Gilead Files For FDA Approval of Integrase Inhibitor–Based HIV Regimen

The company will soon seek U.S. and European approval of a single-tablet regimen contaning bictegravir plus Descovy.

June 13, 2017

Gilead Sciences has filed a new drug application (NDA) with the U.S. Food and Drug Administration (FDA) for approval of a fixed-dose, single-tablet HIV treatment regimen including the investigational integrase inhibitor bictegravir and the contents of Descovy (emtricitabine/tenofovir alafenamide).

The NDA is based on 48-week results from four ongoing Phase III trials of the triple-drug combination tablet, which all showed that the treatment was non-inferior, or as effective as, various approved antiretroviral regimens.

Studies 1489 and 1490 are double-blind trials each including 600 participants new to HIV treatment. Half of the participants in each study were randomized to receive bictegravir plus Descovy. In Study 1489, the other half of the participants were randomized to receive Triumeq (dolutegravir/abacavir/lamivudine); in Study 1490, the other half were randomized to receive Tivicay (dolutegravir) plus Descovy. These studies will remain blinded (meaning that participants will not know which regimen they received) through week 144.

In these two studies, the researchers were primarily looking at whether comparable proportions of participants had an undetectable (fully suppressed) viral load (less than 50) at week 48 of treatment.

Study 1844 includes 520 individuals who started the study with a fully suppressed viral load while taking either Triumeq or Tivicay plus Epzicom (abacavir/lamivudine), which has the same components as Triumeq. They were evenly randomized in a blinded manner to stay on their original regimen or switch to bictegravir plus Descovy.

Study 1878 includes 520 participants who had a fully suppressed viral load on a regimen including either the boosted protease inhibitor Prezista (darunavir) or Reyataz (atazanavir) plus a nucleoside/nucleotide backbone of Epzicom or Truvada (tenofovir disoproxil fumarate/emtricitabine). They were randomized on an open-label basis (meaning that they knew what they were receiving) to stay on their current regimen or switch to bictegravir plus Descovy.

After 48 weeks, all participants received bictegravir plus Descovy on an open-label basis.

In Studies 1844 and 1878, the researchers were primarily looking at whether comparable proportions of participants had a detectable viral load at week 48 of treatment.

In Studies 1844 and 1878, the researchers were primarily looking at whether comparable proportions of participants had an undetectable viral load at week 48 of treatment.

In Studies 1489 and 1490, comparable proportions of participants had an undetectable viral load, while in Studies 1844 and 1878, comparable proportions of participants had a detectable viral load at week 48 of treatment.

Bictegravir plus Descovy proved well tolerated in all the studies. No one discontinued treatment with the regimen because of kidney-related health problems. No one randomized to receive the regimen developed drug resistance as a result. One person who was randomized to the protease inhibitor arm in Study 1878 developed a resistance mutation to Ziagen (abacavir).

Gilead intends to submit more detailed results from these studies at scientific conferences this year. The company also intends to seek European approval of the triple-drug treatment in the third quarter of 2017.

To read a press release about the research, click here.
