the first day, followed by 9 days of 100 mg IV daily) as part of the GS-US-540-5773 study. After resolution of symptoms and undetectable viral RNA in blood and stool samples, the patient was discharged. However, after 8 days, she was readmitted with detectable SARS-CoV-2 in blood and sputum samples and received another 5 days of RDV treatment (100 mg daily) through the compassionate use program. Convalescent plasma treatment was initiated (two courses of 6 units; 2 units administered every other day) to replace the Abs the patient was unable to produce due to her prior exposure to immunosuppressant therapy. Three weeks after the last plasma infusion, she remained asymptomatic and had no positive SARS-CoV-2 identification from nasal swabs or blood samples.

Repeated RDV treatment administered concomitantly with convalescent plasma in a patient receiving ongoing chemotherapy[6]

A 60-year-old male with refractory mantle cell lymphoma who was receiving ongoing chemotherapy (including a CD20-CD3 T-cell engaging, bispecific Ab, mosunetuzumab; cyclophosphamide; doxorubicin; prednisone; and a CD79b-directed Ab-drug conjugate, polatuzumab vedotin) presented with a 1-week history of epistaxis, cough, and blood-streaked sputum and was admitted to the hospital (on Day 7). After clinical stabilization that occurred with transfusion of platelets for chemotherapy-induced thrombocytopenia, he was discharged on Day 13. After he was readmitted on Day 22 for additional COVID-19–related symptoms, a 10-day course of RDV was initiated on Day 30, and convalescent plasma therapy was initiated on Day 31. The patient improved clinically, and he was discharged on Day 39. Chemotherapy was restarted on Day 85 and finished on Day 106. Re-emergence of COVID-19-related symptoms prompted another admission on Day 119, and a second 10-day RDV course along with two convalescent plasma infusions began on Day 122. After the infusions, he was weaned off supplemental O_2, discharged on Day 131, readmitted on Day 156 due to lymphoma progression, and ultimately discharged to home hospice care. Upon his last admission, nasal swabs remained positive for SARS-CoV-2.

Repeated RDV treatment followed by treatment with convalescent plasma in a patient recently treated with chemotherapy[7]

A Caucasian male in his 50s who completed chemotherapy for chronic lymphocytic leukemia (six cycles of fludarabine, cyclophosphamide, and RTX that ended 3 months prior) began self-isolation after diagnosis of COVID-19 and fever onset (Day 1). On Day 14, he was admitted; his condition worsened, which prompted his enrollment in the Adaptive COVID-19 Treatment Trial -1 study (study treatment began on Day 24; 10-day course), and he improved 2 days after treatment began. Later unblinding of the study revealed that he had been randomly assigned to receive RDV. He was discharged on Day 35 but was readmitted the next day. His condition did not improve after empiric meropenem, and a throat swab was positive SARS-CoV-2 per PCR test, so a second 10-day RDV course was initiated on Day 45. His clinical condition and markers of inflammation improved after the reinitiation of RDV treatment; however, his fever returned the day after he completed the second course of RDV, and he was admitted again on Day 55. He received convalescent plasma on Day 58 and was discharged on Day 65 in good condition.

Repeated RDV treatment in a pediatric patient with pre-B-cell ALL[8]

A 17-year-old female with a central nervous system relapse of pre-B-cell ALL in the maintenance phase of chemotherapy (as part of the AALL1131 study that included blinatumomab and three intrathecal drugs) was admitted to an outside facility with fever after a COVID-19 exposure. She was started on empiric cefepime and had elevated LFTs (AST, 92 U/L; ALT, 115 U/L), but she maintained O_2 saturation levels on room air. On hospital Day 3, she tested positive for SARS-CoV-2 from a nasal PCR test. Due to worsening dyspnea, she required supplemental low-flow O_2 on hospital Day 6 and began hydroxychloroquine (800 mg × 1 followed by 400 mg 6, 24, and 48 hours later), and IVIG (2 g/kg divided over 3 doses) on hospital Days 6 to 8. On hospital Day 9, anakinra was initiated (200 mg IV once every 8 hours; 12-day course), and methylprednisolone was started on hospital Day 11 (1 mg/kg once every 12 hours, followed by a taper over 1 week). The patient did not clinically improve; thus, a 10-day course of RDV was initiated on Day 13 (illness Day 16; 200 mg IV × 1, followed by 100 mg IV × 9 days). No laboratory abnormalities or AEs were noted during RDV treatment, and she was weaned from supplemental O_2 on hospital Day 17. On hospital Day 20, her fever and cough resolved, and she was discharged on hospital Day 22 with normalized AST and ALT levels.

The patient was readmitted 52 days after the first admission with fever, neutropenia, mildly elevated LFTs (AST, 40 U/L; ALT, 73 U/L), and a positive SARS-CoV-2 PCR test. On hospital Day 5, she required supplemental O_2, and cefepime was restarted due to neutropenia. On hospital Day 7, increased supplemental O_2 requirements (6 L via nasal cannula) and fevers were noted, and a second course of IVIG (2 g/kg) was initiated due to low IgG levels. A second 10-day course of RDV was started on hospital Day 8, and no laboratory abnormalities or AEs were attributed to RDV. The next day she required NIPPV, was transferred to the intensive care unit, and received convalescent plasma. Her fever resolved, and she was weaned from NIPPV to room air on hospital Day 13. She was discharged on hospital Day 19 and remained stable on room air. A subsequent SARS-CoV-2 PCR test remained positive, but no further readmissions related to SARS-CoV-2 occurred.

Repeated RDV treatment followed by combination with MOL in a patient with follicular lymphoma[9]

A male in his late 60s was initially diagnosed with follicular lymphoma in 2010. Due to disease progression with CD20-positive follicular lymphoma, in September 2020 he began

treatment with the bispecific CD3 × CD20 Ab, EPC, as part of a phase 1 trial. He achieved complete metabolic remission by October 2020, which was sustained through 2021. In May 2022, he developed upper respiratory symptoms with fever and tested positive for SARS-CoV-2 Omicron BA.2. All symptoms resolved after 3 days of RDV treatment. After 3 weeks, he developed a high fever and cough with a SARS-CoV-2 antigen level >1000 ng/L and was admitted to the hospital. The antigen level decreased to 0.88 ng/L, and his symptoms resolved after receiving RDV for 9 days with one dose of tixagevimab/cilgavimab. No lymphoma treatment was administered after June 2022, though EPC was administered 11 and 6 days after the first and second RDV courses, respectively.

He experienced multiple relapses of COVID-19 symptoms (fever, cough, and fatigue) over several months. He ultimately received a total of five courses of RDV treatment (durations of additional RDV courses: 5, 10, and 20 days) and experienced temporary symptom resolution after each course. After the fifth course of RDV treatment, whole-genome sequencing revealed ongoing viral replication and the accumulation of mutations (≤7 mutations in the final sample), including SQ1180K in the spike protein. After the fifth RDV course, his symptoms returned, and he was treated with a 10-day course of RDV and MOL. His symptoms resolved and a reduction in antigen level from 293 ng/L to <0.1 ng/L was observed, which indicated that the patient had cleared his infection. In December 2022, after 61 symptom-free days, he presented again with symptoms and tested positive for SARS-CoV-2 Omicron XBC.1; he fully recovered after 5 days of NMV/r treatment. In April 2023, a PET-CT confirmed complete remission of his lymphoma, and he was withdrawn from the study protocol.

References

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Abbreviations

Ab=antibody
AE=adverse event
ALL=acute lymphocytic leukemia
CAR-T=chimeric antigen receptor T-cell therapy
CD=cluster of differentiation
CNI=calcineurin inhibitors
EPC=epcoritamab
HSCT=hematopoietic stem cell transplantation
ICU=intensive care unit
LFT=liver function test
MMF=mycophenolate mofetil
MOL=molnupiravir
NIPPV=non-invasive positive pressure ventilation
NMV/r=nirmatrelvir/ritonavir
O_2=oxygen
PCR=polymerase chain reaction
RDV=remdesivir
RTX=rituximab
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.

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