Disclosures. C. Ford, Seres Therapeutics, Inc: Employee and Shareholder, Salary. M. Henn, Seres Therapeutics, Inc: Employee and Shareholder, Salary. E. Pruitt, Seres Therapeutics, Inc: Employee and Shareholder, Salary. L. Diao, Seres Therapeutics, Inc: Employee and Shareholder, Salary. J. Wortman, Seres Therapeutics, Inc: Employee and Shareholder, Salary. A. Tomlinson, Seres Therapeutics, Inc: Employee and Shareholder, Salary. K. Litton, Seres Therapeutics, Inc: Employee and Shareholder, Salary. P. Bernardo, Seres Therapeutics, Inc: Employee and Shareholder, Salary. B. McGovern, Seres Therapeutics, Inc: Employee and Shareholder, Salary. J. G. Aunins, Seres Therapeutics, Inc: Employee and Shareholder, Salary. D. N. Cook, Seres Therapeutics, Inc: Employee and Shareholder, Salary. M. Truchais, Seres Therapeutics, Inc: Employee and Shareholder, Salary.

1642. Safety and Efficacy of Bacteriophage Therapy: Analysis of Clinical Case Series Data
Saima Aslam, MD, MS; Timothy Gilber, MD; Susan Maddocks, MD; Sandra Morales, PhD; Susan Lehman, PhD; Steven Branston, PhD; Aleksandra Petrovic Fabijan, PhD; Carrey Langlais Furr, PhD; Francisco Rosas, MS/RAC; Igor Bilinsky, PhD; Paul Grind, MD; Robert T. Schooley, MD, FIDSA and Jonathan Iredell, Professor,‡‡, Division of Infectious Diseases, University of California San Diego Health Centers, San Diego, California, ‡Crucial Infectious Diseases, Westmead Hospital, Sydney, Australia. 

1643. Infectious Diseases, Westmead Hospital, Sydney, Australia, ‡Research, AmpliPhi Biosciences, Sydney, Australia, ‡Research, AmpliPhi Biosciences, Richmond, Virginia, ‡Centre for Infectious Diseases and Microbiology, Westmead Institute for Medical Research, Sydney, ‡Research, AmpliPhi Biosciences, San Diego, California, ‡AmpliPhi Biosciences, San Diego, California, ‡Medicine/Infectious Diseases, University of California San Diego, La Jolla, California and ‡Critical Infection, Westmead Institute for Medical Research, Sydney, Australia

Session: 168. Novel Therapies for Superbugs Friday, October 5, 2018: 2:00 PM

Background. Bacteriophage therapy (BT) is a re-emerging strategy to treat antibiotic-resistant infections. Here, we describe our initial experience with intra-vien (IV) and inhaled BT to treat life-threatening Staphylococcus aureus and Pseudomonas aeruginosa infections not responding to antibiotic therapy. Emergency Investigational New Drug application approvals (United States) or Special Access Scheme Category A notifications (Australia) and informed consent from the patients were obtained.

Methods. Patients were treated with AB-SA01 (3-pha ge product targeting S. aureus) and AB-PA01 (4-pha ge product targeting P. aeruginosa) produced in a Good Manufacturing Practice-certified facility. Pre- and posttreatment bacterial iso-

ts were obtained.

Results. As of April 2018, 8 patients were treated with BT. With AB-SA01 (bacteremia, n = 4; endocarditis, n = 1) and 3 with AB-PA01 (lung infection, n = 3). Median duration of BT was 14 days and treated patients received over 90 IV doses of AB-SA01 (3 × 10⁶ PFU/dose) and over 490 IV and nebulized doses of AB-PA01 (4 × 10⁶ PFU/dose). BT was well tolerated, with no treatment-related adverse events. Clinical treatment success was documented in 75% of patients. Isolates collected during therapy showed ongoing susceptibility to the BT products with changes in sensitivity to the individual phage components observed in some cases. Bacteriophage kinetics revealed bloodstream clearance within a few hours after IV infusion and an inferred initial bacteria/bacteriophage ratio of ~200 for the bacteremia patients.

Conclusion. BT was well tolerated as an adjunct to antibiotics, with several exam-

ples presented of microbiological eradication and improvement of objective clinical criteria. BT appears to be a safe adjunct to antibiotic therapy in life-threatening S. aureus and P. aeruginosa infections and is a promising candidate for controlled clinical trials.

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1643. Pharmacodynamics (PD) of Daptomycin (DAP) in Combination Therapy for Entercoccal Bloodstream Infection (BSI)
Lindsay Avery, PharmD; Joseph L. Kuti, PharmD; Maja Weiss, MD; Adrian Egli, MD;§ Michael J. Rybak, PharmD, MPH, PhD; Evan J. Zasowski, PharmD, MPH, BCPS;§ Cesar Arias, MD, PhD, FIDSA;§ German Contreras, MD;§ Pearlee Cheong, MD, MPH;§ MT;§ Adam J. DiPippo, PharmD;§ Iann-Tay Wang, MD, PhD;§ Nicholas S. Britt, PharmD, MS;§ and David P. Nicolau, PharmD, FCCP, FIDSA,§,§,§,§ Citr for Anti-Infect. Res. and Dev., Hartford Hospital, Hartford, Connecticut, ‡Division of Infectious Diseases and Hospital Epidemiology, University Hospital Basel, Basel, Switzerland, §Department of Clinical Microbiology, University Hospital Basel, Basel, Switzerland, ¤Applied Microbiology Research, Department of Biomedicine, University of Basel, Basel, Switzerland, ¶Anti-Infective Research Laboratory, College of Pharmacy, School of Medicine, Division of Infectious Diseases, Wayne State University, Detroit, Michigan, ¶¶Department of Pharmacy Practice, University of Houston College of Pharmacy, Houston, Texas, ¶¶¶Division of Infectious Diseases, University of Texas McGovern Medical School at Houston, Houston, Texas, §§§Division of Infectious Diseases, University of Texas Southwestern Medical Center, Dallas, Texas, §§§ Department of Pharmacy Practice, University of Texas Southwestern Medical Center, Dallas, Texas, §§§§Center for Anti-Infective Research and Development, Hartford Hospital, Hartford, Connecticut and §§§§Division of Infectious Diseases, Hartford Hospital, Hartford, Connecticut

Session: 168. Novel Therapies for Superbugs Friday, October 5, 2018: 2:00 PM

Background. DAP is frequently employed in combination with a second anti-

biotic for enterococcal BSI. We previously observed that a free drug area under the curve to MIC ratio (AUC/MIC) ≥27.43 was predictive of survival when DAP was administered as monotherapy. The extent to which combination therapy affects DAP PD remains unexplored.

Methods. This study pooled data from 7 published trials assessing outcomes in DAP treated enterococcal BSI. AUC/MIC was calculated using a published pop-

ulation pharmacokinetic model based on creatinine clearance, 90% protein bind-

ing, and baseline DAP MIC for each patient that received ≥72 hours of DAP as part of a combination antibiotic regimen. The AUC/MIC threshold predictive of 30-day survival was determined by classification and regression tree analysis and confirmed by multivariable logistic regression. To control for comorbidities, the threshold was examined in the low-acuity patients only (APACHE-II score <21, Charlson co-morbidity index <5, or Pitt bacteremia score <4). Monte Carlo simu-

lation was performed to determine the probability of target attainment (PTA) over a range of MICs.

Results. In total, 240 adults were included and 137 (57.1%) were alive at 30 days. A majority of patients (62.8%) were immunosuppressed. Combination therapy was observed in 177 patients and with a 3-lactic and 1 other active agent in 34 (14.2%) patients. Low-acuity patients (n = 135) were more likely to survive when AUC/MIC > 12.3 was achieved (63.2% ver-

sus 20.0%, P = 0.015). This difference remained significant when controlling for BSI source and immunosuppression (P = 0.017). The PTA for a 6 mg/kg/day dose was 95.2% at MIC=2 mg/L and 43.0% at MIC=4 mg/L; PTA for a 12 mg/kg/day dose was 95.2% at 4 mg/L.

Conclusion. Compared with our previous observations for DAP monotherapy against enterococcal BSI, a lower DAP PD exposure was required when administered with at least one additional antibiotic. For combination therapy with DAP, a (AUC/ MIC > 12.3 was associated with 30-day survival. As part of an active combination therapy regimen, DAP 6 mg/kg/day was appropriate for treatment of BSI caused by enterococci with MICs ≤2 mg/L, while 12 mg/kg/day was optimal for isolates with MICs ≥4 mg/L.

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1644. A Potent Broadly Neutralizing Antibody Isolated From Human Memory B-cells Binding to Conserved Site IV of the RSV F Protein
Elbert Vora, PhD; Zhiding Chen, PhD; Huai Lu, Su, PhD; Aimin Tang, MS; Kara Cox, MS; Cheryl Callahan, MS; Lan Zhang, PhD; Sangita Patel, MS; Debbie Nahas, MS; Mike Citron, PhD; Pedro Cejas, PhD; Ryan Swoyer, MS; Bin Luo, MS; Michael Eddins, MS; John Reid, MS; Arthur Fradman, PhD; Jennifer Galli, MS; Scott Cosmi, MS; Govindarajan Dhansakeran, PhD; Zhiyun Wen, MS; Xi He, MS; Dai Wang, PhD; Gwen Heidecker, MS; Jessica Flynn, PhD; James Cook, PhD; Stephen Soisson, PhD; Danilo Casimiro, PhD; Andrew Britt, PhD; Wade Blain, PhD; Daniel Dostale, MS and Christopher Haines, PhD; MeMed & Co., Inc., Kenilworth, New Jersey, MeMed Research Laboratories, Kenilworth, New Jersey, Vaccine Research, Merck Research Lab, West Point, Pennsylvania and Eurofins Lancaster Laboratories Professional Scientific Services, Lancaster, Pennsylvania

Session: 169. Respiratory and Gastroenteritis Viruses Friday, October 5, 2018: 2:00 PM

Background. Respiratory syncytial virus (RSV) infection is a major public health burden for infants and the elderly worldwide. Currently, there are