Disclosures. **Maria Deloria Knoll, PhD**, **Merck** (Research Grant or Support)**Pfizer** (Research Grant or Support)

1183. Serum Bactericidal Activity Induced by Live Attenuated Pertussis Vaccine BPZE1 is Comparable to Boostrix™

Cheryl A. Keech, MD, PhD[1]; Andrew Gorringe, PhD[2]; Breeze Cavell, PhD[2]; Peter Goldstein, MS[1]; Keith Rubin, MD[1]; [1]ILiAD Biotechnologies, Weston, Florida; [2]Public Health England, Portland, England, United Kingdom

Session: P-69. Pediatric Vaccines

Background. In a Phase 2b, multi-center, placebo-controlled, randomized study, intranasal BPZE1 induced mucosal and serum antibodies to pertussis antigens and protected against subsequent colonization following attenuated challenge with BPZE1 3 months later. Boostrix™ also induced serum but not mucosal antibodies and did not protect against BPZE1 challenge. We have evaluated the induction of serum bactericidal activity (SBA) for *Bordetella pertussis* by BPZE1 or Boostrix vaccination. A previous study showed that Boostrix induction of SBA is dependent on Prn whereas *B. pertussis* infection induces SBA targeting Prn and other antigens.

Methods. A convenience set of subjects who had a broad range of Prn and PT IgG serum concentrations from treatment groups who received BPZE1+BPZE1 or Boostrix+Placebo (Day 1 and 85 vaccination) were randomly selected to assess SBA using *B. pertussis* strain B1917. Three timepoints (baseline, 28 days following first and second vaccination) were analyzed and interpolated 50% killing titers determined. The relationship to Prn IgG concentration was assessed.

Results. BPZE1 and Boostrix elicited similar and significant increases in SBA following vaccination. BPZE1 and Boostrix elicit anti-Prn IgG, with Boostrix eliciting higher concentrations. A greater SBA response relative to PRN IgG was observed for BPZE1 compared to Boostrix. SBA-Prn correlations were high post-Boostrix (0.74) as previously reported; correlation was lower (0.35) following BPZE1, suggesting the involvement of broader antigenic protection beyond Prn alone.

Table of GMT and GMFR in SBA and Prn IgG

Geometric Mean Titers (GMT) and Geometric Mean Fold Rise (GMFR) in SBA and Prn IgG						
Vaccination First (Day 1) + Second (Day 85)	Assay	Baseline (Day 1)	Day 28 following first vaccination (Day 29)		Day 28 following second vaccination (Day 113)	
		GMT (95%CI)	GMT (95%CI)	GMFR* (95% CI)	GMT (95%CI)	GMFR* (95% CI)
BPZE1 + BPZE1 (n=13)	SBA	91.0 (35.0, 238.0)	509.0 (340.0, 764.0)	5.6 (2.7, 11.9)	480.0 (305.0, 754.0)	5.3 (2.5, 11.0)
	Prn IgG IU/ml	47.0 (18.4, 121.0)	159.0 (80.7, 315.0)	3.4 (2.2, 5.3)	137.0 (78.1, 239.0)	2.9 (1.8, 4.7)
Boostrix + Placebo (n=17)	SBA	88.0 (39.0, 196.0)	599.0 (357.0, 1004.0)	6.8 (3.5, 13.2)	345.0 (156.0, 763.0)	3.9 (1.9, 8.2)
	Prn IgG (IU/ml)	31.0 (16.4, 58.7)	352.0 (204.0, 606.0)	11.4 (5.9, 21.8)	205.0 (96.6, 436.0)	6.6 (2.8, 15.8)
*Fold rise from baseline.						

Conclusion. In this exploratory investigation, the novel intranasal live-attenuated pertussis vaccine BPZE1 induced SBA titers that were similar to Boostrix using a *B. pertussis* strain representative of current disease isolates. SBA-Prn correlations were high post-Boostrix, consistent with prior reports showing Prn is the acellular vaccine antigen that mediates SBA. In contrast, BPZE1 bactericidal antibodies appear broader than Prn which may be important given the global rise of Prn-deficient *B. pertussis* strains.

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1184. A Phase 3, Multicenter, Randomized, Double-blind Study to Evaluate the Interchangeability of V114 and Prevnar 13™ with Respect to Safety, Tolerability, and Immunogenicity in Healthy Infants (PNEU-DIRECTION)

Adroniki Bili, MD[1]; Scott Dobson, MD[2]; Jeffrey Quinones, MD[3]; Wanatpreeya Phongsamart, MD[4]; Peninnah Oberdorfer, MD, PhD[5]; Pope Kosalaraksa, MD[6]; Ron Dagan, MD[7]; Marissa B. Wilck, MD[1]; Waldimir Vallejos, MD[1]; Christine Nunn, MS[1]; Richard McFetridge, B.S.[1]; Rong Fu, PhD[8]; Robert Lupinacci, M.S[1]; Luwy Musey, MD[1]; Kara Bickham, MD[1]; [1]Merck & Co., Inc., Kenilworth, New Jersey; [2]Parkside Clinical Research and Tribe Clinical Research, Greenville, South Carolina; [3]Clinical Research of Puerto Rico, Guayama, Puerto Rico; [4]Mahidol University, Bangkok, Krung Thep, Thailand; [5]Chiang Mai University, Chiang Mai, Chiang Mai, Thailand; [6]Khon Kaen University, Khon Kaen, Khon Kaen, Thailand; [7]Ben-Gurion University of the Negev, Beer Sheva, HaDarom, Israel; [8]MSD China, Shangai, Shanghai, China

Session: P-69. Pediatric Vaccines

Background. Pneumococcal diseases (PD) caused by *Streptococcus pneumoniae* are a major health concern globally. In children, currently licensed pneumococcal conjugate vaccines (PCVs) provide protection against PD from vaccine serotypes, but other non-vaccine serotypes have emerged and contribute to most residual disease. V114 is a 15-valent investigational PCV containing serotypes 22F and 33F in addition to the 13 serotypes shared by Prevnar 13™ (PCV13). This phase 3 study evaluated safety and immunogenicity of mixed PCV13/V114 regimens when changing from PCV13 to V114 at doses 2, 3, or 4.

Methods. In this double-blind trial, 900 infants were randomized in equal ratios to five treatment groups using a 3 + 1 immunization schedule (3-dose infant primary series followed by one toddler dose). Groups 2, 3, and 4 started with PCV13 and switched to V114 at doses 4, 3, and 2, respectively. Groups 1 and 5 received four doses of PCV13 and V114, respectively. Immunoglobulin G (IgG) responses to the 15 pneumococcal serotypes in V114 were measured at 30 days post-dose 3, prior to dose 4, and 30 days post-dose 4 (PD4). Primary immunogenicity analysis was based on 13 shared serotype responses at PD4. Safety was evaluated as the proportion of participants with adverse events (AEs).

Results. At 30 days PD4, IgG geometric mean concentrations (GMCs) for the 13 shared serotypes were generally comparable between V114/PCV13 mixed regimens (Groups 2-4) and participants that received the 4-dose PCV13 regimen (Group 1). Additionally, IgG GMCs for the 13 shared serotypes were generally comparable for participants that received the 4-dose V114 regimen (Group 5) and participants that received the 4-dose PCV13 regimen (Group 1). Infants given at least one dose of V114 mounted immune responses to two unique serotypes in V114 (22F and 33F). Frequency of injection-site and systemic AEs among study participants were generally comparable across all study groups.

Conclusion. V114 was well tolerated with a generally comparable safety profile to PCV13. For the 13 shared serotypes, both mixed-dose and 4-dose regimens of V114 induced generally comparable antibody responses to a PCV13 4-dose regimen. Study results support interchangeability of V114 with PCV13 in infants.

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1185. Oseltamivir Prescribing Patterns for Infants with Influenza and Factors Associated with Guideline Adherence

Haniah A. Zaheer, Bachelors of Science[1]; Sarah Chamseddine, MD[2]; Hui Liu, MS[3]; John V. Williams, MD[3]; Judith M. Martin, MD[3]; Anne-Marie Rick, MD MPH PhD[3]; [1]University of Pittsburgh School of Medicine, Pittsburgh, Pennsylvania; [2]UPMC Children's Hospital of Pittsburgh, Pittsburgh, Pennsylvania; [3]University of Pittsburgh, Pittsburgh, Pennsylvania

Session: P-70. Pediatric Viral Studies (natural history and therapeutic)

Background. The Centers for Disease Control and Prevention (CDC) recommends oseltamivir be given to children < 2 years old with confirmed or suspected influenza as they are at high risk for complications. We sought to analyze oseltamivir prescribing patterns and to describe factors associated with adherence and non-adherence to CDC guidelines.

Methods. We used a retrospective cohort of infants ≤ 12 months old born from January 1, 2011 to December 31, 2019 within the University of Pittsburgh Medical Center health system in Southwestern Pennsylvania and who had ≥ 2 well-child visits during their first year. Infants with laboratory-confirmed influenza from January 1, 2011 to April 30, 2020 were included. Electronic health records were reviewed to describe oseltamivir prescriptions and influenza-related characteristics. Factors associated with adherence and non-adherence to CDC influenza treatment guidelines were assessed with univariate logistic regression.

Results. Of 422 infants with laboratory-confirmed influenza, 86% were prescribed oseltamivir. The proportion of infants prescribed oseltamivir increased from an average of 63% during 2011-2016 to 90% during 2016-2020 (OR:5.2; 95%CI: 2.9-9.5). 96% of prescriptions instructed twice daily dosing, 2% had once daily, and 2% were unknown frequency. 91% of prescriptions were for 5 days, 7% had no duration, and 2% were for > 5 days. Infants ≥ 6 months of age compared to < 6 months were less likely to be prescribed oseltamivir (83.3% vs. 100%; p< 0.001); tested for influenza in the emergency room/urgent care (OR: 0.3; 95%CI: 0.2-0.6), or admitted to the hospital (OR:0.5; 95%CI:0.2-0.9). Infants were more likely to be treated with oseltamivir if they had a known influenza positive contact (OR:2.3; 95%CI:1.0-5.2) or had fever ≥ 38.0C (OR:2.0; 95%CI:1.2-3.5). There was no difference in prescribing practices based on history of prematurity or chronic medical conditions.

Conclusion. Adherence to CDC influenza treatment guidelines for infants is high and has improved over time. However, targeted education at high-risk contact points may further improve guideline adherence.

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1186. Increased Respiratory Syncytial Virus (RSV) Viral Replication Leads to Increased Cytokine Production and Polarized Interferon Response in Infant Mucosal Epithelium

Rebecca M. Glowinski, BS[1]; Ki Wook Yun, MD;PHD[2]; Asuncion Mejias, MD, PhD, MsCS[1]; Octavio Ramilo, MD[1]; [1]Nationwide Children's Hospital, Columbus, Ohio;