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### **Week 48 outcomes from the BRAAVE 2020 study: a randomised switch to bicitgravir/emtricitabine/tenofovir alafenamide (B/F/TAF) in African American adults with HIV**

D Hagins

P Kumar

A Wurapa

Indira Brar

*Henry Ford Health*, [ibrar1@hfhs.org](mailto:ibrar1@hfhs.org)

D Berger

*See next page for additional authors*

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**Authors**

D Hagins, P Kumar, A Wurapa, Indira Brar, D Berger, O Osiyemi, C Hileman, M Ramgopal, C McDonald, C Blair, K Andreatta, S E. Collins, D Brainard, G Gohlar, and H Martin

cumulative outcomes from open-label extension (OLE) that followed 144 Weeks (W) of blinded treatment in phase 3 studies in treatment-naïve PWH.

**Method:** We conducted 2 randomised, double-blind, phase 3 studies of B/F/TAF in treatment-naïve adults – Study 1489: B/F/TAF vs dolutegravir/abacavir/lamivudine (DTG/ABC/3TC) and Study 1490: B/F/TAF vs DTG+F/TAF. After completing 144W of blinded treatment, participants were offered to continue on B/F/TAF for 96W in the OLE. Efficacy was assessed as the proportion with HIV-1 RNA <50 copies/mL at each visit after starting B/F/TAF using missing = excluded (M = E) analysis; safety by adverse events (AEs) and laboratory results. Bone mineral density (BMD) in OLE was measured in those randomised to B/F/TAF in Study 1489. We present cumulative results for all participants treated with B/F/TAF in the randomised or OLE phases through a maximum of 192 weeks of follow up (i.e. OLE W48).

**Results:** In Study 1489, 314 participants were randomised to B/F/TAF and 315 to DTG/ABC/3TC; 252 and 254 entered the OLE. In Study 1490, 320 were randomised to B/F/TAF and 325 to DTG+F/TAF; 254 and 265 entered the OLE. Efficacy was >98% after W48 at each study visit through W192 in both studies. Across both studies, only one participant experienced an AE that led to drug discontinuation during the OLE analysis window. Grade 3 or 4 drug-related AEs were rare. In participants initially randomised to B/F/TAF, the median change in weight from baseline to W192 was 4.6kg in Study 1490 and 5.0kg in Study 1489. 13% of participants with baseline osteopaenia in hip and 3% with osteopaenia of the spine improved to normal at W192, 4% with normal baseline hip and 6% with normal baseline spine BMD progressed to osteopenia and none developed osteoporosis.

**Conclusion:** Over 4 years of follow-up in treatment-naïve participants, B/F/TAF was generally well-tolerated and highly efficacious. Similar outcomes were demonstrated in participants who switched from DTG-containing regimens to B/F/TAF.

### **P050 | Week 48 outcomes from the BRAAVE 2020 study: a randomised switch to bicitgravir/emtricitabine/tenofovir alafenamide (B/F/TAF) in African American adults with HIV**

D Hagins<sup>1</sup>, P Kumar<sup>2</sup>, A Wurapa<sup>3</sup>, I Brar<sup>4</sup>, D Berger<sup>5</sup>, O Osiyemi<sup>6</sup>, C Hileman<sup>7</sup>, M Ramgopal<sup>8</sup>, C McDonald<sup>9</sup>, C Blair<sup>10</sup>, K Andreatta<sup>10</sup>, SE Collins<sup>10</sup>, D Brainard<sup>10</sup>, G Gohlar<sup>11</sup> and H Martin<sup>10</sup>

<sup>1</sup>Georgia Department of Public Health, Savannah, USA, <sup>2</sup>MedStar Georgetown University Hospital, Washington, USA, <sup>3</sup>Infectious Disease Specialists of Atlanta, Decatur, USA, <sup>4</sup>Henry Ford Health System, Detroit, USA, <sup>5</sup>Northstar Medical Centre, Chicago, USA, <sup>6</sup>Triple O Research Institute PA, West Palm Beach, USA, <sup>7</sup>Case Western Reserve University School of Medicine, Cleveland, USA, <sup>8</sup>Midway Research Centre, Fort Pierce, USA, <sup>9</sup>Tarrant County Infectious Disease Associates, Fort Worth, USA, <sup>10</sup>Gilead Sciences Inc, Foster City, USA, <sup>11</sup>Gilead Sciences Ltd, London, UK

**Background:** Black Americans are disproportionately impacted by HIV. The BRAAVE 2020 study, evaluated the safety and efficacy of switching to the guidelines-recommended single-tablet regimen bicitgravir, emtricitabine, tenofovir alafenamide (B/F/TAF) in Black adults through week (W) 48.

**Method:** Adults with HIV self-identifying as Black or African American and virologically suppressed on 2 NRTIs plus a 3<sup>rd</sup> agent were randomised (2:1) to switch to open-label B/F/TAF once daily or stay on their baseline regimen (SBR). Prior virologic failure was allowed except failure on an INSTI. Prior resistance to NNRTIs, PIs and/or NRTIs was permitted except K65R/E/N, ≥3 thymidine analog mutations or T69-insertions. Primary INSTI-resistance was excluded. SBR participants switched to B/F/TAF at W24. Efficacy was assessed at W24 (Primary endpoint, noninferiority margin 6%) and at W48 as the proportion with HIV-1 RNA ≥50 c/mL by FDA Snapshot and by changes in CD4 count. Safety was assessed by adverse events (AE) and lab results.

**Results:** 495 were randomised and treated (B/F/TAF n = 330, SBR n = 165): 32% cis women, 2% transgender women, median age 49 years (range 18–79) and 10% had pre-existing M184V/I mutation. At W24, 1% (2/328) on B/F/TAF vs 2% (3/165) on SBR had HIV-1 RNA ≥50 c/mL (difference -1.2%; 95% CI -4.8% to 0.9%) demonstrating non-inferiority of B/F/TAF; 2 with pre-existing primary INSTI resistance were excluded from analysis. 163 assigned to SBR completed W24 and switched to B/F/TAF (SBR to B/F/TAF). At W48 1% (3/328) originally randomised to B/F/TAF and 0 SBR to B/F/TAF had HIV-1 RNA ≥50 c/mL. Baseline NRTI resistance did not affect the efficacy of B/F/TAF. No treatment emergent resistance was detected. Median (IQR)

weight increased 0.9 kg (-1.5, 4.1) and 0.6 kg (-1.0, 3.1) for B/F/TAF and SBR to B/F/TAF groups, respectively. Study drug-related AEs occurred in 10% of participants while on B/F/TAF; most were grade 1.

**Conclusion:** Switching to B/F/TAF was highly effective for Black adults regardless of baseline regimen or pre-existing NRTI resistance and was associated with few treatment related AEs or discontinuations.

#### P051 | The sensitivity and clinical features of pharyngeal gonorrhoea cultures in men who have sex with men

Daniel Trotman<sup>1</sup>, Alice Pickering<sup>1</sup>, Kayleigh Nichols<sup>1</sup>, Zoe Buss<sup>1</sup>, John Devlin<sup>1</sup>, Fionnuala Finnerty<sup>1</sup> and Daniel Richardson<sup>1,2</sup>

<sup>1</sup>Brighton and Sussex University Hospitals NHS Trust, UK,

<sup>2</sup>Brighton and Sussex Medical School, UK

**Background:** *Gonorrhoea* remains a global health threat, due to increasing infection rates and antimicrobial resistance (AMR). Pharyngeal *gonorrhoea* in MSM drives ongoing transmission and AMR: taking pharyngeal *gonorrhoea* culture samples before antibiotic treatment is essential for monitoring AMR and is recommended by international guidelines. We aimed to review how frequently pharyngeal culture samples (modified Thayer Martin©) are taken in MSM with a positive *gonorrhoea* NAAT (BD Probetec©), the sensitivity of *gonorrhoea* culture compared to NAAT and any associated demographic and clinical features associated with positive *gonorrhoea* cultures.

**Method:** We reviewed the electronic case notes of MSM presenting between January-December 2019 with a positive pharyngeal *gonorrhoea* NAAT. We collected data on demographics, *gonorrhoea* culture sampling and positivity, the presence of throat symptoms and simultaneous pharyngeal chlamydia and urethral and rectal *gonorrhoea*. We excluded repeat testers within 3 months of treatment including test of cure samples from the analysis.

**Results:** A total of 6613 MSM attended for pharyngeal testing and 383/6613 (5.8%) had a confirmed positive pharyngeal *gonorrhoea* NAAT. Pharyngeal *gonorrhoea* culture samples were taken in 270/383 (70%) and 73/270 (27%) were culture positive with available antimicrobial sensitivities. Only 7/73 (10%) had a fully sensitive organism. 28 (7%, 95% CI = 5.11–10.36) reported throat symptoms at presentation. Overall, the presence of pharyngeal symptoms was not associated with positive *gonorrhoea* cultures (OR = 1.9, CI = 0.78–4.62,  $P = 0.2$ ), pharyngeal *chlamydia* (OR = 1.6, CI

= 0.19–13.32,  $P = 0.7$ ), HIV status (OR = 1.1, CI = 0.47–2.57,  $P = 0.8$ ), or age [ $P = 0.3$ ].

**Conclusion:** Pharyngeal *gonorrhoea* is usually asymptomatic and culture sensitivity is poor. Increasing effort is required to increase pharyngeal *gonorrhoea* culture testing and sensitivity, including ensuring clinical staff are using optimal sampling techniques and reliable transport of *gonorrhoea* culture samples to testing laboratories to maintain *gonorrhoea* AMR surveillance.

#### P052 | Primary syphilis presentation characteristics and serological response: is there still more to learn?

Daniel Trotman<sup>1</sup>, Colin Fitzpatrick<sup>1</sup>, John Devlin<sup>1</sup>, Zoe Buss<sup>1</sup>, Luke Parkes<sup>1</sup>, Deborah Williams<sup>1</sup> and Daniel Richardson<sup>1,2</sup>

<sup>1</sup>Brighton and Sussex University NHS Trust, UK, <sup>2</sup>Brighton and Sussex Medical School, UK

**Background:** Rates of infectious syphilis has significantly increased in men who have sex with men (MSM). Recent data has shown that primary syphilis does not always present with painless genital lesions. Our aim was to describe the clinical characteristics, serological response and management of primary syphilis in HIV-positive and negative MSM. **Method:** We reviewed the microbiological and demographic data of MSM presenting with primary syphilis between January 2016 – March 2020 in our clinic-based population in Brighton, UK.

**Results:** There were 111 cases of primary syphilis in MSM, the median age was 46 years (IQR = 37–53 years) and 40 (36%) were living with HIV. 56/111 (50%) of MSM presented with painful lesions and 14% with extra-genital lesions. Extra-genital lesions were significantly more likely to be painful than genital lesions (OR 4.72; 95%, CI 1.25–17.83,  $P = 0.02$ ). Overall, serology had a sensitivity of 80% (57/71) compared with *Treponema pallidum* PCR. Serology was more sensitive in MSM with no previous syphilis (OR = 3.38, 95%CI: 1.002–11.43,  $P < 0.05$ ). There were no differences in the characteristics, serological response or management between HIV positive and negative MSM.

**Conclusion:** Fifty percent of MSM with primary syphilis presented with painful lesions; extra-genital lesions are more likely to be painful than genital lesions and serology is sensitive in 80% of MSM, and there were no differences between HIV positive and negative MSM. Understanding the characteristics of primary syphilis will underpin public health campaigns.