THE ONLY COVID-19 ANTIVIRAL WITH
OUTCOMES ACROSS 3 KEY TREATMENT GOALS:

DISEASE PROGRESSION, RECOVERY TIME, AND READMISSION[1,2]

INDICATION

VEKLURY is indicated for the treatment of COVID-19 in adults and pediatric patients (birth to <18 years of age weighing ≥1.5 kg), who are:

- Hospitalized, or
- Not hospitalized, have mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization or death.

THE ONLY NIH RECOMMENDED COVID-19 TREATMENT OPTION
included for adult patients hospitalized for COVID-19[3]

- Not requiring supplemental O_2 and
- Requiring low- or high-flow O_2

IMPORTANT SAFETY INFORMATION

Contraindication

- VEKLURY is contraindicated in patients with a history of clinically significant hypersensitivity reactions to VEKLURY or any of its components.

Please see additional Important Safety Information within and full Prescribing Information here.

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LEADING THE WAY

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COVID-19 is a year-round disease that remains a public health priority[4,5]

Ongoing epidemiology

COVID-19 remains a significant cause of mortality in the United States[6]

- The CDC reported **97,902 provisional death counts involving COVID-19** in the United States from January 2023 through May 2024[7,*]
- Within the same timeframe, from January 2023 through May 2024, the CDC reported **13,046 provisional deaths attributed to influenza** in the United States[7,†]

*Provisional death counts are based on death certificate data received and coded by the National Center for Health Statistics. These are deaths with confirmed or presumed COVID-19, coded to ICD-10 code U07.1.

†Provisional death counts are based on death certificate data received and coded by the National Center for Health Statistics. Counts of deaths involving influenza (J09-J11) include deaths with pneumonia or COVID-19 also listed as a cause of death.

Older adults and/or patients with certain comorbidities are at higher risk for severe COVID-19[8]

≥65 years

Age remains the strongest risk factor for severe COVID-19 outcomes[8,9]

People aged ≥65 years accounted for ~63% of COVID-19–associated hospitalizations and ~88% of COVID-19–associated in-hospital deaths.[10,‡]

‡Data from January to August 2023.
Source: CDC; COVID-NET conducts population-based surveillance for laboratory-confirmed COVID-19–associated hospitalizations across 13 US states.

Patients with certain comorbidities have an increased mortality risk from COVID-19[11]

Among 540,667 adult patients hospitalized with COVID-19, **a study found the following select comorbidities to be risk factors for progression to severe COVID-19 including death.**

Comorbidities	Death Risk Ratio Increase	aRR (95% CI)
Obesity	30%	1.30 (1.27 to 1.33)
Diabetes with complications	26%	1.26 (1.24 to 1.28)
Chronic kidney disease	21%	1.21 (1.19 to 1.24)
COPD and bronchiectasis	18%	1.18 (1.16 to 1.20)
Neurocognitive disorders	18%	1.18 (1.15 to 1.21)
CAD and other heart disease	14%	1.14 (1.12 to 1.16)

Source: CDC; Premier Healthcare Database, Special COVID-19 Release, March 2020–March 2021. US hospital–based data collected from 540,667 adults hospitalized for COVID-19.

COVID-19 death risk ratio increases as the number of underlying conditions increase[11]

Number of Conditions	Death Risk Ratio Increase	aRR (95% CI)
No conditions	1x	Reference
1 condition	1.53x	**1.53** (1.41 to 1.67)
2 to 5 conditions	2.55x	**2.55** (2.32 to 2.80)
6 to 10 conditions	3.29x	**3.29** (2.98 to 3.63)
>10 conditions	3.82x	**3.82** (3.45 to 4.23)

Source: CDC; Premier Healthcare Database, Special COVID-19 Release, March 2020–March 2021. US hospital–based data collected from 540,667 adults hospitalized for COVID-19.

Of patients hospitalized with COVID-19,[11]

- **~95%** had **≥1 underlying condition**
- **~40%** had **2 to 5 conditions**
- **31%** had **6 to 10 conditions**
- **~17%** had **>10 conditions**

Ever-changing and unpredictable virus

With SARS-CoV-2 constantly changing and accumulating mutations in its genetic code, new variants are expected to continue to emerge[12]:

- To date, **14 variants and >600 sublineages** have been identified[12,13]
- Variants such as **EG.5** have shown the ability to **evade some of the immunity** occurring after an infection or vaccination[14]
- Others variants, such as **JN.1** and **BA.2.87.1**, have shown **high transmissibility** and **>30 mutations at the spike, respectively**[15,16]

aRR=adjusted risk ratio; CAD=coronary atherosclerosis disease; COPD=chronic obstructive pulmonary disease; ICD-10=International Classification of Diseases, 10th Revision.

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SENSE OF URGENCY
MECHANISM OF ACTION
DISEASE PROGRESSION
RECOVERY TIME
ACTT-1 SAFETY & SPECIAL POPULATIONS
REAL-WORLD READMISSION
DOSING & SUMMARY

VEKLURY® has retained antiviral activity against Omicron and all other variants tested in vitro[1,17-20]

The antiviral activity of VEKLURY has been tested in vitro against clinical isolates of SARS-CoV-2 variants. These laboratory findings demonstrated that the antiviral activity of VEKLURY is not reduced against these variants:

Omicron	Delta	Alpha	Beta	Gamma
(B.1.1.529/BA.1, BA.2, BA.2.12.1, BA.2.75, BA.4, BA.4.6, BA.5, BF.5, BF.7, BQ.1, BQ.1.1, CH.1.1, XBB, XBB.1.5, XBB.1.16, XBB.1.9.1, and XBF)	(B.1.617.2)	(B.1.1.7)	(B.1.351)	(P.1)

Epsilon	Zeta	Iota	Kappa	Lambda
(B.1.429)	(P.2)	(B.1.526)	(B.1.617.1)	(C.37)

Viruses like SARS-CoV-2 continuously evolve as changes in the genetic code occur during replication[12]

To date, known novel virus variants show mutations at different locations in the SARS-CoV-2 spike protein, which is on the outer surface of the virus and can cause decreased affinity of anti–SARS-CoV-2 antibodies.[12,21,22]

No known SARS-CoV-2 variants have significantly altered the viral RNA polymerase.[17,20]

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and precautions

- **Hypersensitivity, including infusion-related and anaphylactic reactions:** Hypersensitivity, including infusion-related and anaphylactic reactions, has been observed during and following administration of VEKLURY; most reactions occurred within 1 hour. Monitor patients during infusion and observe for at least 1 hour after infusion is complete for signs and symptoms of hypersensitivity as clinically appropriate. Symptoms may include hypotension, hypertension, tachycardia, bradycardia, hypoxia, fever, dyspnea, wheezing, angioedema, rash, nausea, diaphoresis, and shivering. Slower infusion rates (maximum infusion time of up to 120 minutes) can potentially prevent these reactions. If a severe infusion-related hypersensitivity reaction occurs, immediately discontinue VEKLURY and initiate appropriate treatment (see Contraindications).

RDV-TP=remdesivir triphosphate.

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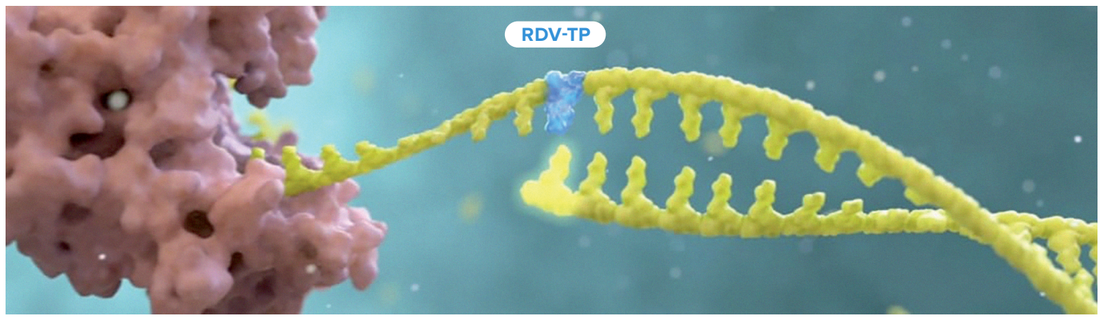
VEKLURY disrupts RNA replication[1,23,24]

VEKLURY is an antiviral medication that directly inhibits viral replication of SARS-CoV-2



VEKLURY acts to inhibit the SARS-CoV-2 RNA-dependent RNA polymerase (RdRp), which is essential for viral replication—and thus creation of virions that circulate in the body.

TAKE A CLOSER LOOK AT THE MECHANISM OF ACTION FOR VEKLURY

Please see clinical studies and efficacy data on the following pages.

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and precautions (cont'd)

- **Increased risk of transaminase elevations:** Transaminase elevations have been observed in healthy volunteers and in patients with COVID-19 who received VEKLURY; these elevations have also been reported as a clinical feature of COVID-19. Perform hepatic laboratory testing in all patients (see Dosage and administration). Consider discontinuing VEKLURY if ALT levels increase to >10x ULN. Discontinue VEKLURY if ALT elevation is accompanied by signs or symptoms of liver inflammation.
- **Risk of reduced antiviral activity when coadministered with chloroquine or hydroxychloroquine:** Coadministration of VEKLURY with chloroquine phosphate or hydroxychloroquine sulfate is not recommended based on data from cell culture experiments, demonstrating potential antagonism, which may lead to a decrease in the antiviral activity of VEKLURY.

Adverse reactions

- The most common adverse reaction (≥5% all grades) was nausea.
- The most common lab abnormalities (≥5% all grades) were increases in ALT and AST.

Please see additional Important Safety Information within and full Prescribing Information here.

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LEADING THE WAY

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VEKLURY significantly reduced risk of progression to severe COVID-19[1,25]

87%

Lower risk of COVID-19–related hospitalization or death from any cause by Day 28

- 0.7% of patients treated with VEKLURY (n=2/279) compared to 5.3% of patients treated with placebo (n=15/283) had a COVID-19–related hospitalization or death from any cause by Day 28; HR: 0.13 (95% CI, 0.03 to 0.59), *P* = 0.008
- No deaths were reported in either group by Day 28

The safety profiles of VEKLURY and placebo were comparable

- The primary safety endpoint of any adverse event was reported in 42.3% of patients treated with VEKLURY vs 46.3% of patients treated with placebo
- The most common adverse reaction (≥5%) in patients taking VEKLURY was nausea

"Remdesivir is another important option for outpatients with Covid-19."

— Gottlieb RL, et al. *N Engl J Med.* 2022;386(4):305-315.

VIEW THE *NEW ENGLAND JOURNAL OF MEDICINE* PUBLICATION

Early Remdesivir to Prevent Progression to Severe COVID-19 in Outpatients

IMPORTANT SAFETY INFORMATION (cont'd)

Dosage and administration

— Administration should take place under conditions where management of severe hypersensitivity reactions, such as anaphylaxis, is possible.

- **Treatment duration:**
  - For patients who **are hospitalized**, VEKLURY should be initiated as soon as possible after diagnosis of symptomatic COVID-19.
  - For patients who are hospitalized and do not require invasive mechanical ventilation and/or ECMO, the recommended treatment duration is 5 days. If a patient does not demonstrate clinical improvement, treatment may be extended up to 5 additional days, for a total treatment duration of up to 10 days.
  - For patients who are hospitalized and require invasive mechanical ventilation and/or ECMO, the recommended total treatment duration is 10 days.
  - For patients who are **not hospitalized**, diagnosed with mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization or death, the recommended total treatment duration is 3 days. VEKLURY should be initiated as soon as possible after diagnosis of symptomatic COVID-19 and within 7 days of symptom onset for outpatient use.

HR=hazard ratio.

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PINETREE study

Early use of VEKLURY helped prevent progression to COVID-19–related hospitalization or death[1,25]

PINETREE (GS-US-540-9012) study design: a phase 3, randomized, double-blind, placebo-controlled clinical trial in patients who were not hospitalized, had confirmed positive results for SARS-CoV-2 infection, showed symptoms of mild-to-moderate COVID-19 for ≤7 days, and had at least 1 risk factor for progression to hospitalization.

Patients were randomized to receive VEKLURY (n=279) or placebo (n=283) for 3 days. Patients in the VEKLURY arm received a single loading dose of VEKLURY 200 mg IV on Day 1 followed by once-daily maintenance doses of VEKLURY 100 mg IV on Days 2 and 3. **Patients who received, required, or were expected to require supplemental oxygen were excluded from the trial.**

Risk factors for disease progression in PINETREE included:

- Hypertension
- Chronic lung disease
- Cardiovascular or cerebrovascular disease
- Diabetes mellitus
- Obesity (BMI ≥30 kg/m²)
- Immunocompromised state
- Chronic mild or moderate kidney disease
- Chronic liver disease
- Current cancer
- Sickle cell disease

60+ All patients 60 years of age or older were considered at high risk

Primary endpoints

The primary efficacy endpoint was a composite of COVID-19–related hospitalization (defined as ≥24 hours of acute care) or death from any cause by Day 28.

The primary safety endpoint was any adverse event.

IMPORTANT SAFETY INFORMATION (cont'd)

Dosage and administration (cont'd)

- **Testing prior to and during treatment:** Perform hepatic laboratory and prothrombin time testing prior to initiating VEKLURY and during use as clinically appropriate.
- **Renal impairment:** No dosage adjustment of VEKLURY is recommended in patients with any degree of renal impairment, including patients on dialysis. VEKLURY may be administered without regard to the timing of dialysis.

Please see additional Important Safety Information within and full Prescribing Information here.

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LEADING THE WAY

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VEKLURY reduced recovery time in patients hospitalized with COVID-19[1,26]

In the ACTT-1 overall study population, patients experienced

5 DAYS SHORTER RECOVERY TIME WITH VEKLURY

Median 10 days with VEKLURY vs 15 days with placebo; recovery rate ratio: 1.29 (95% CI, 1.12 to 1.49), *P* < 0.001

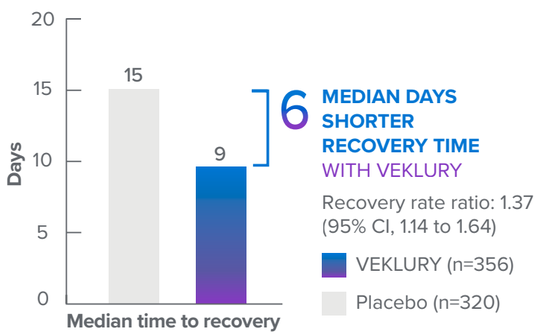
- Recovery was defined as patients who were no longer hospitalized or hospitalized but no longer required ongoing COVID-19 medical care

Treatment with VEKLURY earlier in the disease course resulted in the greatest benefit for patients[26,27]

The median time from symptom onset to randomization was 9 days for patients in both VEKLURY and placebo arms. **45% of patients presented >9 days after symptom onset** (n=477).

A prespecified subgroup analysis showed:

Median time to recovery in patients with symptom onset less than or equal to 10 days



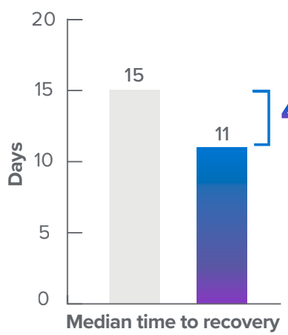
6 MEDIAN DAYS SHORTER RECOVERY TIME WITH VEKLURY

Recovery rate ratio: 1.37 (95% CI, 1.14 to 1.64)

VEKLURY (n=356)

Placebo (n=320)

Median time to recovery in patients with symptom onset greater than 10 days



4 MEDIAN DAYS SHORTER RECOVERY TIME WITH VEKLURY

Recovery rate ratio: 1.20 (95% CI, 0.94 to 1.52)

VEKLURY (n=184)

Placebo (n=199)

VEKLURY is indicated for patients hospitalized with COVID-19, independent of time from symptom onset

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VEKLURY improved clinical outcomes in hospitalized patients across a spectrum of COVID-19 severity[1,26,27]

ACTT-1 study design: a randomized, double-blind, placebo-controlled, phase 3 clinical trial in hospitalized adult patients with confirmed SARS-CoV-2 infection and mild, moderate, or severe COVID-19.

Patients were randomized to receive VEKLURY (n=541) or placebo (n=521) for up to 10 days. Patients in the VEKLURY arm received a single loading dose of VEKLURY 200 mg IV on Day 1 followed by once-daily maintenance doses of VEKLURY 100 mg IV on Days 2 through 10. Treatment with VEKLURY was stopped in patients who were discharged from the hospital prior to the completion of 10 days of treatment.

Primary endpoint

The primary endpoint was time to recovery within 29 days after randomization. Recovery included hospital discharge for some patients with or without limitations on activities, as defined by ordinal scores 1–3.

Treatment with VEKLURY earlier in the disease course resulted in the greatest benefit for patients

VIEW THE *NEW ENGLAND JOURNAL OF MEDICINE* PUBLICATION

Remdesivir for the Treatment of COVID-19 — Final Report

IMPORTANT SAFETY INFORMATION (cont'd)

Pregnancy and lactation

- **Pregnancy:** A pregnancy registry has been established for VEKLURY. Available clinical trial data for VEKLURY in pregnant women have not identified a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes following second- and third-trimester exposure. There are insufficient data to evaluate the risk of VEKLURY exposure during the first trimester. Maternal and fetal risks are associated with untreated COVID-19 in pregnancy.
- **Lactation:** VEKLURY can pass into breast milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for VEKLURY and any potential adverse effects on the breastfed child from VEKLURY or from an underlying maternal condition. Breastfeeding individuals with COVID-19 should follow practices according to clinical guidelines to avoid exposing the infant to COVID-19.

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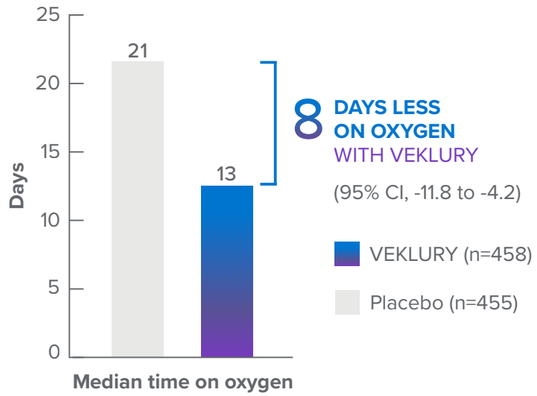
VEKLURY shortened time on oxygen and reduced progression to more severe disease[1,26]

VEKLURY reduced median time on oxygen by 8 days in patients who received oxygen at baseline



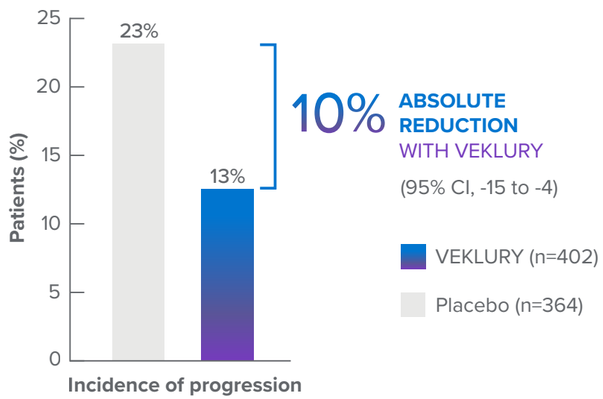
8 DAYS LESS ON OXYGEN WITH VEKLURY

(95% CI, -11.8 to -4.2)

VEKLURY (n=458)

Placebo (n=455)

VEKLURY reduced progression to mechanical ventilation or ECMO vs placebo in patients who did not receive either at baseline



10% ABSOLUTE REDUCTION WITH VEKLURY

(95% CI, -15 to -4)

VEKLURY (n=402)

Placebo (n=364)

- Time on oxygen and reduced disease progression were additional secondary endpoints

INDICATION

VEKLURY is indicated for the treatment of COVID-19 in adults and pediatric patients (birth to <18 years of age weighing ≥1.5 kg), who are:

- Hospitalized, or
- Not hospitalized, have mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization or death.

ECMO=extracorporeal membrane oxygenation.

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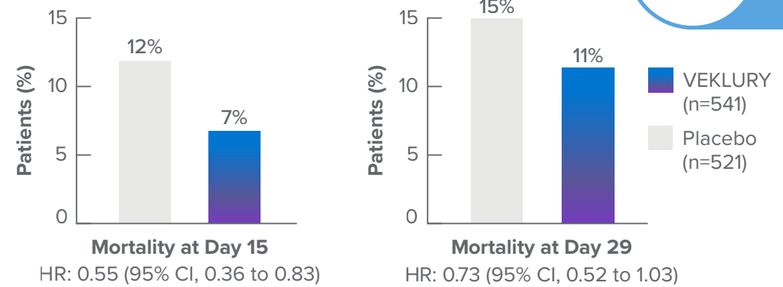
ACTT-1 study

Mortality in the overall population[1,26]

Mortality at Day 29 was a prespecified secondary endpoint

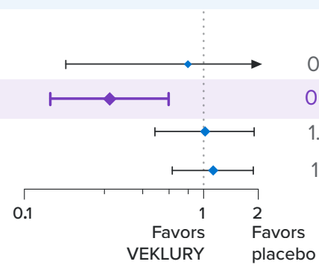
Results in the overall population at Day 29 were not statistically significant.

- The ACTT-1 study was not powered to evaluate a difference in mortality in the overall population



Mortality rates by ordinal scale at Day 29, a post hoc subgroup analysis[1,26,27]

Entire study (Day 29)	Number of deaths/number of patients: VEKLURY	Placebo	HR (95% CI)
Ordinal score at baseline			
4	3/75	3/63	0.82 (0.17 to 4.07)
5	9/232	25/203	0.30 (0.14 to 0.64)
6	19/95	20/98	1.02 (0.54 to 1.91)
7	28/131	29/154	1.13 (0.67 to 1.89)



VEKLURY reduced mortality rates at Day 29 in patients on low-flow oxygen at baseline by 70% vs placebo. HR: 0.30 (95% CI, 0.14 to 0.64)

- No difference was demonstrated in the other baseline oxygen status subgroups
- There was no adjustment to control for multiple testing in this post hoc analysis

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LEADING THE WAY

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ACTT-1: VEKLURY had a demonstrated safety profile in patients hospitalized with COVID-19[1]

Comparable frequency of adverse reactions vs placebo

Types of adverse reactions	VEKLURY (n=532) n (%)	Placebo (n=516) n (%)
Any adverse reaction, Grades ≥3	41 (8)	46 (9)
Serious adverse reactions	2 (0.4)[§]	3 (0.6)
Adverse reactions leading to treatment discontinuation	11 (2)[‖]	15 (3)

Laboratory abnormalities (Grades 3–4) reported in ≥3% of patients

Laboratory parameter abnormality[¶]	VEKLURY (n=532)	Placebo (n=516)
ALT increased	3%	6%
AST increased	6%	8%
Bilirubin increased	2%	5%
Creatinine clearance decreased[#]	18%	20%
Creatinine increased	15%	16%
eGFR decreased	18%	24%
Glucose increased	12%	13%
Hemoglobin decreased	15%	22%
Lymphocytes decreased	11%	18%
Prothrombin time increased	9%	4%

[§]Seizure (n=1), infusion-related reaction (n=1).
[‖]Seizure (n=1), infusion-related reaction (n=1), transaminases increased (n=3), ALT increased and AST increased (n=1), GFR decreased (n=2), acute kidney injury (n=3).
[¶]Frequencies are based on treatment-emergent laboratory abnormalities graded per Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events, Version 2.1, dated July 2017.
[#]Based on the Cockcroft-Gault formula.

IMPORTANT SAFETY INFORMATION (cont'd)

Contraindication

- VEKLURY is contraindicated in patients with a history of clinically significant hypersensitivity reactions to VEKLURY or any of its components.

CYP3A4=cytochrome P450 3A4; DDI=drug-drug interaction; OATP 1B1/1B3=organic anion–transporting polypeptides 1B1/1B3; P-gp=P-glycoprotein.

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VEKLURY can be used across a broad range of patients with COVID-19[1]

Renal impairment

- No dosage adjustment of VEKLURY is recommended for patients with any degree of renal impairment, including those on dialysis
- No renal laboratory testing is required before or during treatment

Hepatic impairment

- No dosage adjustment is recommended for patients with mild to severe hepatic impairment (Child-Pugh Class A, B, or C)
- Perform hepatic laboratory and prothrombin time testing prior to initiating VEKLURY and during use as clinically appropriate

Pregnant or breastfeeding patients

- VEKLURY may be administered in patients who are pregnant and have COVID-19
- No drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes following exposure in the second and third trimesters have been identified in available data. There are insufficient data to evaluate the risk of VEKLURY exposure during the first trimester
- VEKLURY can pass into breast milk. Available data from pharmacovigilance reports (n=11) do not indicate adverse effects on breastfed infants from exposure to VEKLURY and its metabolites through breast milk

Pediatric patients

- VEKLURY may be administered in children, starting from as early as birth and weighing at least 1.5 kg

VEKLURY has no known DDI-related contraindications and few expected clinically significant drug interactions

- Based on a drug interaction study conducted with VEKLURY, no clinically significant drug interactions are expected with inducers of CYP3A4 or inhibitors of OATP 1B1/1B3 and P-gp
- There is a risk of reduced antiviral activity when coadministered with chloroquine or hydroxychloroquine. Due to potential antagonism observed in vitro, concomitant use of VEKLURY with chloroquine phosphate or hydroxychloroquine sulfate is not recommended

Update your hospital protocols and order sets to ensure appropriate patients can access VEKLURY

Please see additional Important Safety Information within and full Prescribing Information here.

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LEADING THE WAY

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In a real-world study, patients treated with VEKLURY were significantly less likely to be readmitted across variant periods[2]

A large, real-world, retrospective, observational study examined 30-day readmission to the same hospital after COVID-19 hospitalization in adult patients (≥18 years of age) who were treated with VEKLURY vs those not treated with VEKLURY across variant periods: pre-Delta (5/2020–4/2021), Delta (5/2021–11/2021), and Omicron (12/2021–4/2022). The study period was from May 2020 through April 2022, which covered the pre-BA4/5 variant period.

Main outcomes

The main outcomes were 30-day COVID-19–related** and all-cause†† readmission to the same hospital after being discharged alive from the index hospitalization for COVID-19 between May 1, 2020, and April 30, 2022.

- Data were examined using multivariate logistic regression. The model adjusted for age, corticosteroid use, variant period, Charlson Comorbidity Index (CCI), maximum oxygenation requirements, and ICU admission during COVID-19 hospitalization
- VEKLURY-treated patients received at least 1 dose of VEKLURY during the index COVID-19 hospitalization‡‡
- This study was sponsored by Gilead Sciences, Inc.

Data source[2,28]

PINC AI™ Healthcare Database: This US hospital–based, service-level, all-payer (commercial, Medicare, Medicaid, others) database **covered approximately 25% of all US hospitalizations from 48 states**.

Study population

- **440,601 patients** with a primary diagnosis of COVID-19 and who were discharged alive
- **248,785 VEKLURY patients** were compared to **191,816 non-VEKLURY** patients

The patient population included a broad range of:

- Comorbidities
- Supplemental oxygen requirements
- Ages
- Concomitant medications used§§

**Defined as a readmission with a primary or secondary discharge diagnosis of COVID-19.
††Defined as readmission to the same hospital within 30 days of being discharged alive from the hospitalization for COVID-19.
‡‡Refer to the VEKLURY Prescribing Information for Dosage and Administration recommendations.
§§Other treatments administered at baseline for patients (across both study arms) included corticosteroids, tocilizumab, and baricitinib, as well as combinations of the aforementioned treatments.

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and precautions

- **Hypersensitivity, including infusion-related and anaphylactic reactions:** Hypersensitivity, including infusion-related and anaphylactic reactions, has been observed during and following administration of VEKLURY; most reactions occurred within 1 hour. Monitor patients during infusion and observe for at least 1 hour after infusion is complete for signs and symptoms of hypersensitivity as clinically appropriate. Symptoms may include hypotension, hypertension, tachycardia, bradycardia, hypoxia, fever, dyspnea, wheezing, angioedema, rash, nausea, diaphoresis, and shivering. Slower infusion rates (maximum infusion time of up to 120 minutes) can potentially prevent these reactions. If a severe infusion-related hypersensitivity reaction occurs, immediately discontinue VEKLURY and initiate appropriate treatment (see Contraindications).

NSOc=no supplemental oxygen charges.
PINC AI™ is a trademark of Premier, Inc. (formerly Premier Healthcare Database).

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Select population characteristics

Compared to nonreadmitted patients, readmitted patients:

- **Were older:** median 71 years vs 63 years
- **Had more comorbidities:** CCI ≥4: 36% vs 16%
- **Were more likely to have NSOc** (42% vs 39%) and **less likely to be on low-flow oxygen** (40% vs 42%)
- **Were less likely to be treated with VEKLURY:** 48% vs 57%
- **Were more likely to have received corticosteroid monotherapy during index hospitalization:** 38% vs 29%

Compared to non-VEKLURY patients, VEKLURY patients:

- **Were younger:** median 62 years vs 64 years
- **More likely to have received some level of supplemental oxygen support (any supplemental oxygen support, 1-NSOc):** 70% vs 48%

Study considerations

Real-world studies should be interpreted based on the type and size of the source datasets and the methodologies used to mitigate potential confounding bias. Real-world data should be considered in the context of all available data; results may vary between studies.

Strengths

- Large study population enabled subgroup analyses across variant periods and supplemental oxygen requirements
- Well-defined cohort of patients hospitalized for COVID-19

Limitations

- Potential for residual confounding due to unmeasured variables, including differences in groups that could not be accounted for
- The database did not capture data relating to time from symptom onset, infecting viral lineages, and prehospital care such as other treatments
- Due to the absence of billing charges for supplemental oxygen, some patients who received supplemental oxygen could be misclassified as NSOc
- Patients readmitted to a different hospital were not accounted for

See the data on the following pages.

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and precautions (cont'd)

- **Increased risk of transaminase elevations:** Transaminase elevations have been observed in healthy volunteers and in patients with COVID-19 who received VEKLURY; these elevations have also been reported as a clinical feature of COVID-19. Perform hepatic laboratory testing in all patients (see Dosage and administration). Consider discontinuing VEKLURY if ALT levels increase to >10x ULN. Discontinue VEKLURY if ALT elevation is accompanied by signs or symptoms of liver inflammation.
- **Risk of reduced antiviral activity when coadministered with chloroquine or hydroxychloroquine:** Coadministration of VEKLURY with chloroquine phosphate or hydroxychloroquine sulfate is not recommended based on data from cell culture experiments, demonstrating potential antagonism, which may lead to a decrease in the antiviral activity of VEKLURY.

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Real-world study

Patients treated with VEKLURY had significantly reduced readmission rates[2]

40%

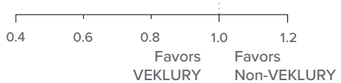
Reduced likelihood of 30-day COVID-19–related readmission was observed with VEKLURY[2]

aOR: 0.60 (95% CI, 0.58 to 0.62), *P* < 0.0001

- 3.0% of VEKLURY patients vs 5.4% of non-VEKLURY patients experienced COVID-19–related readmission within 30 days

Reduction of 30-day COVID-19–related readmission with VEKLURY was consistently observed across variant periods and all supplemental oxygen requirements (May 2020 through April 2022)

	Unadjusted		Adjusted		
	Readmitted patients/ Total number of patients		Likelihood of 30-day COVID-19 readmission aOR with 95% CI	aOR (95% CI)	*P* value
	VEKLURY	Non-VEKLURY			
Overall cohort	7,453/248,785	10,396/191,816		0.60 (0.58 to 0.62)	< 0.0001
Variant period					
Pre-Delta	3,921/122,560	6,656/109,348		0.54 (0.52 to 0.57)	< 0.0001
Delta	2,031/83,178	2,021/44,215		0.61 (0.57 to 0.65)	< 0.0001
Omicron	1,501/43,047	1,719/38,253		0.77 (0.72 to 0.83)	< 0.0001
Maximum oxygenation in index hospitalization					
No supplemental oxygen charges	2,555/73,859	5,883/99,030		0.55 (0.52 to 0.57)	< 0.0001
Low-flow oxygen	3,487/115,923	3,630/68,389		0.61 (0.58 to 0.65)	< 0.0001
High-flow oxygen/NIV	1,301/50,029	795/19,815		0.73 (0.67 to 0.80)	< 0.0001
IMV/ECMO	110/8,974	88/4,582		0.72 (0.54 to 0.97)	0.0301



- Patients treated with VEKLURY **not requiring supplemental oxygen showed the greatest reduction in readmission**—45% less likely to be readmitted

IMPORTANT SAFETY INFORMATION (cont'd)

Adverse reactions

- The most common adverse reaction (≥5% all grades) was nausea.
- The most common lab abnormalities (≥5% all grades) were increases in ALT and AST.

Dosage and administration

— Administration should take place under conditions where management of severe hypersensitivity reactions, such as anaphylaxis, is possible.

aOR=adjusted odds ratio; IMV=invasive mechanical ventilation; NIV=noninvasive ventilation.

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27%

Reduced likelihood of 30-day all-cause readmission was observed with VEKLURY[2]

aOR: 0.73 (95% CI, 0.72 to 0.75), *P* < 0.0001

- 6.3% of VEKLURY patients vs 9.1% of non-VEKLURY patients experienced all-cause readmission within 30 days

30-day all-cause readmission across variant periods and by maximum oxygenation in index hospitalization (May 2020 through April 2022)

	Unadjusted		Adjusted		
	Readmitted patients/ Total number of patients		Likelihood of 30-day all-cause readmission aOR with 95% CI	aOR (95% CI)	*P* value
	VEKLURY	Non-VEKLURY			
Overall cohort	15,780/248,785	17,437/191,816		0.73 (0.72 to 0.75)	< 0.0001
Variant period					
Pre-Delta	7,766/122,560	10,176/109,348		0.69 (0.67 to 0.71)	< 0.0001
Delta	4,256/83,178	3,466/44,215		0.72 (0.68 to 0.76)	< 0.0001
Omicron	3,758/43,047	3,795/38,253		0.87 (0.83 to 0.92)	< 0.0001
Maximum oxygenation in index hospitalization					
No supplemental oxygen charges	4,806/73,859	9,055/99,030		0.70 (0.67 to 0.73)	< 0.0001
Low-flow oxygen	7,025/115,923	6,181/68,389		0.73 (0.70 to 0.76)	< 0.0001
High-flow oxygen/NIV	3,379/50,029	1,834/19,815		0.82 (0.77 to 0.87)	< 0.0001
IMV/ECMO	570/8,974	367/4,582		0.87 (0.76 to 1.01)	0.0613

- **A statistically significant reduction in the likelihood of 30-day all-cause readmission was observed for all supplemental oxygen levels**, except in the IMV/ECMO group, which did not meet statistical significance due to low sample size in this group[28]

IMPORTANT SAFETY INFORMATION (cont'd)

Dosage and administration (cont'd)

- **Treatment duration:**
  - — For patients who **are hospitalized**, VEKLURY should be initiated as soon as possible after diagnosis of symptomatic COVID-19.
  - — For patients who are hospitalized and do not require invasive mechanical ventilation and/or ECMO, the recommended treatment duration is 5 days. If a patient does not demonstrate clinical improvement, treatment may be extended up to 5 additional days, for a total treatment duration of up to 10 days.
  - — For patients who are hospitalized and require invasive mechanical ventilation and/or ECMO, the recommended total treatment duration is 10 days.
  - — For patients who are **not hospitalized**, diagnosed with mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization or death, the recommended total treatment duration is 3 days. VEKLURY should be initiated as soon as possible after diagnosis of symptomatic COVID-19 and within 7 days of symptom onset for outpatient use.

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VEKLURY is administered via intravenous infusion[1]

Recommended dosing

Adult and pediatric patients weighing ≥40 kg should receive:

DAY 1 — 200 mg — Loading dose of 200 mg IV

DAYS AFTER — 100 mg — Once-daily maintenance dose of 100 mg IV

Pediatric patients ≥28 days old and weighing ≥3 kg to <40 kg should receive:

DAY 1 — 5 mg/kg — Loading dose of 5 mg/kg IV

DAYS AFTER — 2.5 mg/kg — Once-daily maintenance dose of 2.5 mg/kg IV

Pediatric patients (including term[‖‖] neonates and infants) from birth to <28 days old and weighing ≥1.5 kg, and pediatric patients ≥28 days old and weighing 1.5 kg to <3 kg should receive[¶¶]:

DAY 1 — 2.5 mg/kg — Loading dose of 2.5 mg/kg IV

DAYS AFTER — 1.25 mg/kg — Once-daily maintenance dose of 1.25 mg/kg IV

Recommended total treatment duration

Flexible infusion time between **30** and **120** minutes

3 days — For patients who are NOT hospitalized, have mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization or death

5 days — For hospitalized patients NOT requiring invasive mechanical ventilation and/or ECMO

If a patient does not demonstrate clinical improvement, treatment may be extended for up to 5 additional days for a total treatment duration of up to 10 days

10 days — For hospitalized patients requiring invasive mechanical ventilation and/or ECMO

[‖‖]Gestational age >37 weeks.

[¶¶]For pediatric patients weighing ≥1.5 kg to <40 kg, a small 0.9% sodium chloride injection infusion bag (eg, 25 mL, 50 mL, or 100 mL) or an appropriately sized syringe should be used for pediatric dosing. A syringe and syringe pump may be used for infusion volumes <50 mL.

IMPORTANT SAFETY INFORMATION (cont'd)

Dosage and administration (cont'd)

- **Testing prior to and during treatment:** Perform hepatic laboratory and prothrombin time testing prior to initiating VEKLURY and during use as clinically appropriate.
- **Renal impairment:** No dosage adjustment of VEKLURY is recommended in patients with any degree of renal impairment, including patients on dialysis. VEKLURY may be administered without regard to the timing of dialysis.

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Summary

VEKLURY reduced disease progression and recovery time, and demonstrated real-world readmission outcomes across a broad range of COVID-19 severity[1,2,26]

87% **Lower risk of COVID-19–related hospitalization** from any cause by Day 28 when treated with VEKLURY vs placebo in the PINETREE study

- 0.7% of patients treated with VEKLURY (n=279) compared to 5.3% of patients treated with placebo (n=283) had a COVID-19–related hospitalization or death from any cause by Day 28; HR: 0.13 (95% CI, 0.03 to 0.59), *P* = 0.008. No deaths occurred in either arm

5 **Days shorter recovery time** in the overall ACTT-1 study population

- Median 10 days with VEKLURY (n=541) vs 15 days with placebo (n=521); recovery rate ratio: 1.29 (95% CI, 1.12 to 1.49), *P* < 0.001

The adverse reaction frequency of VEKLURY and placebo were comparable in both the ACTT-1 and PINETREE studies. The most common adverse reaction (≥5%) in patients receiving VEKLURY was nausea.

The results above are from PINETREE (N=562), a placebo-controlled trial in nonhospitalized patients with mild-to-moderate COVID-19, and ACTT-1 (N=1062), a placebo-controlled trial in hospitalized patients with mild, moderate, or severe disease.

40% reduced likelihood of 30-day COVID-19–related readmission

- Patients treated with VEKLURY compared to patients who did not receive VEKLURY in the overall cohort; aOR: 0.60 (95% CI, 0.58 to 0.62), *P* < 0.0001; N=440,601[##]

27% reduced likelihood of 30-day all-cause readmission

- Patients treated with VEKLURY compared to patients who did not receive VEKLURY in the overall cohort; aOR: 0.73 (95% CI, 0.72 to 0.75), *P* < 0.0001; N=440,601[##]

Real-world studies should be interpreted based on the type and size of the source datasets and the methodologies used in order to mitigate potential confounding bias. Real-world data should be considered carefully in the context of all available data; results may vary between studies.

[##]Results were from a large, real-world, retrospective, observational study that analyzed data from May 2020 through April 2022 and evaluated 30-day readmission to the same hospital after COVID-19 hospitalization.

IMPORTANT SAFETY INFORMATION (cont'd)

Pregnancy and lactation

- **Pregnancy:** A pregnancy registry has been established for VEKLURY. Available clinical trial data for VEKLURY in pregnant women have not identified a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes following second- and third-trimester exposure. There are insufficient data to evaluate the risk of VEKLURY exposure during the first trimester. Maternal and fetal risks are associated with untreated COVID-19 in pregnancy.
- **Lactation:** VEKLURY can pass into breast milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for VEKLURY and any potential adverse effects on the breastfed child from VEKLURY or from an underlying maternal condition. Breastfeeding individuals with COVID-19 should follow practices according to clinical guidelines to avoid exposing the infant to COVID-19.

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#1 PRESCRIBED ANTIVIRAL

FOR PATIENTS HOSPITALIZED WITH COVID-19[29]

Premier, Inc., and HealthVerity, Inc.; 03/2023 to 02/2024.

3.1+ million US patients treated with VEKLURY[30]

Gilead Sciences, Inc.; 07/2020 to 01/2024.

INDICATION

VEKLURY is indicated for the treatment of COVID-19 in adults and pediatric patients (birth to <18 years of age weighing ≥1.5 kg), who are:

- Hospitalized, or
- Not hospitalized, have mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization or death.

EXPLORE MORE VEKLURY CLINICAL DATA

IMPORTANT SAFETY INFORMATION

Contraindication

- VEKLURY is contraindicated in patients with a history of clinically significant hypersensitivity reactions to VEKLURY or any of its components.

Please see additional Important Safety Information within and full Prescribing Information here.

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