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LB-4. Phase 3 Randomized, Controlled Trial of Switching to Fixed-dose Bictegravir/Emtricitabine/Tenofovir Alafenamide (B/F/TAF) from Boosted Protease Inhibitor-based Regimens in Virologically Suppressed Adults: Week 48 Results

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Background. Boosted protease inhibitor regimens (bPIs) are effective and often used in HIV-infected individuals with difficulties with adherence, but they can have drug–drug interactions and GI adverse effects. Bictegravir (B), a novel, potent integrase strand transfer inhibitor with a high barrier to resistance and low potential for drug–drug interactions, was coformulated with the recommended nucleoside reverse transcriptase inhibitor backbone emtricitabine (FTC)/tenofovir alafenamide (F/TAF) and demonstrated high efficacy and tolerability in randomized studies in treatment-naïve adults. This randomized Phase 3 study assesses efficacy and safety of switching to B/F/TAF from a multi-tablet regimen containing a bPI.

Methods. HIV-infected adults suppressed on regimens of boosted atazanavir (ATV) or darunavir (DRV) + abacavir/lamivudine (ABC/3TC) or FTC/tenofovir disoproxil fumarate (TDF) were randomized 1:1 to continue their current bPI regimen or switch to open-label coformulated B/F/TAF (50/200/25 mg) once daily. Primary endpoint was proportion with HIV-1 RNA ≥50 copies/mL (c/mL) at W48 (FDA snapshot). Noninferiority was assessed through 95.002% confidence intervals (CI) using a margin of 4%. Secondary endpoints included proportion with HIV-1 RNA <50 c/mL and safety measures at W48.

Results. A total of 577 participants were randomized and treated with B/F/TAF (n = 290) or current bPI regimens (n = 287): 17% women, 26% Black, median age 48 years. Most were receiving a bPI with FTC/TDF (85%) at screening. At W48, switching to B/F/TAF was noninferior to continuing bPI with 1.7% in each group having HIV-1 RNA ≥50 c/mL (difference −0.0%; 95.002% CI −2.5% to 2.5%, P = 1.00); the proportion with HIV-1 RNA <50 c/mL was 92.1% in B/F/TAF vs. 88.9% in bPI. No participant on B/F/TAF developed resistance to study drugs. One participant on DRV/ritonavir + ABC/3TC developed a treatment-emergent L74V mutation. Incidence of grade 3 or 4 AEs was similar (B/F/TAF 4%, bPI regimens 6%). No renal discontinuations or tubulopathy cases occurred with B/F/TAF.

Conclusion. Adults switching to B/F/TAF from a boosted PI maintained high rates of virologic suppression without resistance. B/F/TAF was safe and well tolerated.

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LB-5. The SEP-SEQ Trial: Clinical Validation of the Karius Plasma Next-Generation Sequencing Test for Pathogen Detection in Sepsis

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Background. Sepsis is a leading cause of death and can be caused by a wide range of potential pathogens. In up to 40% of cases, a causative pathogen is never identified. There is a need for improved diagnostic tests that can accurately identify the breadth of potential pathogens to inform effective antimicrobial therapy.

Methods. We enrolled a prospective cohort of patients presenting to the hospital with signs and symptoms of sepsis. Plasma samples were collected for NGS testing at time of initial blood culture. Extracted plasma cell-free DNA was sequenced, human sequences removed and remaining reads aligned against a pathogen database consisting of viruses, bacteria, and eukaryotic pathogens. Relative abundance was estimated; pathogens present at high statistical significance were identified. NGS results were compared with a composite reference standard of all microbiology testing performed within 7 days of admission and clinical diagnosis.

Results. Of 286 patients enrolled, plasma NGS identified potential pathogens in 60.1% (172 of 286) of septic subjects including DNA viruses, bacteria (including fastidious/unculturable bacteria like *Mycobacterium tuberculosis*), and fungi. In contrast, 15.7% (45 of 286) subjects had a positive initial blood culture and 38.1% (109 of 286) had a potential infectious etiology identified using a composite microbiology laboratory standard. The NGS plasma assay had a positive agreement of 86.7% (39 of 45) and 79.5% (78 of 98) compared with initial blood culture (after excluding contaminants) and the composite laboratory reference standard, respectively. After clinical adjudication, 81.4% (140 of 172) of the positive plasma NGS results were deemed to be consistent with the septic event. Of the remaining 32 subjects, 15 had NGS results that were plausible causes of sepsis but clinical were insufficient to confirm this.

Conclusions. With a single blood draw, the Karius plasma NGS assay identified a broad range of pathogens in septic patients three times more often than blood culture and more often than all microbiology tests combined. This plasma NGS test can identify a viruses, bacteria, and eukaryotic pathogens which can provide valuable information to help clinicians better target antimicrobial therapy for patients with sepsis.

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LB-6. Ethanol Lock Treatment and Secondary Prophylaxis for Central Line-Associated Bloodstream Infection in Pediatric Hematology and Oncology: A Randomized, Double-Blind, Placebo-Controlled, Intervention Trial

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Background. Central line-associated bloodstream infection (CLABSI) commonly affects children with cancer and hematological disorders, with significant attributable costs and morbidity. Treatment failure, comprising persistent infection, infection relapse or new infection, occurs in ~50% of cases. Adjunctive ethanol lock therapy (ELT) has been proposed to prevent failure, but has never been tested in a prospective controlled study.

Methods. A prospective, dual-center, double-blind, block-randomized, placebo-controlled trial of ELT (70% ethanol in water) for CLABSI, given as treatment (2 hours per lumen per day) for 5 days, followed by secondary prophylaxis (2 hours per lumen up to 3 days per week) for 24 weeks, in children with oncologic or hematologic disorders (NCT01472965). Risk of treatment failure was compared between intervention and control groups according to proportional and cumulative incidence models,