Cobicistat Challenge to Norvir (Ritonavir)

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A series of applications submitted to the U.S. Food and Drug Administration (FDA) in April have Gilead Sciences' cobicistat poised to possibly nudge aside Norvir (ritonavir) as a "boosting agent" that raises the blood levels of two specific antiretrovirals (ARVs). So far, cobicistat has only been approved as a component of the fixed-dose combination treatment Stribild (elvitegravir/tenofovir/emtricitabine/cobicistat).

Now Gilead has requested specific approval for cobicistat's use in combination with Bristol-Myers Squibb's Reyataz (atazanavir) and also with Janssen's Prezista (darunavir). Each of those two companies has filed its own application to the FDA for fixed-dose, combination tablets of its respective ARVs in combination with the boosting agent.

Tim Horn, HIV project director at Treatment Action Group, says that while cobicistat doesn't necessarily have a safety advantage over Norvir, the question remains whether the combination pills will be cheaper than Norvir when paired with Reyataz or Prezista as separate tablets.

"Whether a somewhat simplified regimen—one with cobicistat that involves taking two pills once a day versus one with Norvir that involves taking three pills once a day—merits a higher price tag and an increased financial burden to the health care system and HIV-positive people is seriously questionable," Horn says.

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