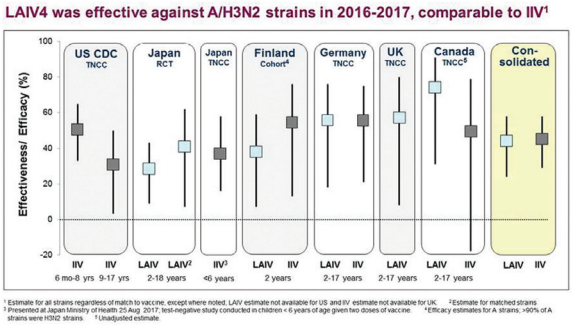

¹ Estimate for all strains regardless of match to vaccine, except where noted. LAIV estimate not available for US and IIV estimate not available for UK. ² Estimate for matched strains. ³ Presented at Japan Ministry of Health 25 Aug 2017; test-negative study conducted in children < 6 years of age given two doses of vaccine. ⁴ Efficacy estimates for A strains, >90% of A strains were H3N2 strains. ⁵ Unadjusted estimate.

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1974. Ceftriaxone-Sulbactam-EDTA vs. Meropenem in PLEA (a Phase 3, Randomized, Double-Blind Trial): Outcomes by Baseline MIC in Adults With Complicated Urinary Tract Infections or Acute Pyelonephritis

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Background. Ceftriaxone–sulbactam–disodium EDTA (CSE) is being developed for Gram-negative infections caused by multidrug-resistant (MDR) bacteria. PLEA was a Phase 3, double-blind, multicenter, randomized study of CSE vs. meropenem (MR) for treatment of adults with complicated urinary tract infections (cUTI) or acute pyelonephritis (AP). Non-inferiority of CSE over MR at the EMA/FDA primary endpoints has been reported. The effect of baseline MIC on clinical and microbiological outcome at the test of cure (TOC) visit was investigated.

Methods. Adult patients were randomized 1:1 to receive either CSE (1 g ceftriaxone/500 mg Sulbactam/37 mg EDTA) every 12 h or MR 1g every 8 hours as 30 minutes IV infusion for 5–14 days. Oral step-down therapy was not allowed. Prior to dosing, urine specimens were collected, and MICs were conducted using CLSI methods for both study drugs. Patients that were nonsusceptible to MR were not included in the mMITT population.

Results. Of 230 subjects randomized, 143 (62.2%) were included in the mMITT population. Baseline Enterobacteriaceae was found in 131 (91.6%) patients, 67/74 (90.5%) in CSE and 64/69 (92.8%) in MR arm. Mean duration of IV therapy was 7 days. Favorable clinical and microbiological outcomes were observed in ≥90% patients for all MICs across the two study groups, with the exception of MIC 1 µg/mL in MR (associated with >20% failures). Overall, both clinical cure and microbiological eradication rates were higher in CSE as compared with MR (95.9% Vs. 89.9% and 94.6% vs. 88.4% respectively) (Table 1).

CSE			MR		
MIC (µg/mL)	Clinical Cure *n/N* (%)	Microbiological Eradication *n/N* (%)	MIC (µg/mL)	Clinical Cure *n/N* (%)	Microbiological Eradication *n/N* (%)
<0.25	16/16 (100)	16/16 (100)	<0.25	20/22 (90.9)	21/22 (95.4)
0.25	4/4 (100)	4/4 (100)	0.25	12/12 (100)	11/12 (91.7)
0.5	3/3 (100)	2/3 (66.7)	0.5	14/14 (100)	13/14 (92.7)
1	9/10 (90)	9/10 (90)	1	16/21 (76.2)	16/21 (76.2)
2	23/23 (100)	23/23 (100)			
4	16/17 (94.1)	16/17 (94.1)			
8	0/1 (0)	0/1 (0)			
Overall	71/74 (95.9)	70/74 (94.6)	Overall	62/69 (89.9)	61/69 (88.4)

Conclusion. CSE showed a high *in vitro–in vivo* correlation of >97% for MICs up to 4 µg/mL and is a potential new treatment option in patients with cUTI or AP.

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1975. 1 g vs. 2 g Daily Intravenous Ceftriaxone in the Therapy of Community-onset Pneumonia: A Propensity Score Analysis From a Data of Japanese Multicenter Registry

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Background. Community-acquired pneumonia (CAP) is one of the most common infectious diseases and is an important cause of mortality and morbidity worldwide. The prognosis of CAP in adults is associated with factors such as age, comorbidities, vital signs, laboratory data, and other factors on admission. Usually, ceftriaxone (CTRX) is used to treat CAP. However, whether 1 or 2 g of CTRX daily has better efficacy remains unclear.

Methods. This study is an analysis of prospectively registered data from four Japanese hospitals for patients with community-onset pneumonia (COP) from September 2011 to August 2014 (the Adult Pneumonia Study Group-Japan: APSG-J). Subjects who were initially treated solely with 1 g or 2 g of CTRX were enrolled. Propensity score was estimated from the 33 pretreatment variables including age, sex, weight, comorbidities, medications, risk factors for aspiration, whether background was consistent with CAP or not, vital signs, laboratory data, and findings of a chest x-ray. The primary endpoint was cure rate, for which a noninferiority analysis was performed with a margin of 0.05. The secondary outcomes included in-hospital mortality, duration of antibiotic treatment, and length of hospital stay, which were assessed using superiority analyses.

Results. Of the 3,817 adult subjects with pneumonia who were registered in the APSG-J study, 290 and 216 were initially treated solely with 1 g or 2 g of CTRX, respectively. Propensity score matching was used to finally extract 175 subjects in each group. Overall, the cure rate was 94.6% in the 1 g group and 93.1% in the 2 g group (risk difference, 1.5 percentage points; 95% confidence interval [CI], −3.1 to 6.0; $P = 0.009$ for noninferiority). The in-hospital mortality rate was 4.7% and 4.0% ($P = 0.740$ for superiority), length of hospital stay was 17 and 26 days ($P < 0.001$ for superiority), and duration of antibiotic treatment was 8 and 10 days ($P = 0.002$ for superiority) in the 1 g and 2 g groups, respectively.

Conclusion. Propensity score-matched analysis of multicenter cohort data from Japan revealed that the cure rate for COP patients treated with 1 g of CTRX was non-inferior to that in the patients treated with 2 g of CTRX.

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

1976. Pooled Analysis of Safety Data From Phases 2 and 3 Clinical Trials Evaluating Eravacycline in Complicated Intra-Abdominal Infections

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Background. Eravacycline is a novel, fully synthetic fluorocycline antibiotic that was evaluated in three comparator-controlled studies for the treatment of complicated intra-abdominal infections (cIAI). The objective of this analysis was to evaluate the safety profile of eravacycline 1 mg/kg IV q12h for the treatment of cIAI.

Methods. Pooled data from one phase 2 and two phase 3 (IGNITE1 and IGNITE4) clinical trials in cIAI were analyzed. Patients in the trials were randomized to receive eravacycline 1 mg/kg IV q12h, ertapenem 1 g IV q24h, or meropenem 1 g IV q8h for 4–14 days. Overall treatment-emergent adverse events (TEAEs), serious TEAEs, and laboratory assessments were evaluated.

Results. Five hundred seventy-six patients were treated with eravacycline 1 mg/kg IV q12h and 547 patients with comparators (ertapenem and meropenem). Demographic and baseline characteristics were similar among the groups. Overall summary and common TEAEs are presented in Table 1. None of the serious TEAEs or those leading to death were related to the study drug. Clinically notable laboratory abnormalities were relatively uncommon and occurred at similar frequencies in eravacycline- and comparator-treated patients.

Table 1. Overall Summary of Treatment Emergent Adverse Events—Eravacycline Phases 2 and 3 Clinical Studies

	Eravacycline 1 mg/kg IV q12h, *N* = 576, *n* (%)	Comparators[a], *N* = 547, *n* (%)
Any TEAEs	217 (37.7)	152 (27.8)
Nausea	40 (6.9)	5 (0.9)
Vomiting	20 (3.5)	13 (2.4)
Diarrhea	13 (2.3)	8 (1.5)
Infusion phlebitis	13 (2.3)	1 (0.2)
Pyrexia	11 (1.9)	11 (2.0)
Anemia	7 (1.2)	12 (2.2)
Treatment-related TEAEs	71 (12.3)	20 (3.7)
TEAEs leading to discontinuation from study drug	9 (1.6)	12 (2.2)
Serious TEAEs	33 (5.7)	33 (6.0)
TEAEs leading to death	7 (1.2)	7 (1.3)

[a]Comparators include ertapenem 1 g IV q24h and meropenem 1 g IV q8h.