Table. Hepatic Safety Parameters in Participants with HIV+HCV Co-infection and HCV Mono-infection Receiving CAB + RPV LA DAW or QW through Week 48 in ATLAS-2M

| Liver abnormality, n(%) | HIV/HCV co-infection | HIV mono-infection |
|-------------------------|----------------------|-------------------|
| ALT ≥ 3 x ULN           | 15 (15)              | 25 (25)           |
| ALT ≥ 3 x ULN, BIL ≥ 2 x ULN, and ALP ≥ 2 x ULN | 3 (3) | 4 (4) |
| Hepatocellular injury    | 15 (15)              | 25 (25)           |
| Hepatocellular injury and BIL ≥ 2 x ULN | 3 (3) | 4 (4) |
| Liver stopping event     | 4 (4)                | 12 (12)           |

ALT, alanine aminotransferase; BIL, bilirubin; CAB, cabotegravir; HCV, hepatitis C virus; LA, long-acting; Q4W, every 4 weeks; Q6W, every 6 weeks; RPV, rilpivirine; ULN, upper limit of normal.

*N=1031 for laboratory abnormalities. Defined as (ALT/ALP/TOTAL/BIL/ULN) ≥ 3 x ULN and ALT/ALP must be measured on the same day. All liver stopping events occurred after treatment started. Events included acute hepatitis B virus infection (>2; both participants withdrew from the study), acute hepatitis E virus infection (n=1; continued CAB + RPV LA dosing), and acute hepatitis C virus infection (n=1; continued CAB + RPV LA dosing, not resolved).

Conclusion. CAB + RPV LA was effective and well tolerated in this small cohort of participants with HIV and asymptomatic HCV co-infection.

Disclosures. Ronald D’Amico, DO, MSc, GlaxoSmithKline (Shareholder) ViiV Healthcare (Employee) Paul Benn, MB ChB FRCP, ViiV Healthcare (Employee) Shanker Thakirajah, MB ChB, GlaxoSmithKline (Employee, Shareholder) Susan L. Ford, PharmD, GlaxoSmithKline (Shareholder) ViiV Healthcare (Employee) Eileen Birmingham, MD, MPH, Janssen Research and Development (Employee, Shareholder) Ojesh R. Upadhyay, MPH, MBA, GlaxoSmithKline (Employee) Louise Garside, PhD, GlaxoSmithKline (Employee) Rodica Van Solingen-Rista, MD, Janssen Research and Development (Employee) ViiV Healthcare (Employee) Kati Vandermeulen, MSc, Janssen Research and Development (Employee) William Spreen, PharmD, GlaxoSmithKline (Shareholder) ViiV Healthcare (Employee)

834. Characterization of Heavily Treated Experienced HIV-1 Infected Clinical Trial Participants Infected with SARS-CoV-2 COVID 19: Fastestavir BRIGHTE Phase 3 Clinical Trial

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Session: P-46: HIV: Complications and Co-infections

Background. BRIGHTE is an ongoing global study evaluating the gP120 attachment inhibitor fostemsavir (FTS) in heavily treatment-experienced (HTE) adults with multidrug resistant (MDR) HIV-1 unable to form a viable antiretroviral (ARV) regimen. An estimated 2 million people living with HIV-1 have been infected with SARS-CoV-2. Those with HIV viremia and/or low CD4+ counts are at increased risk of infection.

Methods. At the start of the COVID pandemic, all ongoing BRIGHTE subjects (14 RC, 3 NC) had confirmed COVID-19 infection (positive PCR test). Severity diagnosis and reported exposure, testing results and symptom presence.

Results. 371 subjects [272 Randomized Cohort (RC), 99 Non-Randomized Cohort (NC)] were enrolled; 44% were ≥ 50 years of age and 86% had an AIDS history. Median CD4+ count at study start of was 60 cells/mm^3 [IQR 11–202]; 30% with ≥20 cells/mm^3. 250 subjects remained in BRIGHTE at pandemic start. By April 2021, 17 subjects (14 RC, 3 NC) had confirmed COVID-19 infection (positive COVID test). Of these, 14 were Grade 1-3, all cases resolved with no deaths. Six subjects were hospitalized (Table 1); most recent CD4+ count prior to COVID were 293–1641 cells/mm^3 and 5/6 subjects were virologically suppressed. Treatments often included prophylactic anticoagulants and supplemental oxygen; no CART changes were made. The remaining 11/17 confirmed cases were managed outpatient. Five more subjects had suspect COVID not confirmed by PCR and 2 subjects had negative PCR tests.

Table 1. Characterization of Participants with Serious AE of Confirmed COVID-19 Infections – All Hospitalizations

Conclusion. A total of 22/250 COVID-19 cases (17 confirmed, 5 unconfirmed) have been reported in BRIGHTE. Outcomes were reassuring with no deaths or known persistent sequelae, despite having advanced HIV and comorbid diseases at baseline associated with poorer COVID outcomes. Outcomes may have benefited from immunologic improvement during the trial.

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Session: P-46: HIV: Complications and Co-infections

Background. Weight gain among PWH on ART is a growing clinical concern. We explore factors associated with weight gain at The Ohio State University Wexner Medical Center Infectious Diseases Clinic.

Methods. This was a single-center, retrospective, cohort study of adult PWH on ART for at least 3 months seen at our clinic from 1/1/2015 to 1/1/2019. Patients with CD4+ T cell count < 200 cells/mm^3, viral load >200 copies/mL, history of malignancy, or pregnancy were excluded. 870 patients met criteria. Patient demographics, lifestyle factors, medical co-morbidities, concurrent medications, and ART regimens were documented during the study period. The primary outcome was percent weight change over the follow up period. Secondary outcome was the odds of >5kg weight gain over the study period. The effects of concurrent medications, medical comorbidities, ART combinations, and self-reported lifestyle behaviors on these outcomes were modeled using mixed effect linear and logistic regression analysis.

Results. At baseline. 83.6% were male, 29.2% were African American, and 65.6% had a body mass index ≥25 kg/m². Over a mean follow up of 1.86 years, the study population gained a mean percent weight of 2.12 ± 0.21% (p < 0.001) with an odds of weight gain >5kg of 0.293 (p < 0.001). Male sex and increasing age were significantly associated with a decrease in percent weight over the study period as reflected in the table below. Diet was also significantly associated with a decrease in percent weight change over the study period of -1.99 ± 0.47 %, p= < 0.001 and a lower odds of > 5kg of weight gain (OR: 0.70, 95% CI: 0.50 – 0.97, p=0.03). In regression models, combination therapy with tenofovir alafenamide (TAF) and integrase strand transfer inhibitor (INSTI) containing regimens were significantly associated with an increase in percent weight over the study period. Other significant factors including demographics and ART regimens are noted in Table 1.

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Conclusion. HIV/HCV co-infected patients who received DAA + RIB had a significant increase in CD4+ lymphocyte counts (p < 0.05) (unlike interferon-based regimen). Chronic opioid use and mental health treatment were not a hindrance to successful therapy. The clinical impact of our findings on long-term complications including cirrhosis, hepatocellular carcinoma, and extra-hepatic manifestations of HCV remain to be seen. Recognition of positive predictive markers will delineate the cohort of co-infected veterans who would benefit from DAA therapy beyond HCV eradication.

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837. Performance of Blood (1->3)-β-D-Glucan in People with AIDS Presenting with Respiratory Symptoms
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Session: P-46. HIV: Complications and Co-infections

Background. The gold standard for diagnosis of Pneumocystis jiroveci pneumonia (PCP) is direct visualization of the microorganism in respiratory samples, usually obtained via bronchoalveolar lavage (BAL). Blood (β-D-glucan) (BDG) is used as a non-invasive adjunctive diagnostic test for PCP, but specificity is only modest, in part because other opportunistic fungal infections cause high BDG. We previously showed BDG-positivity in 94% of people with AIDS (PWA), progressive disseminated histoplasmosis (PDH), and respiratory symptoms in our hospital. In this study, we aim to assess the performance of BDG as a diagnostic test for PCP in PWA who have respiratory symptoms.

Methods. We retrospectively identified PWA who had a BDG result between 2014 and 2019. AIDS was defined as past or current absolute CD4 count <200 cells/µL, or a past or current AIDS-defining condition. Positive cytological or histological evidence of P. jiroveci in bronchoalveolar lavage (BAL) fluid or lung biopsy, or positive Pneumocystis PCR on sputum or BAL confirmed PCP. The Fungitell Assay (Associates of Cape Cod, East Falmouth, MA) determined BDG levels as follows: negative, < 60 pg/mL; indeterminate, 60-79 pg/mL, and positive, ≥ 80 pg/mL. Values < 31 pg/mL and those >500 pg/mL were censored at 30 pg/mL and 500 pg/mL, respectively. Respiratory symptoms were defined as cough, dyspnea, chest pain, or hypoxia. We compared BDG results for participants with proven PCP and participants without proven PCP.

Results. We identified 260 PWA with a BDG result, of whom 183 had at least one respiratory symptom. 84 (45.9%) of these participants had a positive BDG. BDG results among participants with and without PCP are shown in Table 1. Of the 44 participants with a positive BDG who did not have PCP, 29 (65.9%) had PDH. Other diagnoses included cryptococcosis and candidemia. The test performance of BDG for the diagnosis of PCP is shown in Table 2. Exclusion of participants with PDH increased the specificity of BDG for PCP to 86.4%.

Table 1. Results of (1->3)-β-D-Glucan Testing by Pneumocystis jiroveci Pneumonia Diagnosis Among Participants with AIDS and Respiratory Symptoms

| BDG (pg/mL) | Pneumocystis jiroveci Pneumonia (PCP) |
|------------|-------------------------------------|
| 0-30        | Negative (97.5%)                     |
| 31-500      | Positive (67.9%)                     |

Table 2. Test Performance of (1->3)-β-D-Glucan for the Diagnosis of Pneumocystis jiroveci Pneumonia

| Sensitivity | Result (95% CI) |
|-------------|----------------|
| 97.5% (87.1%-99.9%) |

| Specificity | Positive predictive value | Negative predictive value |
|-------------|---------------------------|---------------------------|
| 60.7% (67.5%-75.6%) | 47.6% (41.4%-53.86%) | 98.9% (93.3%-99.8%) |

*Using > 80 pg/mL as the cutoff for a positive result

Conclusion. At our center where histoplasmosis is endemic, a positive BDG should not be attributed to PCP among PWA with respiratory symptoms because of...