December 21, 2021

CLINICAL HOLD OF ALL ONGOING TRIALS WITH LENACAPAVIR INJECTION

Further to discussion with the U.S. Food and Drug Administration (FDA), Gilead Sciences is writing to inform you that the FDA has placed a full clinical hold on the use of injectable lenacapavir in borosilicate vials in all ongoing clinical studies for HIV treatment and prevention. The clinical hold is due to emerging concerns about the compatibility of vials made of borosilicate glass with lenacapavir solution, which could potentially lead to the formation of sub-visible glass particles in the solution of lenacapavir. We remain confident about the future potential of lenacapavir and are committed to resolving this vial quality issue.

As the borosilicate vials are used for LEN injection, which is supplied to fulfil compassionate use requests, we are taking the same measures as in our clinical studies to inform you of immediate actions. During the clinical hold, dosing of injectable lenacapavir in any patient is not permitted. If your patient is due for their injectable lenacapavir in the next few weeks, we ask that you contact us to discuss options.

To document these communications and decisions from Gilead, we request that you submit this letter to your ethics committee as required and retain a copy of this notification in your study specific files. Gilead has informed the regulatory authorities of those countries where LEN compassionate use has been provided.

We are committed to working diligently with FDA to resolve this glass vial quality issue and resume injectable lenacapavir dosing in a timely fashion. We will continue to communicate any important updates over the next few weeks and work with you to ensure careful oversight and clinical management of your patient. In the meantime, the entire Gilead team is available to discuss these issues at any time by email or phone, please in the first instance contact your local Gilead office.

We thank you for your partnership in this work.

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