Disclosures. **P. De Wals**, GlaxoSmithKline: Grant Investigator and Scientific Advisor, Grant recipient and travel expenses. Pfizer: Grant Investigator and Scientific Advisor, Grant recipient and travel expenses. Sanofi-Pasteur: Grant Investigator and Scientific Advisor, Grant recipient and travel expenses. Novartis: Grant Investigator and Scientific Advisor, Grant recipient and travel expenses.

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.

Disclosures. **E. Daar**, Bristol-Myers Squibb: Consultant, Consulting fee. Gilead Sciences, Inc.: Consultant, Grant Investigator and Scientific Advisor, Consulting fee and Research support. Janssen: Consultant, Grant Investigator and Scientific Advisor, Consulting fee and Research support. Merck: Consultant, Grant Investigator and Scientific Advisor, Consulting fee and Research support. Teva Pharmaceuticals: Consultant and Scientific Advisor, Consulting fee. ViiV: Consultant, Grant Investigator and Scientific Advisor, Consulting fee and Research support. **E. DeJesus**, Abbott Laboratories; Achillion Pharmaceuticals, Avexa, Boehringer Ingelheim, Bristol-Myers Squibb, Gilead Sciences, GlaxoSmithKline, Hoffmann LaRoche, Idenix, Janssen, Merck, Pfizer, Sangamo, Taimed, Tobira, and Vertex: Grant Investigator, Research grant. Bristol-Myers Squibb, Gilead Sciences, Janssen, Merck, and Vertex: Scientific Advisor, Consulting fee. **P. Ruane**, Gilead: Investigator, Scientific Advisor and Shareholder, Consulting fee and Research support. Merck: Speaker's Bureau, Speaker honorarium. Boehringer: Investigator, Scientific Advisor and Speaker's Bureau, Consulting fee, Research support and Speaker honorarium. Janssen: Investigator, Scientific Advisor and Speaker's Bureau, Consulting fee, Research support and Speaker honorarium. Abbott: Investigator, Scientific Advisor and Speaker's Bureau, Research support and Speaker honorarium. Idenix: Investigator, Research support. ViiV: Scientific Advisor and Speaker's Bureau, Consulting fee and Speaker honorarium. BMS: Consultant, Investigator and Speaker's Bureau, Consulting fee, Research support and Speaker honorarium. **G. Crofoot**, Gilead: Investigator and Scientific Advisor, Advisory honorarium and Research grant. ViiV: Investigator and Scientific Advisor, Advisory honorarium, Research grant and Research support. **C. Creticos**, Thera Technologies and ViiV Healthcare: Scientific Advisor, Consulting fee. Gilead sciences, Merck, and ViiV Healthcare: Investigator, Research support. Pfizer: Speaker's Bureau, Speaker honorarium. **J. K. Rockstroh**, Abbvie: Consultant and Investigator, Consulting fee and Speaker honorarium. Gilead: Consultant, Investigator and Scientific Advisor, Consulting fee and Speaker honorarium. ViiV: Scientific Advisor, Consulting fee. Janssen: Investigator and Speaker at educational event, Speaker honorarium. **J. M. Molina**, Gilead, ViiV, Merck, Janssen, BMS and TEVA: Scientific Advisor, Speaker honorarium. **Y. P. Liu**, Gilead: Employee and Shareholder, Salary and Shareholder. **K. Andreatta**, Gilead: Employee and Shareholder, Salary and Shareholder. **H. Graham**, Gilead Sciences: Employee and Shareholder, Salary. **A. Cheng**, Gilead: Employee and Shareholder, Salary. **H. Martin**, Gilead Sciences: Employee, Salary. **E. Quirk**, Gilead: Employee and Shareholder, Salary

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.

Disclosures. **H. Seng**, Karius, Inc.: Employee, Salary. **D. Hollemon**, Karius, Inc.: Employee, Salary. **D. Hong**, Karius, Inc.: Employee, Salary. **T. Blauwkamp**, Karius, Inc.: Employee, Salary. **M. Kertesz**, Karius, Inc.: Employee, Salary. **S. Yang**, Karius, Inc.: Research Contractor, Research grant.

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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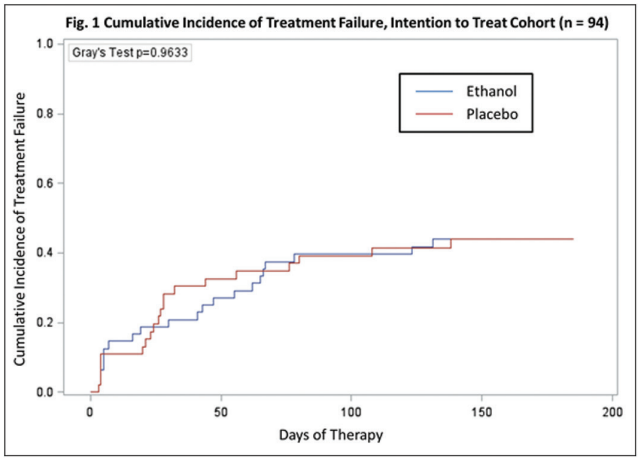
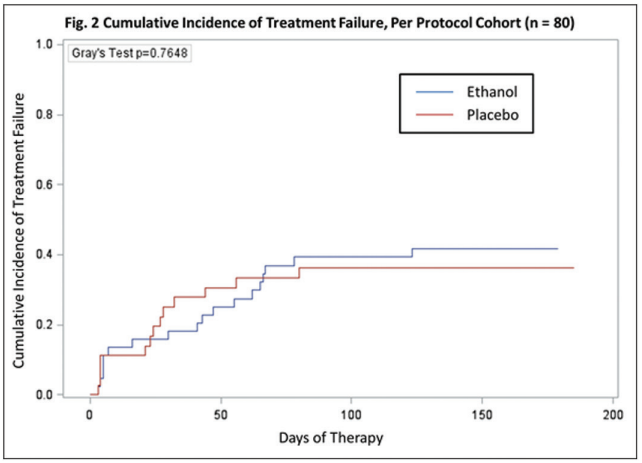
Background. Central line-associated bloodstream infection (CLABSI) commonly affects children with cancer and hematological disorders, with significant attributable costs and morbidity. Treatment failure, comprising persistent infection, infection relapse or new infection, occurs in ~50% of cases. Adjunctive 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,

using intention-to-treat and per-protocol analyses. The study was discontinued at a pre-specified futility analysis.

Results. Of 94 evaluable participants, 48 were randomized to ELT and 46 to placebo; groups were similar at baseline for all measured variables. Forty-one (43.6%) participants had treatment failure (11 early failure, 9 relapse, and 21 reinfection). There was no difference between patients receiving ELT or placebo for risk of treatment failure (43.8% vs. 43.5%; $P = 0.9$) or for cumulative incidence of treatment failure in intention to treat (Figure 1) and per-protocol analyses (Figure 2). Catheter occlusion was significantly more common in participants receiving ethanol (58.3% vs. 32.6%, $P = 0.01$) but other adverse events, including LFT elevations (14.6% vs. 26.1%) and infusion reactions (18.8% vs. 8.7%), were not significantly different between groups.





Conclusion. Although observational studies suggested ELT might be effective for treatment of CLABSI in pediatric oncology, we found no benefit in treatment outcome and an increase in adverse effects. These results may not apply to patients receiving dialysis or with fungal CLABSI as these were not well-represented. Routine use of ELT for CLABSI in children with oncologic or hematologic disorders is not recommended.

Disclosures. All authors: No reported disclosures.

LB-7. Prevention of Recurrent Acute Uncomplicated Cystitis by Increasing Daily Water in Premenopausal Women: A Prospective, Randomized, Controlled Study

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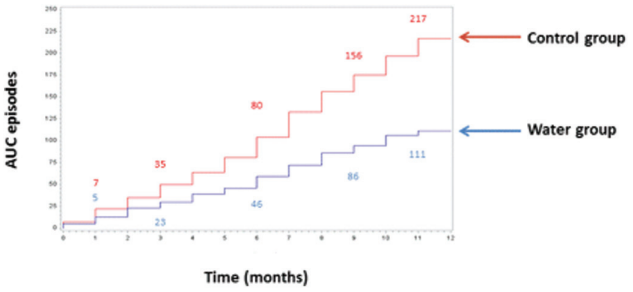
Background. Increased hydration is commonly recommended as a preventive measure for women with recurrent acute uncomplicated cystitis (rAUC), but supportive data are sparse. The aim of this study was to assess the efficacy of increased daily water intake on the frequency of rAUC in premenopausal women.

Methods. 140 healthy premenopausal asymptomatic women drinking less than 1.5 L of total fluid daily (24 hours) and suffering from rAUC (^{3}3 episodes in the past year) were randomized to receive, in addition to their usual daily fluid intake, either 1.5 L water daily (water group) or no additional fluids (control group), for 12 months. Assessments of daily water and total fluid intake, urine volume and osmolality, number of urine voids, and occurrence of AUC symptoms and a reminder to notify investigators of any such symptoms were performed at baseline, 6- and 12-month clinic visits in addition to monthly telephone calls. The primary outcome was frequency of rAUC episodes (^{3}1 AUC symptom and ^{3}10^3 CFU/mL of a uropathogen in voided urine) over 12 months.

Results. Between baseline and 12 month's follow-up, the water group, compared with the control group, had statistically significant increases in mean daily water intake (1.15 vs. −0.01 L), total fluid intake (1.65 vs. 0.03 L), urine volume (1.40 vs. 0.04 L), and number of urine voids (2.2 vs. −0.2), and a decrease in urine osmolality (−408 vs. −35 mOsm/Kg). The mean number of rAUC episodes in the water group was significantly less than in the control group (1.6 vs. 3.1; odds ratio 0.52, 95% CI 0.46–0.60, $P < 0.0001$) (figure shows cumulative sum of AUC episodes over 12 months in both study groups). The mean number of antimicrobial regimens used to treat AUC events was 1.8 in the water group vs. 3.5 in the control group ($P < 0.0001$). In addition, the mean number of days to first rAUC and the mean number of days between rAUC episodes was longer in the water group compared with the control group (148 vs. 93, $P = 0.0005$ and 143 vs. 85, $P < 0.0001$, respectively).



Conclusions. Our results provide strong evidence that increased water intake is an effective antimicrobial-sparing preventive strategy for women with rAUC. Increasing daily water intake by approximately 1.5 L reduced rAUC episodes by 48% and antimicrobial regimens by 47% over 12 months.

Disclosures. **M. Vecchio**, Danone Research: Employee, Salary. **A. Iroz**, Dzanone Research: Employee, Salary. **I. Tack**, Danone Research: Consultant, Consulting fee and Speaker honorarium. **Q. Dornic**, Danone research: Employee, Salary. **I. Seksek**, Danone Research: Employee, Salary.

LB-8. Sorting the Wheat from the Chaff: Vaccine-Associated Rash Illness Occurring amidst a Large Measles Outbreak—Minnesota, 2017

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Background. During April–June 2017, Minnesota experienced the state's largest measles outbreak in 27 years. A vaccination campaign was implemented. Numerous vaccine-associated rash illnesses (VARI) were detected. VARI is non-contagious, but difficult to distinguish from measles clinically. Often, public health control measures need to be implemented before wild-type measles can be differentiated from VARI by viral genotyping. We compared clinical characteristics of VARI and confirmed measles cases to inform testing practices.

Methods. We defined measles cases per the Council of State and Territorial Epidemiologists. VARI was defined as a rash occurring in a person within 21 days after receipt of measles, mumps, and rubella (MMR) vaccine, and in whom a measles vaccine strain (genotype A) was detected in naso/oro- pharyngeal swab or urine samples. Minnesota's immunization information system monitored MMR doses administered. We collected clinical information through routine case investigation.

Results. Over 42,000 MMR doses above expected were administered during the outbreak. We identified 71 measles cases and 30 VARI. The median age of VARI patients was 1.2 years (range 10 months–48 years) and for measles cases 2.8 years (range 3 months–57 years). VARI diagnosis increased with rising MMR administration (figure); rash onset occurred a median of 11 (range 7–18) days after MMR receipt. Most VARI (97%) occurred following first MMR dose. The presence of fever was similar among VARI and measles cases (97% of VARI vs. 100% of measles cases; $P = 0.12$), but differences were seen in the proportion with cough (30% vs. 96%; $P < 0.001$), coryza (47% vs. 85%; $P < 0.001$), conjunctivitis (23% vs. 68%; $P < 0.001$), and exposure to infectious measles cases (0% vs. 96%).