Results. Of the 28 samples tested, 13 were C-N and 15 C-P. The extraction-free method generated an amplicon in 13/15 C-P cases, with CPs ranging from 26 to 36 cycles *vs.* 100% (15/15) detected with the DNA extraction method and Cps of 19 to 32. Usable sequence length for the extraction-free method was of 359 (interquartile range, 307–390) *vs.* 390 (interquartile range, 308–396) base pairs with DNA extraction. Genus-level concordance between bacteria detected by culture in C-P samples and those found using the extraction-free and extraction methods was 92% (12/13) and 93% (14/15), respectively. Bacteria were detected by the extraction method in 2/13 C-N specimens, with none detected with an extraction-free method.

Conclusion. The described extraction-free method may be suitable for testing SF derived from CIEDs using 16S rRNA gene PCR/sequencing, saving time and cost. More studies are needed to establish clear cutoffs for interpretation of results and to assess for PCR inhibitors in the studied specimen-type.

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661. Ibalizumab Efficacy and Safety Through 48 Weeks of Treatment: Results of an Expanded Access Protocol (TMB-311)

Brinda Emu, MD[1]; Edwin DeJesus, MD[2]; Mezgebe Berhe, MD[3];
Jason Leider, MD, PhD[4]; Catherine Creticos, MD[5]; Steve Weinheimer, PhD[6];
Zvi Cohen, PhD[7]; [1]Yale University, New Haven, Connecticut; [2]Orlando Immunology Center, University of Central Florida College of Medicine, Orlando, Florida; [3]North Texas Infectious Diseases Consultants, Dallas, Texas; [4]Jacobi Medical Center, Bronx, New York; [5]Howard Brown Health, Chicago, Illinois; [6]TaiMed Biologics USA, Houston, Texas; [7]Theratechnologies Inc., Montreal, QC, Canada

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Background. Ibalizumab (IBA), a humanized monoclonal antibody, is the first CD4-directed post-attachment HIV-1 inhibitor. It was approved by the FDA in March 2018 based on results from the pivotal Phase 3 TMB-301 clinical study.

The TMB-311 expanded access protocol Cohort 2 enrolled treatment-experienced patients with multidrug-resistant (MDR) HIV-1 infection to further evaluate the efficacy, safety and tolerability of IBA in combination with an optimized background regimen (OBR). Here, we report the results through 48 weeks of treatment in these patients.

Methods. Major eligibility criteria included HIV-1 viral load (VL) >1000 copies/mL, resistance to ≥1 antiretroviral (ARV) medication from three different ARV classes and full viral sensitivity to ≥1 ARV agent. Treatment started with IBA 2000 mg intravenously (IV) on Day 0 and then 800 mg IV (maintenance) every 2 weeks thereafter. OBR with ≥1 fully active agent also started at Day 0.

Results. Cohort 2 enrolled 38 patients with a median age of 53 years, mostly male (87%) and white (53%). At Baseline, median VL was 4.7 $\log_{10}$ copies/mL, CD4 cell count was 26 cells/mm^3 and overall susceptibility score of 1. A ≥0.5 $\log_{10}$ decrease in VL from Baseline was achieved in 28 of 37 patients (76%) at Day 7. Of 24 patients who completed the Week 24 visit, 11 (46%) had HIV-1 RNA levels <50 copies/mL. Of 17 patients with a VL assessment at Week 48, 8 (47%) achieved <50 copies/mL. Seven patients did not have a Week 48 endpoint because they withdrew from the study to receive commercial IBA. At both time points, the median change in VL from Baseline was -2.6 $\log_{10}$ copies/mL. The most frequently reported treatment-emergent adverse events (TEAEs) were diarrhea (24%), headache (21%), and nausea, cough, rash, and fatigue (16% each). No injection site reactions related to IBA were reported. Most events were mild; 9 patients reported Grade ≥3 TEAEs. Two events were fatal (sepsis and cardiac arrest); neither related to IBA. One event of immune reconstitution inflammatory syndrome was reported and considered possibly related to IBA.

Conclusion. Results from Cohort 2 patients of TMB-311 (IBA + OBR) demonstrate durable viral suppression in this difficult-to-treat patient population and with a safety profile consistent with pivotal Phase 3 study of IBA.

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

662. Recurrence of Infection and Emergence of Drug Resistance After Treatment with Meropenem/Vaborbactam Compared with Ceftazidime/Avibactam in Carbapenem-Resistant *Enterobacteriaceae* Infections

Renee Ackley, PharmD, BCPS[1]; Danya Roshdy, PharmD, BCPS, BCIDP[2];
Jacqueline Isip, PharmD, BCPS, BCIDP[1];
Sarah B,. Minor, PharmD, BCPS-AQ ID[3];
Amanda L. Elchynski, Doctor of Pharmacy[4]; William E. Anderson, MS[1];
Gerald A. Capraro, PhD, D(ABMM)[1]; Christopher Polk, MD[1]; [1]Atrium Health, Charlotte, North Carolina; [2]Atrium Health - Antimicrobial Support Network, Charlotte, North Carolina; [3]AdventHealth, Winter Springs, Florida; [4]AdventHealth Orlando, Orlando, Florida

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Background. Options for treatment of carbapenem-resistant *Enterobacteriaceae* (CRE) infections were historically limited to antibiotics with limited efficacy and significant toxicities. Ceftazidime/avibactam (CA) and meropenem/vaborbactam (MV) are superior to older regimens; however, a direct comparison of the agents is lacking. This study compared clinical outcomes including recurrence of infection and emergence of drug resistance in patients who received CA vs. MV for CRE infections.

Methods. This was a multicenter, retrospective cohort study of adults with CRE infections who received CA or MV for ≥72 hours from February 2015 to October 2018. Patients with localized urinary tract infection were excluded. The primary endpoint was clinical success (30-day survival, resolution of signs and symptoms of infection, sterilization of blood cultures within 7 days in patients with bacteremia, absence of recurrent infection). Secondary endpoints included 30- and 90-day mortality, adverse events (AE), recurrent CRE infection within 90 days, and development of resistance in patients with recurrent infection. We conducted a post hoc subgroup analysis in patients with recurrence to compare development of resistance in those who received CA monotherapy, CA combination therapy, and MV monotherapy.

Results. 131 patients were included (CA: 105 patients, MV: 26 patients), 40% had bacteremia. No statistical difference in clinical success was observed between groups (62% vs. 69%, respectively, $P = 0.49$). Patients in the CA arm received combination therapy more often than patients in the MV arm (61% vs. 15%, $P < 0.01$). No difference in 30- and 90-day mortality resulted among groups, but numerically higher rates of AE were observed in the CA group (38% vs. 23%, $P = 0.17$). In patients with recurrent infection, development of resistance occurred more often with CA monotherapy, though not statistically significant (Table 1). One case of MV resistance was observed in a patient who had received 4 prior courses of MV, but this episode was outside of the study period.

Conclusion. Clinical success was similar between the groups despite MV being used more often as monotherapy. Development of resistance and rates of AE were higher in the CA group compared with MV therapy.

Table 1. Post-hoc subgroup analysis of patients with recurrent CRE infection

n (%)	CA monotherapy n = 41	CA combination n = 64	MV monotherapy n = 22	P value
Recurrent CRE infection	9 (22.0)	6 (9.4)	3 (13.6)	0.20
MIC increase	5 (12.2)	1 (1.6)	0	0.13
Development of resistance	3 (7.3)	0	0	0.21

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

663. Efficacy and Safety of Lefamulin (LEF) vs. Moxifloxacin (MOX) for *Legionella pneumophila* (*LP*) in Patients with Community-Acquired Bacterial Pneumonia (CABP): Pooled Results From the Lefamulin Evaluation Against Pneumonia (LEAP) 1 and LEAP 2 Phase 3 Clinical Trials

Andrew F. Shorr, MD, MPH, MBA[1]; Jennifer Schranz, MD[2];
Lisa Goldberg, MS[2]; Susanne Paukner, PhD[3]; Anita F. Das, PhD[4];
Gregory J. Moran, MD[5]; Christian Sandrock, MD[6];
Thomas M. File, Jr., MD[7]; Elizabeth Alexander, MD, MSc., FIDSA[2];
Steven P. Gelone, PharmD[2]; [1]Medstar Washington Hospital Center, Washington, DC; [2]Nabriva Therapeutics US, Inc., King of Prussia, Pennsylvania; [3]Nabriva Therapeutics GmbH, Vienna, Wien, Austria; [4]Das Consulting, Guerneville, California; [5]Olive View-UCLA Medical Center, Sylmar, California; [6]UC Davis School of Medicine, Sacramento, California; [7]Summa Health, Akron, Ohio

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Background. *LP* is associated with severe CABP, rapid onset, and high morbidity/mortality. Poor outcomes in CABP have been linked to receiving inappropriate empiric therapy or delayed treatment (tx). LEF, a novel IV/oral pleuromutilin, demonstrated efficacy/safety in noninferiority studies (LEAP 1/2) vs. MOX in adults with CABP. We report efficacy/safety of LEF in patients with *LP* based on a pooled analyses of LEAP 1/2 data.

Methods. In LEAP 1, PORT III–V patients received LEF 150 mg IV q12h for 5–7 days or MOX 400 mg IV q24h for 7 days, with optional IV-to-oral switch (600 mg LEF q12h or 400 mg MOX q24h). In LEAP 2, PORT II–IV patients received oral LEF for 5 days or oral MOX for 7 days. Both studies assessed early clinical response (ECR) at 96 ± 24 hours after first dose in the intent-to-treat (ITT; all randomized patients) population and investigator assessment of clinical response (IACR) at test-of-cure (TOC; 5–10 days after last dose) in the modified ITT (received ≥1 dose) and clinically evaluable (met predefined evaluability criteria) populations. *LP* was identified from baseline (BL) samples by culture, serology (IgG, Zeus *L. pneumophila* group 1–6 indirect fluorescent antibody assay), urine antigen testing (BinaxNOW), and real-time PCR (positive for *ssrA*). Efficacy analyses herein were done in the microbiological ITT (microITT, treated patients with BL CABP-causing pathogen), microITT-2 (no PCR), and microbiologically evaluable populations; safety analyses included all randomized/treated patients.

Results. Of 65 pooled microITT patients, median age was 60 y, 66% were male, 51% had a normal renal function, and 54%/25% were PORT III/IV. *LP* was identified in 9.3% (34/364) of LEF patients (7 [20.6%]/19 [55.9%]/8 [23.5%] PORT II/III/IV) and in 9.0% (31/345) of MOX patients (7 [22.6%]/16 [51.6%]/8 [25.8%] PORT II/III/IV), primarily by urine antigen or serology (table). Patients with *LP* in both tx groups achieved high and similar responses across all endpoints (Figures 1 and 2). In both tx groups, TEAE rates were low and comparable (~32%) and most were mild to moderate; 5 patients (3 LEF; 2 MOX) had treatment-emergent SAEs, all unrelated to tx. No patients died due to TEAEs; no LEF patients and 2 MOX patients discontinued tx due to TEAEs.