Selzentry Wins Approval Recommendation for First-Line Treatment

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A Food and Drug Administration (FDA) advisory panel has recommended that the FDA grant approval to Selzentry (maraviroc) for HIV-positive people who have never used antiretroviral (ARV) therapy, according to a press release by Pfizer. Selzentry is currently approved for people who are more heavily treatment experienced.

Selzentry is an HIV entry inhibitor that stops HIV from entering cells by blocking a key cell receptor called CCR5. HIV can use other cell receptors, however, so a tropism test is required before starting Selzentry to ensure that a person's virus uses only CCR5. This is the case for about half of people who are more heavily treatment experienced and in the majority of people who've never taken HIV treatment before.

The data reviewed by the advisory panel included Phase III study results from the MERIT clinical trial, which compared Selzentry with Sustiva (efavirenz) in first-time treatment takers, and a later reanalysis of those data using a newer, more sensitive tropism test. In an original analysis, significantly more people experienced virologic failure in the Selzentry arm. When the data were reanalyzed using a more sensitive tropism test—which found that some people's HIV had originally been judged incorrectly to use only CCR5—the drug was found to be comparable to Sustiva.

Though the FDA is not bound to follow the recommendation of its advisory panels, it typically does.