of Merck & Co., Inc.: Employee and Shareholder, May hold stock/stock options in the company and Salary. **S. Kumar**, Merck & Co., Inc.: Employee and Shareholder, Salary. **P. Sklar**, Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.: Employee and Shareholder, Salary. **G. J. Hanna**, Merck Sharp & Dohme, a subsidiary of Merck & Co., inc.: Employee and Shareholder, May hold stock/stock options in the company. and Salary. **C. Hwang**, Merck Sharp & Dohme, a subsidiary of Merck & Co., Inc.: Employee and Shareholder, Salary. **W. Greaves**, Merck Sharp & Dohme, a subsidiary of Merck & Co., Inc.: Employee, May hold stock/stock options within the company.

DRIVE-SHIFT Phase 3 Trial: Efficacy & Safety Outcomes

Efficacy (FDA Snapshot Approach)	DOR/3TC/TDF QD (ISG) N=447		Baseline Regimen (DSG) N=223		ISG minus DSG
ISG vs DSG, Week 24	n	(%)	n	(%)	Difference (95% CI)
HIV-1 RNA <50 copies/mL	419	(93.7)	211	(94.6)	-0.9 (-4.7, 3.0)
HIV-1 RNA ≥50 copies/mL	8	(1.8)	4	(1.8)	-0.0 (-2.3, 2.3)
ISG Week 48 vs DSG Week 24	n	(%)	n	(%)	Difference (95% CI)
HIV-1 RNA <50 copies/mL	406	(90.8)	211	(94.6)	-3.8 (-7.9, 0.3)
HIV-1 RNA ≥50 copies/mL	7	(1.6)	4	(1.8)	-0.2 (-2.5, 2.1)
Safety Outcomes, Week 24	**DOR/3TC/TDF QD (ISG) N=447**		**Baseline Regimen (DSG) N=223**		**ISG minus DSG**
Lipids, Change from Baseline (PI+rtv Stratum)	Mean Change (95% CI)		Mean Change (95% CI)		Difference (95% CI)
Fasting LDL-C (mg/dL)	-16.5 (-19.4, -13.7)		-1.9 (-6.5, 2.6)		-14.6 (-18.9, -10.4)
Fasting non-HDL-C (mg/dL)	-24.7 (-28.3, -21.2)		-1.3 (-6.2, 3.6)		-23.0 (-28.0, -18.1)
Adverse Event (AE) Summary	n	(%)	n	(%)	Difference (95% CI)
One or more AE	308	(68.9)	117	(52.5)	16.4 (8.6, 24.2)
Drug-related† (DR) AE	87	(19.5)	5	(2.2)	17.2 (13.0, 21.5)
Discontinued due to AE	11	(2.5)	1	(0.4)	2.0 (-0.2, 4.0)
Discontinued due to DR AE	7	(1.6)	0	(0.0)	1.6 (-0.1, 3.2)

† Determined by the investigator to be related to study treatment.
ISG = Immediate Switch Group; DSG = Delayed Switch Group. Baseline Regimen = ritonavir or cobicistat-boosted PI, or cobicistat-boosted elvitegravir, or NNRTI, each administered with two NRTIs.

LB3. Daptomycin Plus Fosfomycin vs. Daptomycin Monotherapy for Methicillin-Resistant *Staphylococcus aureus* Bacteremia: A Multicenter, Randomized, Clinical Trial

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Background. Daptomycin plus fosfomycin combination has demonstrated synergistic and bactericidal effect in animal models of methicillin-resistant *Staphylococcus aureus* bacteremia (MRSAB), but there is lack of data in humans.

Method. A randomized (1:1), open-label, clinical trial involving adults with MRSAB was conducted at 18 medical centers in Spain. Patients were assigned to receive daptomycin, 10 mg/kg IV daily plus fosfomycin, 2 g IV/6 hour (combination therapy) or to receive daptomycin 10 mg/kg/24 h IV (monotherapy) during 10 up to 14 days for uncomplicated bacteremia and 28 up to 42 days for complicated bacteremia. The primary efficacy endpoints were: (a) treatment success at Test-of-Cure visit (ToC: 6 weeks after end of therapy) and (b) treatment success at 7 days (defined as alive at day 7 and clearance of bacteremia without relapse from 8 to 90 days after randomization), according with the proposed primary endpoints for use in clinical trials in bloodstream infections in adults.

Result. Between December 2013 and November 2017, 674 patients with MRSAB were evaluated and 155 patients were randomized: 74 received combination therapy and 81 monotherapy. In intention-to-treat analysis, (a) at ToC visit successful outcome was achieved in 40 of 74 patients (54,1%) who received combination therapy as compared with 34 of 81 patients (42%) who were given monotherapy (54.1% vs. 42.0%; absolute difference, 12.1%; 95% confidence interval, 0%-27.0%); (b) at 7 days after starting the therapy: a successful outcome was achieved in 69 of 74 patients who received combination therapy as compared with 62 out of 81 patients who received monotherapy (93.2% vs. 76.5%; absolute difference, 16.7%; 95% confidence interval, 5.4%–27.7%). Combination therapy was associated with lower rates of microbiologic failure than monotherapy at ToC visit (0 vs. 9 patients, $P = 0.009$). Combination therapy, as compared with daptomycin monotherapy, was associated with a nonsignificantly higher rate of adverse events due to study medication leading to treatment failure and discontinuation of therapy: 6/74 (8.1%) vs. 3/81 (3.7%) ($P = 0.31$).

Conclusion. The combination of daptomycin plus fosfomycin was more effective than daptomycin alone for treating MRSAB (NCT01898338).

Disclosures. **All authors:** No reported disclosures.

LB4. A Phase 3, Randomized, Controlled Clinical Trial of Bictegravir in a Fixed-Dose Combination, B/F/TAF, vs. ABC/DTG/3TC in Treatment-Naïve Adults at Week 96

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Background. Bictegravir (B), a potent INSTI with a high barrier to resistance, is coformulated with emtricitabine (F) and tenofovir alafenamide (TAF) as the FDA-approved single-tablet regimen B/F/TAF. We report Week 96 results from an ongoing phase 3 study comparing B/F/TAF to coformulated dolutegravir, abacavir, and lamivudine (DTG/ABC/3TC) in treatment-naïve adults living with HIV-1. Primary outcome at W48 demonstrated noninferior virologic responses, similar bone and renal profiles, and no viral resistance.

Methods. We randomized 1:1 HLA-B*5701-negative adults, without HBV and with estimated glomerular filtration rate (eGFR) ≥50 mL/minute to receive blinded B/F/TAF (50/200/25 mg) or DTG/ABC/3TC (50/600/300 mg) with matching placebos QD. Primary endpoint was proportion with HIV-1 RNA <50 copies/mL at W48 (FDA snapshot), with secondary analyses at W96. Noninferiority was assessed with 95% confidence intervals (CI) (12% margin). Other secondary endpoints were safety (adverse events [AEs], laboratory abnormalities) and predefined analyses of bone mineral density (BMD) and measures of renal function (eGFR, proteinuria).

Results. A total of 629 adults were randomized/treated (314 B/F/TAF, 315 DTG/ABC/3TC). At W96, B/F/TAF was noninferior to DTG/ABC/3TC: 87.9% vs. 89.8%, respectively, achieved HIV-1 RNA <50 copies/mL (difference −1.9%; 95%CI −6.9% to 3.1%, $P = 0.45$). In per-protocol analysis, 99.6% on B/F/TAF vs. 98.9% on DTG/ABC/3TC achieved HIV-1 RNA <50 copies/mL ($P = 0.33$). Most common AEs overall were nausea (11% B/F/TAF, 24% DTG/ABC/3TC, $P < 0.001$), diarrhea (15%, 16%), and headache (13%, 16%). Through W96, no participant had emergent resistance to study drugs. No participant discontinued B/F/TAF due to AEs; five (2%) discontinued DTG/ABC/3TC due to AEs (one after W48). Treatment-related AEs occurred in 28% B/F/TAF vs. 40% DTG/ABC/3TC ($P = 0.002$); most common was nausea (6%, 17%. $P < 0.001$). At W96, mean percentage changes in spine and hip BMD were small and similar between groups (table); median change in eGFR was significantly less with B/F/TAF, while median % changes in proteinuria were similar.

Conclusion. At W96, B/F/TAF was virologically noninferior to DTG/ABC/3TC, with no viral resistance or safety-related discontinuations. B/F/TAF was well tolerated with less nausea than DTG/ABC/3TC and similar bone and renal safety.

Table. Changes from baseline in safety parameters at W96

	B/F/TAF (n=314)	DTG/ABC/3TC (n=315)	P value
eGFR, median (mL/min)	-7.8	-9.6	0.01
Renal Biomarkers, median (%)			
Urine Albumin: Creatinine Ratio	-0.3	+5.2	0.25
Urine Retinol Binding Protein: Creatinine Ratio	+21.2	+22.1	0.91
Urine Beta-2-Microglobulin: Creatinine Ratio	-30.8	-29.4	0.96
BMD, mean (%)			
Spine[a]	-0.71	-0.22	0.14
Hip[b]	-1.13	-1.26	0.59

[a] n=256 (B/F/TAF), n=258 (DTG/ABC/3TC)
[b] n=250 (B/F/TAF), n=258 (DTG/ABC/3TC)

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LB5. Safety of In Utero Antiretroviral (ARV) Exposure: Neurologic Outcomes in HIV-Exposed, Uninfected Children

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Background. Antiretroviral therapy for pregnant women with HIV has dramatically decreased perinatal transmission of HIV, but concerns remain regarding adverse neurologic outcomes from possible mitochondrial dysfunction or other mechanisms in children exposed in utero to antiretroviral (ARV) medications.

Method. We evaluated HIV-exposed uninfected (HEU) children enrolled in the Surveillance Monitoring for ART Toxicities (SMARTT) study, a longitudinal observational cohort study conducted by the Pediatric HIV/AIDS Cohort Study (PHACS) network. The primary outcome of interest was a "neurologic case" (microcephaly, febrile seizures, seizure disorders, ophthalmologic disorders, other neurologic conditions) as determined by clinical review blinded to ARV exposure. Log-binomial regression analysis was used to obtain adjusted relative risks (aRRs) for associations between in utero ARV exposure and neurologic case status, accounting for potential confounders including Hispanic ethnicity, tobacco use during pregnancy, and birth cohort (2011–2014 and 2015–2017 vs. <2011). To account for variable person-time follow-up within the cohort, Poisson regression models for adjusted incidence rate ratios (aIRRs) were also fitted.

Result. Among 3,747 eligible HEU children enrolled in SMARTT (52% male, 68% Black and 31% Hispanic), 237 were diagnosed with neurologic conditions, yielding an event rate of 6.3% (95% CI: 5.6%, 7.2%). Tobacco and alcohol use during pregnancy were common (17% and 8%, respectively). The majority of children had in utero ARV exposure (87%); 60% to PI-based regimens, 16% to NNRTI-based regimens and 7% to PI + NNRTI-based regimens. In adjusted models, there was a trend towards an association between efavirenz exposure (EFV) and neurologic case status (aRR: 1.60, 95% CI: 0.99, 2.58). This association was statistically significant in sensitivity analyses restricted to children enrolled prior to or shortly after birth (aRR: 1.80, 95% CI: 1.06, 3.05), excluding children with confirmed congenital anomalies (aRR: 1.66, 95% CI: 1.02, 2.64), and accounting for person-time follow-up (aIRR: 1.55, 95% CI: 1.00, 2.76).

Conclusion. EFV exposure during pregnancy was associated with a higher risk of neurologic abnormalities in infancy and childhood.

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LB6. Oral Lefamulin Is Safe and Effective in the Treatment of Adults With Community-Acquired Bacterial Pneumonia (CABP): Results of Lefamulin Evaluation Against Pneumonia (LEAP 2) Study

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Background. Lefamulin, a first in class pleuromutilin, is being developed as an IV and oral formulation for treating CABP. The second of 2 phase 3 Lefamulin Evaluation Against Pneumonia studies, LEAP 2 (NCT02813694; EudraCT 2015-004782-92) evaluating an oral 5-day regimen, is presented here. LEAP 2 complements the positive results from LEAP 1, an IV-to-oral switch study in patients with PORT Risk Class III-V.

Methods. In this multicenter, randomized, double-blind, double dummy study, patients with CABP were randomized to oral lefamulin 600 mg q12h for 5 days or moxifloxacin 400 mg q24h for 7 days. Adults with PORT Risk Class II–IV were eligible (≥50% were to have PORT Risk Class III or IV). The US FDA primary endpoint was early clinical response (ECR) (96 ± 24 h after first dose) in the intent-to-treat (ITT) population. The EMA coprimary endpoints (FDA secondary endpoints) were investigator assessment of clinical response (IACR) at test of cure (TOC) (5–10 days after last dose) in the modified ITT (mITT) and clinically evaluable (CE) TOC populations. For FDA and EMA endpoints, noninferiority was concluded if the lower limit of the two-sided 95% CI was greater than −10% (Figure 1).

Results. A total of 738 patients were randomized (n = 370 lefamulin, n = 368 moxifloxacin). Five days of lefamulin was noninferior to 7 days of moxifloxacin for both FDA and EMA primary endpoints (Figure 2). Lefamulin was efficacious regardless of PORT Risk Class (ECR responder rates for PORT II, III, and IV: 91.8% [168/183], 91.0% [132/145], and 85.0% [34/40] for lefamulin; 93.1% [176/189], 90.2% [120/133], and 85.7% [36/42] for moxifloxacin, respectively). Both agents demonstrated similar ECR responder and IACR success rates across baseline CABP pathogens. Rates of serious adverse events (AEs) and AEs leading to discontinuation were low and similar between groups. Most frequently reported AEs were gastrointestinal, the majority of mild severity with few discontinuations.

Conclusion. Five-day oral lefamulin demonstrated noninferiority for both FDA and EMA efficacy endpoints vs. 7-day oral moxifloxacin. Both agents were safe and generally well tolerated. Lefamulin shows promise as an oral monotherapy with a complete spectrum of antibacterial activity against CABP pathogens.

Figure 1. LEAP 2 Phase 3 Trial Design, Oral Administration

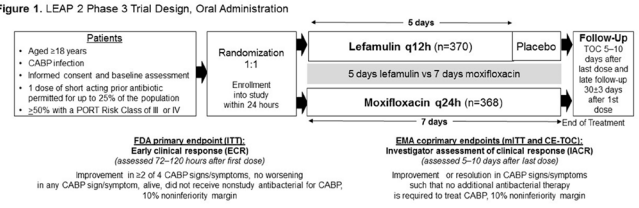
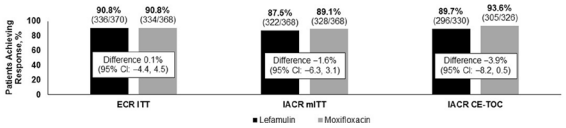


Figure 2. FDA (ECR) and EMA (IACR) Primary Endpoints



Disclosures. **E. Alexander**, Nabriva: Employee and Shareholder, Salary and Stock Options. **L. Goldberg**, Nabriva: Employee, Employee Stock Options and Salary. **A. Das**, Achaogen: Consultant, Consulting fee. Cempra: Consultant, Consulting fee. Contrafect: Consultant, Consulting fee. Paratek: Consultant, Consulting fee. Tetraphase: Consultant, Consulting fee. Wockhardt: Consultant, Consulting fee. Theravance: Consultant, Consulting fee. Zavante: Consultant, Consulting fee. Utility: Consultant, Consulting fee. Former Employee of Nabriva: Employee, Salary. Nabriva: Consultant, Consulting fee. **G. J. Moran**, Nabriva: Scientific Advisor, Consulting fee. **C. Sandrock**, Nabriva: Consultant, Consulting fee. **L. B. Gasink**, Former Employee of Nabriva: Employee, Salary. **P. Spera**, Nabriva: Employee and Shareholder, Salary. **C. Sweeney**, Nabriva: Employee, Employee Stock Options and Salary. **S. Paukner**, Nabriva: Employee and Shareholder, Salary. **W. W. Wicha**, Nabriva: Employee and Shareholder, Salary. **J. Schranz**, Nabriva: Employee and Shareholder, Salary.

LB7. Contract Tracing Investigation Following First Case of Andes Virus in the United States

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