by Cello Health MedErgy and funded by Astellas. and Salary. R. Van Maanen, Astellas Pharma: Employee and Non-Financial Support, Medical writing support was provided by Cello Health MedErgy and funded by Astellas. and Salary.

LB13. Candida auris in NYC: A Health System's Experience Treating the Emerging Drug-Resistant Yeast
Dana Mazo, MD, MSc; Lindsey Gottlieb, MD; Sarah Schaefer, MD; Kimberly Alexander, MPhil, CIC; Jordan Ehn, MPH, CIC; Idael Javaid, MD;®; Gopi Patil, MD, MSc; Judith Aber, MD;® and Scott Lorin, MD, MBA, 1, 1Medicine, Division of Infectious Diseases, Icahn School of Medicine at Mount Sinai, New York, NY; 2Infection Prevention, Mount Sinai Brooklyn, Brooklyn, New York; 3Infection Prevention, Mount Sinai Downtown, New York, New York; 4Mount Sinai Brooklyn, Brooklyn, New York.

Session: 167. Late Breaker Oral Abstracts: Emerging Infections
Friday, October 5, 2018: 2:00 PM

Background. Candida auris is emerging multiresistant yeast that can cause serious infections with published mortality rates as high as 60%. It was first recognized in 2009 and has been reported in over a dozen countries. The current United States outbreak was identified in 2016 with New York City (NYC) as the epicenter. The aim of this presentation was to describe the clinical infections and outcomes with C. auris in a large health system in NYC.

Methods. Cases were identified from clinical specimens collected December 2015–June 2018 from the Mount Sinai Hospital Clinical Microbiology Laboratory, the central laboratory for the Mount Sinai Health System, which encompasses seven hospitals across NYC. All C. auris isolates were confirmed by the New York State Department of Health Wadsworth Center. Medical charts were reviewed. A case was included if C. auris grew from a sterile body site, an antifungal treatment was initiated or the pathogen was isolated before the yeast was identified on Gram stain.

Results. Twenty-nine possible cases were identified with 23 meeting the case definition. These cases included 19 bloodstream infections (BSI), two intra-abdominal abscesses, one skin soft tissue infection, and one otitis externa. Using the MIC breakpoint recommending by the Centers for Disease Control and Prevention, 100% of isolates tested were susceptible to caspofungin, 29% were susceptible to amphotericin B, and 17% were susceptible to fluconazole. Nineteen patients received antifungal treatment, 13 with caspofungin monotherapy and four with sequential therapy of caspofungin followed by an azole (three with fluconazole, one with posaconazole). Fifteen (65%) patients expired within 90 days of the positive culture. Fourteen of the deaths were in candidemic patients, despite that eight (57%) of these patients had documented microbiologic clearance after appropriate therapy. The 90-day mortality rate was 74%, for both cases and controls.

Conclusions. This case series is the largest reported in the United States. Candidemia was the most common site of infection and had a very high 90-day mortality rate, despite sterilization of the blood. These findings highlight the significant morbidity and mortality associated with C. auris and the need to focus efforts on rapid diagnostics and infection prevention.

Disclosures. No reported disclosures.

LB14. Safety and Immunogenicity of High-Dose Quadrivalent Influenza Vaccine Administered by Intramuscular Route in Subjects Aged 45 Years and Older
Lee Chang, MD,®; Ya Meng, PhD; Heloise Janosczyk, MA,®; Victoria Landolfi, MSc, MBA;®; H. Keipp, MD, MPH; and the QHD00013 Study Team. 1Sanofi Pasteur, Swiftwater, Pennsylvania; 2Infectious Diseases, Vanderbilt University Medical Center, Nashville, Tennessee.

Session: 213. Late Breaker Oral Abstracts: Influenza and Vaccines
Saturday, October 6, 2018: 10:30 AM

Background. Older adults (≥65 years of age) remain at increased risk of influenza because they do not respond to standard dose influenza vaccines as well as younger adults. A high dose, inactivated trivalent influenza vaccine, IIV3-HD, containing four times the antigen content (60 µg hemagglutinin per influenza strain) of standard-dose influenza vaccines has been available in the United States since 2010. Two distinct B influenza lineages (Victoria and Yamagata) have co-circulated in the United States during each influenza season. IIV3-HD has been developed to address the frequent influenza B strain changes. Using the hemagglutinin inhibition (HAI) GMTs and seroconversion rates. Moreover, IIV4-HD induced a superior immune response (HAI GMTs and seroconversion rates) compared with the IIV3-HD vaccine.

Method. A randomized, modified double-blind, multicenter study (NCT03282240) was conducted in 2670 healthy subjects in the United States, who were randomly assigned to receive IVIV4-HD, a licensed IIV3-HD, or an IIV3-HD with 75% of the antigen content. A third group received IIV3-HD containing the alternate B strain for all four influenza strains as assessed by HAI GMTs and seroconversion rates. Moreover, IIV4-HD induced a superior immune response (HAI GMTs and seroconversion rates) compared with the IIV3-HD vaccine.

Results. IVIV4-HD was noninferior to the licensed IIV3-HD and the investigational IIV3-HD (containing the alternate B strain) for all four influenza strains as assessed by HAI GMTs and seroconversion rates. Moreover, IIV4-HD induced a superior immune response (HAI GMTs and seroconversion rates) compared with the IIV3-HD vaccine.

Conclusion: The IIV4-HD profile of IIV4-HD compared with IIV3-HD.

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LB16. Phase 3 Trial of Baloxavir Marboxil in High-Risk Influenza Patients (CAPSTONE-2 Study)
Michael G. Boro, MD MS, FIDSA; Simon Portland, MD,°; Yuki Yoshida, MS; Takah Shishido, PhD; Frederick Hayden, MD and Takeaki Uehara, PhD,°; Northwestern University, Chicago, Illinois; °Shionogi Inc., Florham Park, New Jersey; Shinomi & Co., Ltd, Oshika, Japan; °Medicine, University of Virginia, Charlottesville, Virginia.

Session: 213. Late Breaker Oral Abstracts: Influenza and Vaccines
Saturday, October 6, 2018: 10:30 AM

Background. Baloxavir marboxil (BXM), an oral selective cap-dependent endonuclease inhibitor, is effective and safe for treating acute influenza in otherwise healthy patients.

Method. We conducted an international, randomized, double-blind, placebo (PLC)- and oseltamivir (Os)-controlled treatment study in patients at higher risk (HR) of influenza complications. Inclusion criteria included age ≥21 years, fever + influenza symptoms of ≤48 hours duration, and presence of at least 1 HR factor adapted from CDC criteria. Patients were randomized (1:1:1) to a single oral dose of BXM (40/80 mg for BW ≥<80 kg), PLC, or 75 mg Os BID for 5 days. The primary endpoint was time to improvement of influenza symptoms (TTISS) in those with RT-PCR confirmed influenza (TTIT). Secondary endpoints included infectious virus detection in serial nasopharyngeal swabs, prescription of antibiotics, and influenza-related complications.

Result. Among 2,184 randomized patients, 1,163(53%) comprised the TTI population (47.9% A/H3N2, 6.9% A/H1N1, 41.6% B). The most common risk factors were asthma or chronic lung disease (39.2%) and age ≥65 years (27.4%). TTI was significantly shorter in BXM than PLC (median 73.2 hours vs. 102.2 hours, P = 0.0001) and numerically shorter than Os (81.0 hours, P = 0.68347). TTI in BXM patients with A/
H3N2 virus (median: 74.5 hours) was significantly shorter than in PLC (100.4 hours; \(P = 0.0144\)) and was significantly shorter in patients with influenza B (74.6 hours) than in either PLC (100.6 hours; \(P = 0.0138\)) or Os (101.6 hours; \(P = 0.0251\)). Median time to cessation of viral shedding in BXM patients was 48 hours, significantly less than 96 hours in both PLC and Os patients. Systemic antibiotic use and influenza-related complications correlated with higher nAb titers, with higher geometric mean gB binding titers, and there was a correlation between a non-specific nAb to CMV envelope glycoprotein B (gB) in natural infection are thought to confer protection, but some vaccine candidates based on this protein alone have been insufficiently immunogenic. In this FiH dose-ranging, controlled, observer-blinded study the safety and immunogenicity of a CMV eVLP expression the ectodomain of gB to transmembrane and cytoplasmic domains of the vesicular stomatitis virus G protein (gb-G) was evaluated.

Method. Healthy CMV-seronegative 18–40 year olds at three sites in Canada (Vancouver, Montreal, Halifax) were randomized to one of four dose formulations (0.5 µg, 1 µg, or 2 µg gB content with Alum) or 1 µg gB without Alum, or placebo given on days 0, 56, and 168. Outcome measures were solicited and unsolicited adverse events (AE), severe AE, gB binding antibody titers and avidity assessment, and nAb to CMV infection of fibroblast and epithelial cells. A Data Safety Monitoring Board was in place.

Result. Among 128 participants, the most common solicited local and general AEs were injection and headache, respectively. No SAEs or withdrawals occurred. A dose-dependent boosting of nAb titers was observed after doses 2 and 3, with the highest titers in the Alum-adjuvanted 2.0 µg dose recipients. Fibroblast cell nAb were seen in 100% of 2.0 µg dose recipients, and epithelial cell nAb in 31%. Epithelial cell nAb was correlated with higher geometric mean gB binding titers, and there was a correlation between fibroblast and epithelial cell nAb titers.

Conclusion. An eVLP CMV vaccine was immunogenic at very low doses in healthy seronegative adults and no safety signals were seen. Alum adjuvant increased immunogenicity as did higher antigen content and multiple doses. This phase 1 trial supports further development of this eVLP CMV vaccine candidate.

ClinicalTrials.gov NCT02826798

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LB19. Progress Toward a Vaccine for Maternal Immunization to Prevent Respiratory Syncytial Virus (RSV) Lower Respiratory Tract Illness (LRTI) in Infants

Louis Fries, MD,1; D. Nigel Thomas, PhD,2; Gale Smith, PhD,3; Joyce Pleted, PhD,3; Pedro Piedra, MD,2; Nita Patel, MSc,3; Iksong Cho, MS4, and Greg Glenn, MD,1,2,3,5

Clinical Development, Novavax Inc., Gaithersburg, Maryland,1 Clinical Operations, Novavax, Gaithersburg, Maryland,1 Vaccine Discovery, Novavax, Gaithersburg, Maryland,2 Clinical Immunology, Novavax, Gaithersburg, Maryland,2 Molecular Virology and Microbiology, Baylor College of Medicine, Houston, Texas,3 Biostatistics, Novavax, Gaithersburg, Maryland,1 Vaccine R&D, Novavax, Gaithersburg, Maryland

Session: 231. Late Breaker Oral Abstracts: Influenza and Vaccines Saturday, October 6, 2018: 10:30 AM

Background. RSV is the leading cause of infant LRTI and hospitalization worldwide. The greatest burden of severe disease is in term infants <5 months old. Novavax