The fusion of HIV-1 to CD4 cells results in post-infection intermediates that involves gq240 and the CD4 receptor. The FSLC chimeric protein vaccine is a single chain polypeptide molecule that replicates the structural, functional, and antigenic properties of Hiv gq240/CD4 complex intermediate. Fouts TR, et al. J Virol 2000; 74(21):11427-36.

Methods. Subjects with PCR-confirmed SA colonization of the lower respiratory tract were randomized to either a single intravenous infusion of 5,000 mg suvra (n = 96) or placebo (n = 108) and followed for 190 days post dose. Efficacy endpoints were compared with Adjudication Committee-determined relative risk reduction (RRR) of SA pneumonia incidence in suvra vs. placebo recipients within 30 days post dose (primary endpoint, tested at 2-sided α = 0.1), incidence of all-cause pneumonia, and all-cause pneumonia or death. Serum suvra PK and levels of AT NAbs were measured through 90 days post dose and analyzed for statistical correlation. Treatment-emergent adverse events (TEAEs) and serious AEs (SAEs) were assessed through 190 days post dose.

Results. Baseline characteristics were similar between groups. Suvra provided 31.9% RRR in vs. placebo (17.7% vs. 26%, P = 0.164) in incidence of all-cause pneumonia, and 23% RRR (P = 0.146) in incidence of all-cause pneumonia or death. Suvra reduced mean hospital stay and ICU duration by 3.0 and 2.4 days, resp. vs. placebo. Mean serum ± 2 suvra level was 296 ± 141 μg/mL at 30 days post dose. Serum AT NaB ± SD suvra reached 156.03 ± 72.12 IU/mL at 2 days post dose, declining slowly to 33.74 ± 16.04 IU/mL by 90 days post dose. AT NAbs correlated with PK (r² = 0.7), thereby confirming functional activity of suvra over time. Proportion of subjects with TEAEs or SAEs was similar between groups: ± 1 TEAE (93.8% suvra; 93.0% placebo); ± 1 serious; and/or ≥2 grade 3 severity SAE (66.7% suvra; 58.0% placebo).

Conclusion. A single intravenous dose of suvra produced a trend toward reduced incidence of SA pneumonia, health resource savings, sustained functional exposure in serum, and an acceptable safety profile. These results support continued development of suvra in MV ICU patients.

Disclosures. All Authors: No reported Disclosures.

2840. Long-term Efficacy, Safety, and Durability of CAB and RPV as Two Drug Oral Maintenance Therapy: LATTE Week 312 Results

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Background. Cabotegravir (CAB), an INI, is under development in both oral and long-acting (LA) injectable formulations. LATTE (NCT01641809) was designed to select a daily oral dose of CAB and evaluate a two-drug ART regimen with rilpivirine (RPV), as suppressive maintenance therapy. Results enabled the LATTE-2 (NCT02120352) study to evaluate CAB LA + RPV LA dosed once every 1 or 2 months.

Methods. Phase 2b, multicentre, partially blinded dose-ranging study in ART-naive HIV infected adults, randomized 1:1:1 to the induction regimen of once-daily CAB 10, 30, or 60 mg or efavirenz (EFV) 600 mg, or placebo. Patients were randomized to either a single intravenous infusion of 5,000 mg suvra (93.8% suvra; 93.0% placebo); ≥1 serious; and/or ≥grade 3 severity SAE (66.7% suvra; 58.0% placebo).

Conclusion. A single intravenous dose of suvra produced a trend toward reduced incidence of SA pneumonia, health resource savings, sustained functional exposure in serum, and an acceptable safety profile. These results support continued development of suvra in MV ICU patients.

Disclosures. All Authors: No reported Disclosures.

2839. Efficacy, Pharmacokinetics (PK), and Safety Profile of Suvratoxumab (MED14983), a Staphylococcus aureus Alpha Toxin (AT)-Neutralizing Human Monoclonal Antibody in Mechanically Ventilated Patients in Intensive Care Units: Results of the Phase 2 SAATELLITE Study Conducted by the Public-Private COMBACTE Consortium

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Background. Suvratoxumab (suvra) pneumonia imposes significant morbidity and mortality in mechanically ventilated, intensive care unit (MV ICU) patients despite best clinical care. We assessed efficacy, PK, AT-neutralizing antibodies (AT NAbs), and safety of suvratuxumab (suvra) in MV ICU subjects in the placebo-controlled, randomized Phase 2 SAATELLITE study (NCT02296320; EudraCT 2014-001097-34).

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Abstracts
2841. Durable Efficacy of Two-Drug Regimen (2DR) of Dol Twice-Daily (DTG) plus Lamivudine (3TC) in Antiretroviral Treatment-Naive Adults with HIV-1 Infection at 96 Weeks: Subgroup Analyses in the GEMINI Studies

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Background. At Weeks 48 and 96 in the GEMINI-1 and GEMINI-2 studies (Clinicaltrials.gov: NCT02831673 and NCT02831764), the 2DR of DTG+3TC was noninferior to the three-drug regimen of DTG + tenofovir/emtricitabine (TDF/FTC) in achieving plasma HIV-1 RNA < 50 c/mL in treatment-naive adults.

Methods. GEMINI-1 and 2 are identical, global, double-blind, multicenter Phase III studies. Participants with screening HIV-1 RNA ≤ 500.00 c/mL were randomized to once-daily DTG+3TC or DTG+TDF/FTC, stratified by plasma HIV-1 RNA and CD4+ cell count. The primary endpoint was the proportion of participants with plasma HIV-1 RNA < 50 c/mL at Week 48 (Snapshot algorithm). We present a secondary end point analysis of efficacy at Week 96 by baseline disease and demographic characteristics. For the overall population, estimates and confidence intervals were based on a stratified analysis using Cochran-Mantel-Haenszel weights.

Results. In total, 714 patients were randomized and treated in GEMINI-1 and -2, respectively. Based on a 10% noninferiority margin, DTG+3TC was noninferior to DTG+TDF/FTC at Week 96 in both GEMINI-1 and -2 and in the pooled analysis. Response rates across baseline HIV-1 RNA subgroups were high and similar in both arms in the pooled analysis, including in participants with baseline HIV-1 RNA > 100,000 c/mL (Table 1). Results were also generally consistent regardless of age, gender, or race. In the CD4+ ≤ 200 cells/mm³ subgroup, response rates were lower in the DTG+3TC group compared with DTG+TDF/FTC; most reasons for nonresponse were unrelated to virologic efficacy or treatment regimen. Across both studies, 11 patients on DTG+3TC and 7 on DTG+TDF/FTC met protocol-defined virologic withdrawal criteria through Week 96; none had treatment emergent integrase-strand-transfer-inhibitor or NRTI resistance mutations.

Conclusion. In GEMINI-1 and 2, DTG+3TC was noninferior to DTG+TDF/FTC in treatment-naive adults at Week 96, demonstrating durable efficacy. The results of subgroup analyses of efficacy at Week 96 were generally consistent with overall study results, and further demonstrate that DTG+3TC is an effective initial treatment for HIV-infected patients across a spectrum of disease characteristics and patient populations. The studies are ongoing.

Table 1. Proportion of participants with plasma HIV-1 RNA < 50 c/mL at Week 96: Snapshot Analysis by subgroups — ITT-E population

| Baseline HIV-1 RNA (c/mL) | DTG+3TC | DTG+TDF/FTC |
|--------------------------|---------|-------------|
| ≤ 100K                   | 0.995   | 0.995       |
| > 100K                   | 0.621   | 0.621       |

Disclosures. All Authors: No reported Disclosures.