Treatment: Lenacapavir on Track

Lenacapavir, a long-acting HIV capsid inhibitor, is back on track after the Food and Drug Administration lifted a clinical hold on the drug.

August 15, 2022 By Liz Highleyman

Lenacapavir, a long-acting HIV capsid inhibitor, is back on track after the Food and Drug Administration (FDA) lifted a clinical hold on the drug. The injectable antiretroviral, administered every six months, has shown promise for both heavily treatment-experienced people with multidrug-resistant virus and those starting antiretroviral therapy for the first time. Lenacapavir is also being studied for pre-exposure prophylaxis (PrEP). In December 2021, the FDA put a clinical hold on lenacapavir due to concerns about the type of borosilicate glass vial used for the injectable formulation, which could result in tiny glass particles in the medication. But in May, the FDA lifted the hold and allowed clinical trials to resume, after Gilead Sciences presented a plan to switch to vials made from aluminosilicate glass. In late June, the company announced that it has resubmitted a New Drug Application for FDA approval of lenacapavir for people with highly resistant HIV, the group with the greatest need for new treatment options.
