High HBV and HIV Suppression With Treatment of HIV/HBV Coinfection in B/F/TAF Studies

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We extend our thanks to the participants, their families, and all participating study investigators and staff

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BACKGROUND/AIMS & METHODS:

- Hepatitis B virus (HBV) is a common coinfection in HIV patients
  - Estimates range from 3 to 6 million individuals coinfected with HIV and HBV with coinfection rates up to 25%[1]
- Coinfection worsens morbidity and mortality synergistically
  - HIV/HBV-coinfected patients have higher HBV DNA levels, are 5 times more likely to progress to chronic HBV than HBV mono-infected patients, and have 2-3 times higher risks of cirrhosis and hepatocellular carcinoma
- Tenofovir alafenamide (TAF) is active against HBV and is approved for treatment of HBV as a single agent[2,3]
- Current HIV guidelines recommend TAF or tenofovir disoproxil fumarate (TDF) as components of regimens for treatment of patients coinfected with HIV and HBV[4-6]
- We report HBV and HIV outcomes in antiretroviral treatment (ART)-naïve and experienced HIV/HBV-coinfected patients enrolled in 2 studies of coformulated bictegravir/emtricitabine/TAF (B/F/TAF)
  - Active HBV infection = HBsAg positive or HBsAg negative, HBsAb negative, HBcAb positive with HBVDNA ≥ 20IU/mL on or prior to 1st dose date

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5. European AIDS Clinical Society. Guidelines. Version 9.0, Oct 2017; www.eacsociety.org/files/guidelines_9.0-english.pdf.
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RESULTS:

Study 1490 Results: HIV/HBV-Coinfected Treatment-Naïve Participants[7]

- 13/645 treatment-naïve participants had HIV/HBV at BL and HBV DNA results at Week 48
  - 11 (85%) achieved HBV DNA <29 IU/mL at Week 48
- 2/13 participants (15%) had HBV DNA ≥29 IU/mL at Week 48
  - Both had HBV DNA >170,000,000 IU/mL at BL and were HBeAg positive
  - Week 48 HBV DNA results were 303 IU/mL and 80 IU/mL
- 2/12 HBsAg+ participants (15%) experienced HBsAg loss: both seroconverted to HBsAb-positive status at Week 48
- All 13 participants had HIV-1 RNA <50 copies/mL at Week 48

Study 1878 Results: HIV/HBV-Co-infected Treatment-Experienced Participants

- Participants with active HBV infection were allowed to enroll in Study 1878.
- 14/577 participants (2%) had HIV/HBV coinfection at BL were randomized and treated; 2 participants discontinued treatment unrelated to study drug and did not have Week 48 HBV DNA assessments.
- All 12 participants with Week 48 data had HIV-1 RNA <50 copies/mL at Week 4

HBV DNA <29 IU/mL, n/n (%)	B/F/TAF, n=8	SBR, n=6
BL	8	4
Week 48	8/8 (100)	4/4 (100)

7. Sax PE, et al. Lancet 2017;390:2073-82.

CONCLUSIONS/IMPLICATIONS:

- B/F/TAF- and F/TAF-containing regimens produced robust HBV antiviral responses in treatment-naïve participants with HIV/HBV coinfection
  - 85% of participants (11/13) achieved HBV DNA <29 IU/mL at Week 48
  - No participant developed HBV resistance to FTC or TAF
  - 100% had HIV-1 RNA <50 copies/mL at Week 48
- B/F/TAF- and F/TDF-containing regimens maintained HIV-1 virologic suppression in HIV/HBV-coinfected participants with HIV-1 suppression at study entry
- No participant treated with B/F/TAF, or an F/TAF- or F/TDF containing regimen acquired HBV infection during the studies
- The results confirm findings from prior studies of ART with anti-HBV activity in patients with HIV/HBV coinfection
  - Higher HBsAb seroconversion rates than in chronic HBV mono-infection[8]
  - Not all patients become undetectable after 48 weeks in the setting of high HBV DNA at baseline[9]
    - To date, there is no evidence of HBV resistance to F/TAF-containing regimens
- B/F/TAF may be a treatment option for HIV-1–infected patients with HBV coinfection
  - Further studies of HBV treatment and prevention with B/F/TAF and other F/TAF-containing ART regimens are warranted in HIV/HBV-coinfected patients

8. Boesecke C, et al. CROI 2017, abstr 580.
9. Price H, et al. PLoS One 2013;8:e68152.