Treatment: Fostemsavir Filed

ViiV applies for FDA approval of HIV drug fostemsavir

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ViiV Healthcare has filed a new drug application for Food and Drug Administration (FDA) approval of fostemsavir, the first-in-class HIV attachment inhibitor. The drug binds to the spikes on HIV's outer coat and prevents the virus from attaching to T cells. The new antiretroviral is meant for people with extensive prior treatment experience and multidrug-resistant HIV who cannot put together a fully suppressive regimen using existing medications. The application is supported by data from the Phase III BRIGHTE study. Among the 272 participants who could still use one or two active approved antiretrovirals, 60% had an undetectable viral load at 96 weeks. Among an additional 99 people with no available fully active approved meds, 37% achieved viral suppression. CD4 counts rose, with the greatest improvement seen in those with the worst immune impairment. Fostemsavir has been granted FDA fast-track status, which aims to speed up approval of promising therapies for unmet medical needs.

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