FDA Grants Priority Review Designation for ViiV's Dolutegravir

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The U.S. Food and Drug Administration (FDA) has granted ViiV Healthcare priority review designation for the company's new integrase inhibitor dolutegravir. Representing a joint effort between GlaxoSmithKline, Pfizer and Shionogi, ViiV submitted dolutegravir to the FDA for use in combination with other antiretrovirals (ARV) in adults and adolescents. The priority review indicates that, if dolutegravir is approved, the drug has to potential to either provide significantly improved therapy as compared with other ARVs or to provide a treatment where there is no adequate existing therapy.

ViiV submitted its application for dolutegravir to the FDA in December 2012 on the basis of results from four Phase III clinical trials. These trials included a total of 2,553 HIV-positive patients from a wide array of treatment backgrounds: from treatment-naive to salvage, in which all other regimens have been exhausted.

The FDA is scheduled to issue a decision on the drug's approval by August 17.

To read the Yahoo News report, click here.

To read the ViiV release, click here.