same-strain relapse and new-strain reinfection of CDI. We used WGS of paired *C. difficile* samples from patients with CDI recurrence in the EXTEND study to assess EPFX and SV in relation to relapse and reinfection.

**Methods.** Patients aged ≥60 years with CDI were randomized (1:1) to receive either EPFX (fidaxomicin 200 mg tablets, twice daily on Days 1–5 and once daily on alternate days on Days 7–25) or SV (125 mg capsules, four times daily on Days 1–10). Paired stool samples were collected from all patients at screening and from patients with recurrence after test-of-cure (TOC). Recurrence was defined as diarrhoea occurring to a greater extent than the frequency recorded at TOC, and confirmed positive for *C. difficile* toxin A/B and requiring further CDI therapy. *C. difficile* isolates from paired samples underwent WGS and single nucleotide variant (SNV) difference analysis. Paired samples with ≤2 SNV differences were considered relapses, paired samples with >10 SNV differences were considered relapses, paired samples with >10 SNV differences were considered indeterminate.

**Results.** At Day 90, 11/177 (6%) patients in the EPFX arm and 34/179 (19%) patients in the SV arm had CDI recurrence. Of these, samples from 7/11 EPFX- and 19/34 SV-treated patients were available for paired WGS analysis. SNV analysis showed that most CDI recurrences were new-strain reinfections (table).

**Conclusion.** Most recurrences were reinfections, but small sample sizes limited definitive conclusions.

Reference

1. Guery et al. (2017). Lancet Inf Dis 18:296-307.

## Table. SNV analysis

Treatment arm	EPFX	SV	Total
Patients with CDI recurrence (n/N)	11/177	34/179	45/356
Tested pairs, n (%*)	7 (15.6)	19 (42.2)	26 (57.8)
Relapse (≤2 SNV)	1 (2.2)	3 (6.7)	4 (8.9)
Reinfection (>10 SNV)	5 (11.1)	15 (33.3)	20 (44.4)
Indeterminate (>2 but ≤10 SNV)	1 (2.2)	1 (2.2)	2 (4.4)
No available SNV results	4 (8.9)	15 (33.3)	19 (42.2)

\*Calculated over total number of patients with CDI recurrence in both treatment arms

Disclosures. M. Wilcox, Astellas Pharma: Consultant and Grant Investigator, Consulting fee, Research grant, Speaker honorarium and This study was initiated and sponsored by Astellas. Medical writing support was provided by Cello Health MedErgy and funded by Astellas. O. A. Cornely, Astellas Pharma: Grant Investigator, Lecture speaker and Scientific Advisor, Research grant, Speaker honorarium and This study was initiated and sponsored by Astellas. Medical writing support was provided by Cello Health MedErgy and funded by Astellas. B. Guery, Astellas Pharma: Consultant, Consulting fee and This study was initiated and sponsored by Astellas. Medical writing support was provided by Cello Health MedErgy and funded by Astellas. C. Longshaw, Astellas Pharma: CL was a full-time employee of Astellas Pharma, Inc., during the study conduct and is now an employee of Shionogi Europe Ltd.; he also has a patent WO2015169451 A1 pending. and Employee, Medical writing support was provided by Cello Health MedErgy and funded by Astellas and Salary. A. Georgopali, Astellas Pharma: Employee, Medical writing support was provided by Cello Health MedErgy and funded by Astellas. and Salary. A. Karas, Astellas Pharma: AK has patents WO2015169451 A1 and EP17167541.6 pending. and Employee, Medical writing support was provided by Cello Health MedErgy and funded by Astellas. and Salary. G. Kazeem, Astellas Pharma: Independent Contractor, Medical writing support was provided by Cello Health MedErgy and funded by Astellas. and Salary. J. A. Palacios-Fabrega, Astellas Pharma: AP-F has a patent EP17167541.6 pending. and Employee, Medical writing support was provided by Cello Health MedErgy and funded by Astellas. and Salary. M. J. G. T. Vehreschild, Astellas Pharma: Consultant and Grant Investigator, Consulting fee, Grant recipient and This study was initiated and sponsored by Astellas. Medical writing support was provided by Cello Health MedErgy and funded by Astellas.

1953. Comparative Effectiveness of High- vs. Standard-Dose Influenza Vaccine on Hospitalization for Acute Myocardial Infarction in Nursing-Home Residents: A Post-hoc Analysis From a Large Cluster-Randomized Trial Elie Saade, MD, MPH<sup>1,2,3</sup>; Nina Joyce, PhD<sup>4</sup>; Jessica Ogarek, MS<sup>4</sup>; H. Edward Davidson, PharmD, MPH<sup>5</sup>; Lisa Han, MPH<sup>5</sup>; David Canaday, MD<sup>2,3</sup>; Abul Yasin, MD<sup>6</sup>; Theresa Shireman, PhD<sup>4</sup>; Vincent Mor, PhD<sup>7,8</sup> and Stefan Gravenstein, MD, MPH<sup>2,7,9,10</sup>; <sup>1</sup>University Hospitals of Cleveland, Cleveland, Ohio, <sup>2</sup>Case Western Reserve University, Cleveland, Ohio, <sup>3</sup>Geriatric Research Education and Clinical Center (GRECC), Cleveland Veterans Hospital, Cleveland, Ohio, <sup>4</sup>Center for Gerontology and Healthcare Research, Brown University School of Public Health, Providence, Rhode Island, <sup>5</sup>Insight Therapeutics, LLC, Norfolk, Virginia, <sup>6</sup>Geriatric Medicine, Brown University School of Medicine, Providence, Rhode Island, <sup>7</sup>Long Term Services and Supports-COIN, Providence VA Medical Center, Providence, Rhode Island, <sup>8</sup>Health Services, Policy and Practice, Brown University School of Public Health, Providence, Rhode Island, <sup>9</sup>Center for Health Services Policy and Practice, Brown University School of Public Health, Providence, Rhode Island, <sup>10</sup>Geriatric Medicine, Warren Alpert Medical School of Brown University, Providence, Rhode Island

### Session: 227. Clinical Trials

Saturday, October 6, 2018: 12:30 PM

**Background.** There is growing evidence supporting the role of influenza vaccine in decreasing the risk of cardiovascular (CV) events, including acute myocardial infarction. The development of vaccines targeting older adults, such as high-dose (HD) and adjuvanted formulations, offers the promise of enhanced CV protection in this high-risk group. We evaluated whether a HD trivalent vaccine was associated with a reduced incidence of acute CV events (ACE) among nursing home (NH) residents, compared with a standard-dose trivalent vaccine (SD).

**Methods.** This is a secondary analysis of data from a single-blind, pragmatic, cluster-randomized comparative effectiveness trial. We recruited and randomized Medicare-certified NHs located within 50 miles of a CDC influenza reporting city to facility-wide standard of care for the residents to either HD or SD as the vaccine offered for the 2013–2014 influenza season. Long-stay residents 65 and older in a fee-for-service Medicare plan were eligible for the study. Study staff were masked to NH allocations and raw data access to minimize bias. Outcome data of interest were obtained from the Centers for Medicare and Medicaid Services (CMS). The primary outcome was hospitalization for an acute cardiovascular event (ACE), defined as acute myo-cardial infarction, atrial fibrillation or heart failure between November 2013 and May 2014. Hazard ratios were estimated from cox-proportional hazard models with facility random effects to account for clustering. We conducted stratified analyses by gender and baseline cardiovascular disease. All models were adjusted for individual and facility level baseline characteristics.

**Results.** A total of 823 facilities with 38,672 eligible residents were randomized into balanced groups. Facility and resident characteristics were comparable. The incidence of hospitalization for ACE was significantly lower in HD than SD facilities (10.1% vs. 11.0%; adjusted HR 0.92; 95% CI 0.85–0.95; *P*-value 0.015). Figure 1 shows adjusted HR for each outcome; selected subgroups are presented in Figure 2.

**Conclusion.** High-dose flu vaccine reduces the risk of hospitalization for ACE in long-term care residents by 8% relative to standard-dose vaccine.

#### Registration NCT01815268. Funding sanofi pasteur.



Figure 1. Adjusted hazard ratio by outcome (HD versus SD vaccine; adjusted for age, gender, race, hypertension, diabetes, dyslipidemia, obesity and tobacco use).



Figure 2. Adjusted hazard ratio of acute cardiac events outcome by subgroup (HD versus SD vaccine; adjusted for age, gender, race, hypertension, diabetes, dyslipidemia, obesity and tobacco use).

Disclosures. E. Saade, sanofi pasteur: Collaborator, Research support. Seqirus: Collaborator, Research support. N. Joyce, sanofi pasteur: Collaborator, Research support. Seqirus: Collaborator, Research support. J. Ogarek, sanofi pasteur: Collaborator, Research support. Seqirus: Collaborator, Research support. D. Canaday, sanofi pasteur: Collaborator, Research support. Seqirus: Collaborator, Research support. J. Canaday, sanofi pasteur: Collaborator, Research support. Seqirus: Collaborator, Research support. Seqirus: Collaborator, Research support. D. Canaday, sanofi pasteur: Collaborator, Research support. Seqirus: Collaborator, Research suppor

# 1954. A Randomized Study to Evaluate the Shedding and Immunogenicity of H1N1 Strains in Trivalent and Quadrivalent Formulations of FluMist in Children 24 to <48 Months of Age

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## Session: 227. Clinical Trials Saturday, October 6, 2018: 12:30 PM