FDA Approves HIV Treatment Boosting Agent Tybost (Cobicistat)

September 25, 2014

On September 24, the U.S. Food and Drug Administration approved Gilead Sciences' Tybost (cobicistat) as a boosting agent to raise the drug levels of Reyataz (atazanavir) or Prezista (darunavir) in combination with other antiretrovirals (ARVs) to treat HIV. The drug is the second boosting agent to hit the market, after the widely used Norvir (ritonavir).

Recommended ARV regimens include 150 milligrams of Tybost once daily plus 300 mg of Reyataz once daily among treatment-naive and treatment-experienced people with HIV, or 150 mg of Tybost once daily plus 800 mg of Prezista once daily among treatment-naive people with HIV and treatment-experienced people with HIV who have no Prezista resistance associated substitutions.

The approval of the Reyataz and Tybost combination was based on a Phase II and III trial among treatment-naive participants that compared that pair of drugs with Reyataz and Norvir; each combination was given with Truvada (tenofovir/emtricitabine). The research found that the regimen with Tybost was "non-inferior" to the regimen with Norvir.

The approval of the Prezista and Tybost combination was based on a multiple-dose trial in HIV-negative participants that compared the bioavailability of that combination with Prezista and Norvir.

The most common side effects reported by those taking Reyataz and Tybost, occurring in more than 10 percent of cases, were jaundice, jaundice of the eyes and nausea.

To read the FDA press release, click here.