

Errata to the FDA Briefing Document for March 16, 2023 Antimicrobial Drugs Advisory Committee Meeting

Corrections:

- On page 18, the enrollment end date for EPIC-PEP of April 12, 2022 is incorrect.

The sentence should read as follows: *“Furthermore, the results from EPIC-PEP, which enrolled from September 9, 2021, to March 1, 2022 (a later enrollment period than for EPIC-HR), indicate that even unvaccinated adults were likely to be SARS-CoV-2 seropositive by 2022, presumably from prior infection.”*

- On page 21, “primarily (~99%)” should be deleted from the following sentence: “While the second half of the EPIC-SR trial was conducted from March to June 2022, in a study population primarily (~99%) infected with the SARS-CoV-2 Omicron variant (mostly BA.2-related subvariants), data from this trial were insufficient to directly determine the clinical efficacy of PAXLOVID in patients infected with the Omicron variant and at high risk for severe COVID-19.”

The sentence should read as follows: *“While the second half of the EPIC-SR trial was conducted from March to June 2022, in a study population infected with the SARS-CoV-2 Omicron variant (mostly BA.2-related subvariants), data from this trial were insufficient to directly determine the clinical efficacy of PAXLOVID in patients infected with the Omicron variant and at high risk for severe COVID-19.”*

- On page 22:

- “Of the 10 M_{pro} polymorphisms, 8 did not significantly affect nirmatrelvir activity in biochemical assays, while 2 (L30I and T45N) have not yet been tested” should be changed.

The sentence should read as follows: *“Nirmatrelvir retained activity against SARS-CoV-2 M_{pro} enzymes with these polymorphisms in biochemical assays (K_i fold-change <3).”*

- “~99%” should be changed to “100%” in the following sentence: “~99% of subjects with available data were infected with the SARS-CoV-2 Omicron variant (mostly BA.2-related subvariants).

The sentence should read as follows: *“100% of subjects with available data were infected with the SARS-CoV-2 Omicron variant (mostly BA.2-related subvariants).”*

- In footnote 7 on page 18 and in the references, the website https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-count-pop12 was accessed on January 31, 2023, not on September 27, 2022.