Early Access Program for Integrase Inhibitor Dolutegravir Launched

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ViiV Healthcare and Shionogi have launched an expanded access program (EAP) for its integrase inhibitor dolutegravir (S/GSK134957), according to details now available on ViiV's website.

The new program is of potential importance for people living with HIV in need of new treatment options, including those with resistance to Merck's Isentress (raltegravir) or Gilead Science's experimental integrase inhibitor elvitegravir, and are unable to access the companies' Phase III clinical trials of the drug. Activists warn, however, that enrollment in this EAP requires caution, particularly for those who have no other fully active antiretrovirals (ARVs) to combine with dolutegravir and run the risk of developing rapid resistance to the drug.

EAPs essentially allow new antiretrovirals (ARVs) to be made available before they are approved to people living with serious or life-threatening conditions who are unable to participate in clinical trials. They are permitted by regulatory agencies, such as the U.S. Food and Drug Administration (FDA), under special circumstances, where the potential benefits may outweigh the risks.

The dolutegravir EAP will be continued until the drug has been approved by the FDA and is made available through pharmacies.

The dolutegravir EAP is open to all men and women 18 years of age and older who are unable to construct a viable ARV regimen with commercially available medications. To qualify, all patients must also have a viral load of at least 400 copies within three months of enrolling and have documented HIV resistance to Isentress or elvitegravir.

Among the exclusion criteria—factors that may disqualify someone from participating in the EAP—include signs of significant liver or kidney impairment, pregnancy or breastfeeding and being eligible, and having access to, an actively enrolling dolutegravir Phase III clinical trial.

The dolutegravir EAP is now open and accepting participants in the United States and Canada. For people living with HIV in Europe and other regions, ViiV and Shionogi anticipate that its EAP will start to open by April 2012, as local regulatory and ethics approvals are obtained.

To enroll in the EAP, patients must be working with a health care provider who has been approved to participate in the program. If a health care provider is not already participating, he or she may

contact PAREXEL, an operating partner that has been designated by the companies to oversee the program.

Health care providers can learn more by contacting PAREXEL at: dolutegravir-eap@parexel.com.

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