GILEAD | Medical Information

Veklury® (remdesivir) SARS-CoV-2 Variants

This document is in response to your request for information regarding Veklury® (remdesivir [RDV]) and SARS-CoV-2 variants of concern (VOCs), including Omicron subvariants.

Please note that this document may not reflect the most recent information regarding SARS-CoV-2 variants. For currently available information on SARS-CoV-2 variants, please contact your local health authorities.

Some data may be outside of the US FDA-approved prescribing information. In providing this data, Gilead Sciences, Inc. is not making any representation as to its clinical relevance or to the use of any Gilead product(s). For information about the approved conditions of use of any Gilead drug product, please consult the FDA-approved prescribing information.

The full indication, important safety information, and boxed warnings are available at: www.gilead.com/-/media/files/pdfs/medicines/covid-19/veklury/veklury_pi.

Product Labeling[1]

Clinical Pharmacology

Microbiology

Antiviral activity: in cell culture

Based on cell culture susceptibility testing by virus yield reduction assay and/or N protein ELISA assay, RDV retained similar antiviral activity against clinical isolates of SARS-CoV-2 variants compared to an earlier lineage SARS-CoV-2 (lineage A) isolate, including Alpha (B.1.1.7), Beta (B.1.351), Gamma (P.1), Delta (B.1.617.2), Epsilon (B.1.429), Zeta (P.2), Iota (B.1.526), Kappa (B.1.617.1), Lambda (C.37), and Omicron variants (including B.1.1.529/BA.1, BA.2, BA.2.12.1, BA.2.75, BA.2.86, BA.4, BA.4.6, BA.5, BF.5, BF.7, BQ.1, BQ.1.1, CH.1.1, EG.1.2, EG.5.1, EG.5.1.4, FL.22, HK.3, HV.1, JN.1, XBB, XBB.1.5, XBB.1.5.72, XBB.1.16, XBB.2.3.2, XBC.1.6, and XBF). For these variants, the EC_{50} fold change values ranged between 0.2 and 2.3 compared to an earlier lineage SARS-CoV-2 (lineage A) isolate. Using the SARS-CoV-2 replicon system, RDV retained similar antiviral activity against Omicron subvariants JN.1.7, JN.1.18, KP.2, KP.3, LB.1, and XBB.1.9.2 compared to the WT reference replicon (lineage B).

Available Data on RDV Use in SARS-CoV-2 Variants

Clinical Trial Data

Currently, there are no phase 3 clinical trial data available on the use of RDV for the treatment of COVID-19 in patients infected with currently circulating SARS-CoV-2 VOCs.

In Vitro Data

Rega Institute

In vitro testing was conducted by the Rega Institute in Belgium, and results indicated that RDV and its parent nucleoside, GS-441524, retained activity against the Alpha, Beta, Gamma, Delta, and Omicron variants.[2]

Gilead studies

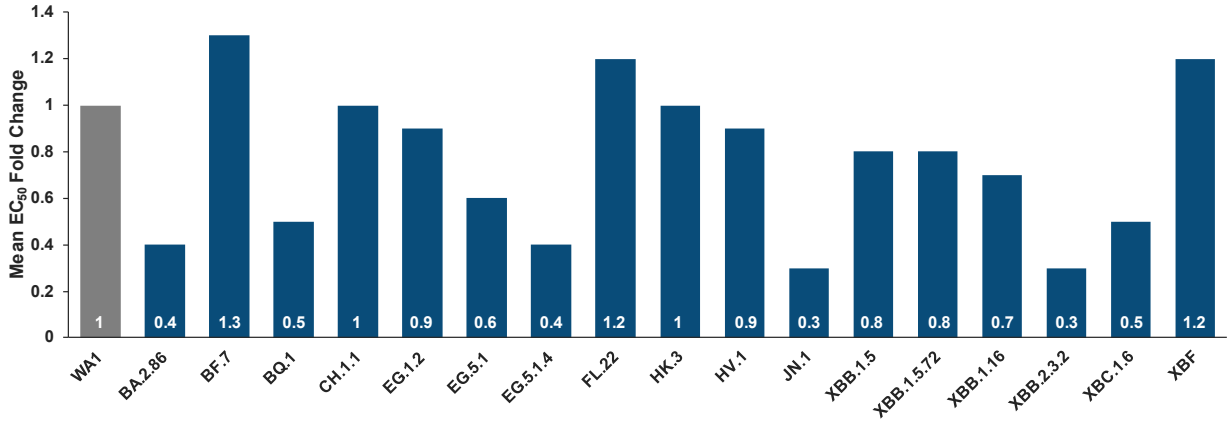
Antiviral activity of RDV against Omicron subvariant clinical isolates (IDWeek 2025)[3]

A study assessed >17 million Omicron subvariants (May 2024–June 2025) using clinical isolates and site-directed mutations in a replicon system. Compared with earlier Omicron subvariants, one Nsp12 substitution (D284Y) was identified in ≥75% of Nsp12 sequences of the subvariant NB.1.8.1 and was also identified in the BA.2.86.1, JN.1.7, KP.2, KP.3.3, KP.3.1.1, LP8.1, XBB.2, XEC, and XFG subvariants. RDV maintained in vitro antiviral activity against Omicron subvariants BA.2.86.1, JN.1.7, KP.2, KP.3.1.1, KP.3.3, XBB.2, and XEC with ≤0.86-fold change compared with the WA1 reference strain. The range of mean RDV EC_{50} values for all tested Omicron subvariants was 21.8 to 87.3 nM, with a 0.14-fold change (BA.2.86.1) to 0.63-fold change (KP.2) compared with WA1 (EC_{50} range, 72.4–190.9; mean EC_{50}, 126.9 nM). Using the replicon system, Omicron subvariants LP.8.1, NB.1.8.1, and XFG retained susceptibility to RDV, with a mean EC_{50} of 12.6 nM (LP.8.1 and XFG) and 16.6 nM (NB.1.8.1), representing a 1.1-fold and 1.2-fold change, respectively, compared with the SH01 reference strain. When the D284Y Nsp substitution was introduced into the replicon system, the mean RDV EC_{50} value was 11.8 nM, with a 0.8-fold change compared with the SH01 reference strain.

Antiviral activity of RDV against Omicron subvariant clinical isolates (Viruses 2025)[4]

Another study analyzed >2 million Omicron subvariant sequences and found 29 polymorphisms in Nsp12 compared with the Wuhan reference strain. New defining mutations observed in ≥75% of Nsp12 sequences included the following: P323L (in all Omicron variants), Y273H (in BQ.1), G671S (in XBB.1.5, CH.1.1, and XBF), D63N (in HK.3), and G823insD (in XBC.1.6). RDV maintained similar in vitro antiviral activity as observed with the reference strain (WA1) against all tested Omicron subvariants: BA.2.86, BF.7, BQ.1, CH.1.1, EG.1.2, EG.5.1, EG.5.1.4, FL.22, HK.3, HV.1, JN.1, XBB.1.5, XBB.1.5.72, XBB.1.16, XBB.2.3.2, XBC.1.6, and XBF. Mean RDV EC_{50} values for Omicron subvariants ranged from 21.8 nM (XBB.2.3.2) to 155 nM (CH.1.1), with a 0.28- (JN.1) to 1.25-fold (BF.7) change compared with the WA1 reference strain (Figure 1).

Figure 1. RDV EC_{50} Fold Change[a] From the WA1 Reference Strain Against Clinical Isolates of SARS-CoV-2 Omicron Subvariants[4]

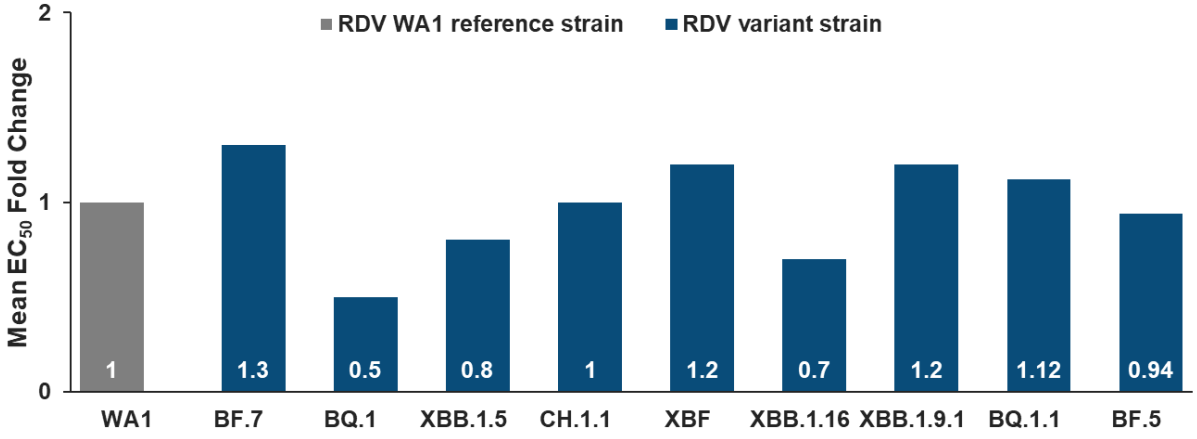


[a]Fold change was calculated for ≥2 experiments, and a mean fold change was calculated with these values. All EC_{50} fold change values were within the variability of the assay.
Note: Values were rounded to the tenths place.

Antiviral activity of RDV against Omicron subvariant clinical isolates (IDWeek 2023)[5]

A study analyzed the antiviral activity of RDV against recent SARS-CoV-2 Omicron VOCs using subvariant clinical isolates. The results confirmed that RDV retained in vitro antiviral activity against the clinical isolates of Omicron subvariants that were assessed (BF.7, BQ.1, XBB.1.5, CH.1.1, XBF, XBB.1.16, XBB.1.9.1), with potencies similar to those for the WA1 reference strain. The mean RDV EC_{50} values ranged from 50.8 nM in subvariant BQ1 to 155.1 nM in subvariant CH.1.1, which represented a 0.5- to 1.3-fold change compared with the reference strain, WA1 (EC_{50}=114.6 nM; Figure 2).

Figure 2. RDV EC_{50} Fold Changes Relative to WT Reference in Clinical Isolates of SARS-CoV-2 Omicron Subvariants[5]



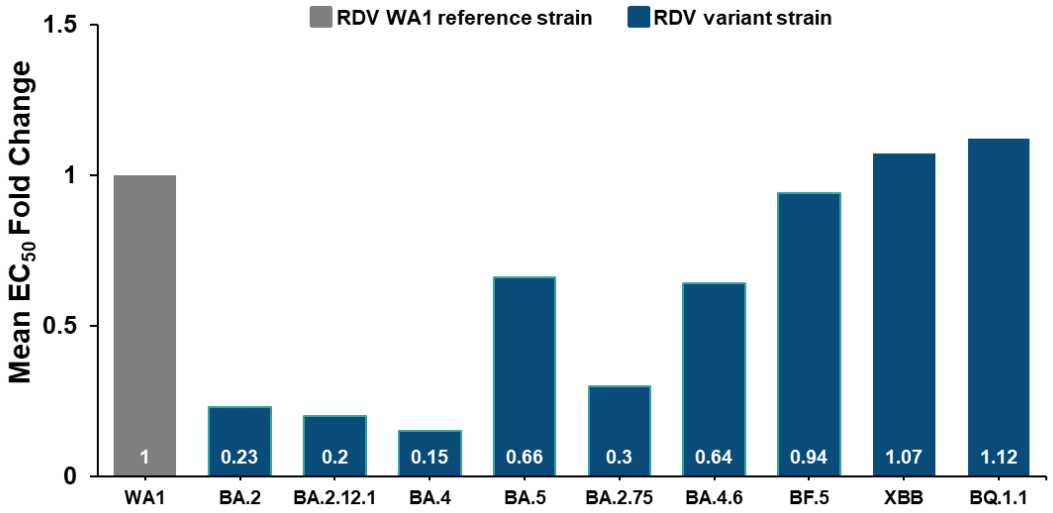
Note: A fold change was calculated for each experiment, and a mean fold change was calculated with these values. Values below 2.8-fold were within the variability of the assay.

Antiviral activity of RDV against Omicron subvariant clinical isolates (CROI 2023)[6]

A Gilead and University of Washington study assessed the antiviral activity of RDV against SARS-CoV-2 Omicron subvariant clinical isolates. Results from this study confirmed that

RDV retained in vitro antiviral activity against the clinical isolates of Omicron subvariants evaluated (BA.2, BA.2.12.1, BA.4, BA.5, BA.2.75, BA.4.6, BF.5, XBB, and BQ.1.1), with potencies comparable to those of the WT reference. The mean RDV EC_{50} values for tested Omicron subvariants ranged from 24.5 nM (BA.2) to 134.1 nM (BF.5), which represented a 0.2- to 1.1-fold change compared with the values for the reference strain, WA1 (mean EC_{50}=121.6 nM; Figure 3).

Figure 3. RDV EC_{50} Fold Changes[a] Relative to WT Reference in Clinical Isolates of SARS-CoV-2 Omicron Subvariants[6]



[a]Values are the mean ± SD of the results of at least two independent experiments.

Nsp12 protein conservation across Delta and Omicron VOCs[7]

Another Gilead study analyzed nearly 6 million publicly available variant isolate sequences and confirmed that the Nsp12 protein, the RNA polymerase target of RDV, was highly conserved across all variants tested, including Delta and Omicron. Further in vitro characterization confirmed that none of the few identified Nsp12 mutations prevalent in some of the SARS-CoV-2 variants affected the virus's susceptibility to RDV.

References

1. Enclosed. Gilead Sciences Inc. Veklury® (remdesivir) for injection, for intravenous use. VEKLURY® (remdesivir) injection, for intravenous use. U.S. Prescribing Information. Foster City, CA.
2. Vangeel L, Chiu W, De Jonghe S, et al. Remdesivir, Molnupiravir and Nirmatrelvir remain active against SARS-CoV-2 Omicron and other variants of concern. *Antiviral Res.* 2022;198:105252.
3. Rodriguez L, Zamora JLR, Li J, et al. Remdesivir and Obeldesivir Retain Potent Activity Against SARS-CoV-2 Omicron Variants. [Poster #P-1276]. Paper presented at: IDWeek; October 19-22, 2025; Atlanta, GA.
4. Rodriguez L, Zamora JLR, Han D, et al. Remdesivir and Obeldesivir Retain Potent Antiviral Activity Against SARS-CoV-2 Omicron Variants. *Viruses.* 2025;17(2):168.
5. Rodriguez L, Li J, Han D, et al. Remdesivir and Obeldesivir Retain Potent Activity Against SARS-CoV-2 Omicron Variants [Poster 545]. Paper presented at: IDWeek; October 11-15, 2023; Boston, MA.
6. Rodriguez L. Remdesivir Retains Potent Antiviral Activity Against SARS-CoV-2 Variants of Concern [Poster 562]. Paper presented at: CROI; February 19-22, 2023; Seattle, USA.

7. Pitts J, Li J, Perry JK, et al. Remdesivir and GS-441524 Retain Antiviral Activity against Delta, Omicron, and Other Emergent SARS-CoV-2 Variants. *Antimicrobial Agents and Chemotherapy,.* 2022.

Abbreviations

EC_{50}=half-maximal effective concentration

Nsp12=SARS-CoV-2 RNA-dependent RNA polymerase

RDV=remdesivir
VOCs=variants of concern
WT=wild-type

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

For any additional questions, please contact Gilead Medical Information at:

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FDA MedWatch Program by ☎ 1-800-FDA-1088 or ✉MedWatch, FDA, 5600 Fishers Ln, Rockville, MD 20852 or 🖱 www.accessdata.fda.gov/scripts/medwatch

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