No Approval (Yet) for Merck's HIV Drug Vicriviroc

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Merck will delay its request for U.S. Food and Drug Administration (FDA) approval for vicriviroc, an experimental CCR5 antagonist, after it failed in two late-stage clinical trials involving treatment-experienced patients, The Wall Street Journal reports. The drug, which Merck obtained after purchasing Schering-Plough, will continue to be explored in clinical trials involving people living with HIV new to antiretroviral (ARV) therapy.

Vicriviroc, a once-daily drug that works similarly to ViiV Healthcare's Selzentry (maraviroc), was initially scheduled to be approved this year, based on the successful completion of two Phase III clinical trials involving HIV-positive participants no longer responding effectively to current ARVs. According to the Journal, Merck said in a posting on its website that the drug "did not meet the primary efficacy endpoint" in these studies.

Though Merck has not yet publicly shared data from the clinical trials, it has already discussed the apparent lackluster results with the FDA and will be presenting the findings at the 17th Conference on Retroviruses and Opportunistic Infections in February.

Merck will continue its Phase II studies involving HIV-positive individuals who haven't received earlier treatment. The company also said treatment-experienced patients who benefited from vicriviroc will continue to have access to it.

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