GI and Liver COVID Task Force Statement on the Hepatic Safety of Molnupiravir as an Oral Antiviral Treatment for COVID-19

Clinical trials have shown that molnupiravir is well-tolerated and does not require dose modifications for patients with impaired liver function.

Healthy volunteers in the first-in-human phase 1 clinical trial of molnupiravir showed no liver-related adverse events. Similar to other nucleoside analogues, molnupiravir is renally metabolized and cleared. Dose escalation did not result in any serious adverse events.[1]

In the phase 1B/2A AGILE trial, one out of four participants in the 600mg group had elevated ALT and GGT. None of the participants in the 400mg group and the 800mg group had abnormal ALT and GGT. All adverse events were mild.[2]

In a phase 2A trial (preprint) with 202 participants, elevated ALT was seen in more than four participants, but did not reach 5% of the total number of participants in any of the groups that received placebo and molnupiravir 200mg, 400mg and 800mg. Adverse events were similar across all groups.[3]

The phase 3 MOVe-OUT clinical trial showed similar adverse events in the placebo and molnupiravir groups. No liver-related adverse events were reported.[4]

No dose modifications are needed for patients with hepatic impairment.[5] Cirrhotic patients are included in the UK National Health Service list of high-risk groups eligible to receive molnupiravir.[6]

Short-course molnupiravir treatment i.e., 800mg twice daily for 5 days, is indicated for mild to moderate COVID-19 infection among adult patients (at least 18 years old) at high risk for progression to clinically severe COVID-19. Molnupiravir should be prescribed with caution to women with childbearing potential and their partners. Refer to "Fact Sheet for Healthcare Providers: Emergency Use Authorization for Molnupiravir" (https://www.fda.gov/media/155054/download)[5]

Molnupiravir is currently available under Emergency Use Authorization (EUA) issued on December 22, 2021 by the Philippine Food and Drug Administration (FDA).[5,7] It may be accessed from health care facilities or physicians with Compassionate Special Permit (CSP) issued by the Philippine FDA.

Patients on molnupiravir must be monitored for Adverse Drug Reaction (ADR). Suspected ADR must be immediately reported to the Philippine FDA through attending physicians, dispensing unit, or FDA Online Adverse Drug Reaction Reporting link: https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=PH

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