BMS HIV Attachment Inhibitor Gets FDA Breakthrough Nod

July 22, 2015

The U.S. Food and Drug Administration (FDA) has granted a breakthrough designation to Bristol-Myers Squibb's investigational HIV attachment inhibitor BMS-663068 (fostemsavir), The Wall Street Journal reports. The designation may expedite the development and review of the drug's use among heavily treatment-experienced people with HIV.

Heavily treatment-experienced individuals are not able to find an effective three-drug antiretroviral (ARV) regimen as a result of drug resistance, problems tolerating specific drugs, or conflicts between certain ARVs and other medications or conditions.

BMS-6630868 is an oral prodrug of the molecule BMS-626529. Prodrugs rely on the body to metabolize them into an active form. This prodrug, if approved, would be the first in a new class of drugs. While entry inhibitors attack HIV after the virus attaches to immune cells, this attachment inhibitor targets an earlier point in the viral lifecycle, apparently preventing the virus' interaction with the cell at all, keeping it from entering the cell.

The breakthrough designation is based on 48-week results from the Phase IIb study that compared BMS-663068 to Norvir (ritonavir)–boosted Reyataz (atazanavir) among treatment-experienced people with HIV who also took Isentress (raltegravir) and Viread (tenofovir).

A Phase III trial of BMS-663068 in heavily treatment-experienced participants began in February.

To read the Wall Street Journal article, click here.

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