Figure 1: Structure of the Full-length Single Chain (FLSC) Vaccine.
The fusion of HIV-1 to CD4+ cells results in post-binding intermediates that involves gp120 and the CD4 receptor. The FLSC chimeric protein vaccine is a single-chain polypeptide molecule that replicates the structural, functional, and antigenic properties of this gp120-CD4 complex intermediate. Fouts TR, et al. J. Virol 2000; 74(24):11427-36.

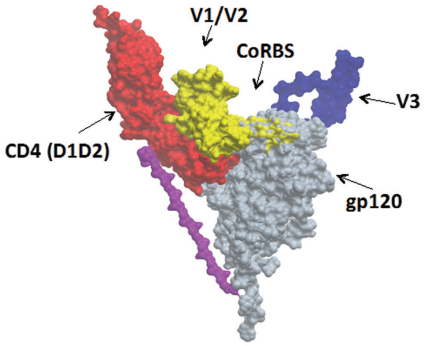
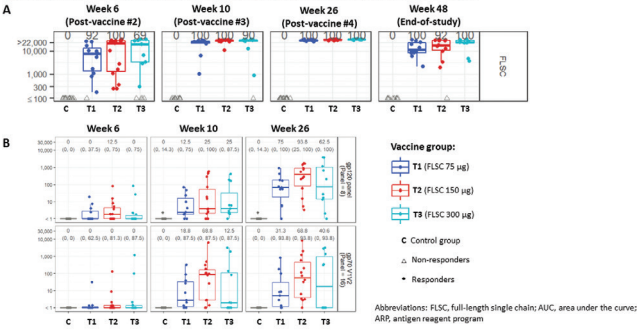


Figure 2: Immunogenicity Results
A. Binding IgG antibody response magnitude for FLSC antigen and time points, colored by group, showing durability of antibody response. B. Magnitude-breath AUC of the gp120 and gp70 V1V2.AFR breath panel by group and time points. The response rate (%) for each group and antigen is displayed.



Binding Antibody Multiplex Array (BAMA) data provided by G. Tomaras et al, Duke Human Vaccine Institute.
Statistical analyses provided by E. Chung et al, Statistical Center for HIV/AIDS Research and Prevention (SCHARP), Fred Hutchison Cancer Research Center

Disclosures. **All Authors:** No reported Disclosures.

2839. Efficacy, Pharmacokinetics (PK), and Safety Profile of Suvratoxumab (MEDI4893), 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. *Staphylococcus aureus* (SA) 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 suvratoxumab (suvra) in MV ICU subjects in the placebo-controlled, randomized Phase 2 SAATELLITE study (NCT02296320; EudraCT 2014-001097-34).

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 = 100) and followed for 190 days post dose. Efficacy endpoints were Endpoint 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 $\alpha = 0.1$), 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 incidence of SA pneumonia vs. placebo (17.7% vs. 26%; $P = 0.166$), 30% RRR ($P = 0.146$) in incidence of all-cause pneumonia, and 23% RRR ($P = 0.164$) 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 ± SD suvra level was 296 ± 131 µg/mL at 30 days post dose. Serum AT Nab ± SD levels reached 156.03 ± 72.48 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 ($r^2 = 0.7$), 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 ≥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-naïve HIV infected adults, randomized 1:1:1:1 to the induction regimen of once-daily oral CAB 10, 30, or 60 mg or efavirenz (EFV) 600 mg with TDF/FTC or ABC/3TC through W24. CAB patients with VL <50 c/mL immediately prior to W24 discontinued NRTIs and began RPV 25 mg as a two-drug oral maintenance regimen through W96. No change was made to the EFV arm. After W96, at the start of the open-label (OL) phase, all patients randomized to CAB were given the option to continue and switch to the sponsor-selected dose of oral CAB 30 mg. EFV patients completed the study at W96. The OL phase was completed at W312 (288 weeks on CAB + RPV). Successful CAB + RPV patients transitioned to the POLAR study (NCT03639311).

Results. A total of 243 patients were randomized and initiated treatment (ITT-E). Of those randomized to CAB (n = 181), 160 patients began CAB + RPV (W24) and 138 continued into OL phase (W96). One hundred and ten patients successfully completed the study (W312). Among patients who began CAB + RPV at W24, 66% maintained <50 c/mL, 9% had HIV-1 RNA ≥ 50 c/mL, and 25% were categorized as "No Virologic Data" by Snapshot at W312 (ITT-ME). There were 11 protocol-defined virologic failures (PDVF) on CAB; only 2 occurring after W144. Six patients developed treatment emergent (TE) resistance to one or both agents during the study; of which 4 patients developed TE major INI resistance mutations, 3 after W96. The median increase in CD4+ cell count from Baseline was 393 cells/mm^3 (−174 to 1118). During the maintenance and OL phases, 4% of CAB patients reported drug-related AEs ≥ Grade 2; SAEs occurred in 9% of CAB patients (none drug related); 3% of CAB patients withdrew due to AEs. 43% of CAB patients who entered maintenance phase reported TE lab abnormalities ≥ Grade 3.

Conclusion. As maintenance therapy in virologically suppressed patients, the 2DR CAB + RPV provided durable viral suppression through W312. Through 7 years of study, CAB + RPV continues to be generally safe and well tolerated.