The following abstracts were accepted for presentation after the deadline for the abstract supplement.

L1  
**Pediatric Patients with Allergic Comorbidities Exhibit Increased IL-9-Producing Mucosal Mast Cells in the Gut**

Dr Dana Shik; Cincinnati Children’s Hospital Medical Center, Cincinnati, OH.

**RATIONALE:** Clinical studies demonstrate that atopic dermatitis (AD) in early life predisposes individuals to develop food allergy and asthma. However, the underlying mechanisms that promote the comorbidity of allergic disorders remain unclear.

**METHODS:** Banked duodenal biopsies and sera from children with food allergy (FA) only or with comorbid allergic disorders (FA+CAD) were evaluated for mast cells (MCs) by flow cytometry, ImmunoCAP, immunofluorescence and immunohistochemistry and compared with non-atopic (Ctrl) individuals.

**RESULTS:** Children with FA+CAD exhibited a significant increase in the accumulation of duodenal-MCs compared with patients with FA only (p 0.005, t-test) or Ctrl individuals (p 0.0004, t-test). Serum total IgE in FA+CAD patients was significantly higher compared with patients with FA only (p 0.05, unpaired t-test). Significantly increased sera IL-9 levels (but not IL-5, TNFα or IL-13) in FA or FA+CAD patients correlated with Duodenal MCs (Pearson 0.39, p 0.04) and total IgE (Pearson 0.3, p 0.03). In an atopic march model, OVA-induced AD in mice exhibit a significant accumulation of IL-9-producing mucosal mast cells (MMC9s) in the gut following repeated OVA ingestions, but not saline. Furthermore, OVA-inhalations induced MMC9-accumulation in the lungs of mice with AD, but not AD alone.

**CONCLUSIONS:** Collectively, these results suggest that the increase of intestinal MCs frequency and sera IL-9 level in FA patients may potentiate the development of comorbid allergic disorders. Mechanistically, repeated food allergen exposures enhance the expansion of intestinal MMC9s which may contribute to the progression of the allergic response to the lungs in a murine model of atopic march.

L2  
**A High-Throughput Genetic Analysis of Common Drug Allergy Labels Using Data from a Large Biobank**

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**RATIONALE:** Adverse drug reactions listed as “drug allergies” have diverse etiologies and mechanisms. DNA biobanks linked with electronic health records (EHRs) and advanced informatics have enabled new genetic discoveries. We used the Vanderbilt DNA biobank paired with the EHR (BioVu) to conduct a high-throughput genetic analysis of “drug allergy” EHR labels.

**METHODS:** As of October 2017, BioVu has 50,275 individuals with paired clinical and genetic data. Natural language processing tools were applied to the EHR allergy sections to identify individuals allergic to penicillin, codeine, or “sulfas” (the three most common drug allergies) or to statins (for which adverse effects have been associated with genetic variation). A genome-wide association study was performed for each drug; cases and controls were defined as individuals with and without the drug documented in the allergy section, respectively.

**RESULTS:** The top three drugs listed in the drug allergy section of the EHR were penicillin (8,474 cases; 12,710 controls), “sulfas” (6,259 cases; 11,871 controls), and codeine (5,240 cases; 13,858 controls). We also identified 2,750 cases labeled as statin allergy and 19,724 controls. Significant associations included SNPs within HSD17B13 for statins and SNPs within WBP2NL and SLC25A5P1 for cutaneous and gastrointestinal reactions to codeine. Query of expression quantitative trait loci (eQTL) databases suggested a strong connection between WBP2NL and CYP2D6, which metabolizes codeine to its active component, morphine.

**CONCLUSIONS:** The extraction of common “drug allergy” information from EHRs for pharmacogenetic studies represents a promising approach to further understand contributing genetic factors and mechanisms of such labels.

L3  
**IL-33, but Not TSLP, Augments Carbachol-Induced Bronchoconstriction and Attenuates Formoterol-Induced Bronchodilation of Human Small Airways**

Cynthia Koziol-White, PhD, and Dr Reynold A. Panettieri, MD; Rutgers University, New Brunswick, NJ.

**RATIONALE:** IL-33 and TSLP, epithelium-derived Th2 cytokines, have been impinged in the pathogenesis of asthma and exacerbations. These cytokines affect maturation and migration of immune cells. However, effects of IL-33 and TSLP on airway contractility have not been well defined. We previously demonstrated that IL-13, another Th2 cytokine, augments contractility and attenuates dilation of airways in human precision cut lung slices (hPCLS). Therefore, we posit that both IL-33 and TSLP augment contractility and attenuate dilation of hPCLS.

**METHODS:** hPCLS were exposed to TSLP or IL-33 (1, 10, 100 nM – 24 hr) and bronchodilation of hPCLS. Therefore, we posit that both IL-33 and TSLP augment contractility and attenuate dilation of hPCLS.

**RESULTS:** Airway responsiveness to Cch following stimulation with IL-33, but not TSLP, was augmented in hPCLS (LogEC50: control vs 100 nM TSLP, 0.56 vs -1.55 M, p = ns; control vs 100 nM IL-33, -0.56 vs -2.02 M, p = 0.01). Airway dilation to Form following stimulation with IL-33, but not TSLP, was attenuated in hPCLS (LogEC50: control vs 100 nM TSLP, -1.70 vs -1.73 M, p = ns; control vs 100 nM IL-33, -1.70 vs 1.97 M, p = 0.003).

**CONCLUSIONS:** We show that the Th2 cytokine IL-33 modulates agonist-induced bronchoconstriction and bronchodilation, but TSLP has little effect. These data suggest that IL-33 may play a role in the airway hyperresponsiveness observed following allergen or virus exposure, providing a target for therapy of allergic asthma and asthma exacerbations.
L4 Soy Isoflavones Improve Poor Asthma Control in Asthmatics with High PAI-1 Producing Genotypes

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RATIONALE: The 4G/4G genotype of plasminogen activator inhibitor-1 (PAI-1) is associated with increased plasma PAI-1 levels and poor asthma control. Previous studies suggest that soy isoflavone may reduce PAI-1 levels.

METHODS: Plasma PAI-1 levels were measured by ELISA and a PAI-1 functional polymorphism (rs1799768, 4G/5G) was characterized in subjects with poorly controlled asthma enrolled in a 24-week randomized, controlled clinical trial of soy isoflavone. Demographic and clinical characteristics were determined for each PAI-1 genotype and genotype-specific treatment responses were compared between asthmatics randomized to soy isoflavone versus placebo.

RESULTS: The 4G/4G genotype was associated with a higher risk for allergy-related worse asthma symptoms and eczema at baseline compared to the 5G/5G genotype (OR 2.5, p=0.02). Soy isoflavone treatment significantly reduced plasma PAI-1 levels compared to placebo regardless of the genotypes. Soy isoflavone treatment significantly reduced the use of oral corticosteroids (number of events/person-year) compared to placebo in the 4G/5G genotype (0.2 vs 0.8, relative risk 0.28, p=0.01) but not in the 5G/5G genotype. TGF-β1 significantly increased the production of PAI-1 from NHBE and genistein treatment reduced TGF-β1-induced PAI-1 production in a dose-dependent manner.

CONCLUSIONS: This study suggests that PAI-1 polymorphisms can be used as a genetic biomarker for soy isoflavone responsive subjects with asthma. Genistein-induced reduction of PAI-1 production from airway epithelial cells may be a part of the underlying mechanism.

L5 The Leukotriene E4 Receptor, CysLT4, Regulates Airway Chemosensory Brush Cell Expansion

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RATIONALE: The receptor for the stable cysteinyl leukotriene (cysLT) LTE4, CysLT4R, is an upper airway epithelial cell (EpC) receptor that mediates mucin release in the nose in response to the mold aeroallergen, Alternaria alternata. CysLT4R distribution and downstream functions in immune responses to aeroallergens in the lung are unknown.

METHODS: CysLT4R distribution in the lower airway epithelium was assessed by X-gal staining of CysLT4R-deficient (Oxgr1-/-) mice. Wild-type (WT), LTC4-synthesise-deficient (Ltc4-/-), and Oxgr1-/- mice received a single intranasal dose of 0 or 30 µg Alternaria, Cladosporium herbarum, or 100 µg Dermatophagoides farinae. After 3 days, airway inflammation and EpC composition were assessed by FACS and immunofluorescence in the lung and trachea, respectively. WT and Oxgr1-/- mice were given 4 daily doses of 0.25 nmol LTE4 and analyzed 24 hours after the last inhalation as above. Antibody blockade with intraperitoneally anti-IL25 was performed on days 0 and 3 in conjunction with Alternaria and LTE4 challenges.

RESULTS: CysLT4R is expressed on airway brush cells (BrCs), specialized chemosensory IL-25 generating EpCs. Inhalation of aeroallergens led to expansion of airway BrCs, which was attenuated in mice lacking either CysLT4R or LTC4 synthe, the biosynthetic enzyme required for cysLT generation. LTE4 inhalation was sufficient to elicit CysLT4R-dependent BrC expansion in the airway, attenuated by IL-25 blockade, indicating a direct action on airway EpCs. Blockade of IL-25 attenuated both aeroallergen and LTE4-elicited CysLT4R-dependent type 2 lung inflammation.

CONCLUSIONS: CysLT4R is activated by endogenously generated lipid ligand LTE4 and regulates airway BrC number and sentinel function through IL-25 signaling pathway.

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RATIONALE: The aims of this study were to: 1) identify clinical practices that influence SRs to SCIT and sublingual immunotherapy (SLIT); and 2) identify SCIT-related infections.

METHODS: From 2008-2016, 27.5-51% of AAAAI/AACAI members completed an annual survey of SCIT/SLIT-related SRs of varying severity (WAO Grades 1-4). Cutaneous and systemic infections were queried for 2014-2016. For 2015-2016, questions included timing of onset of SRs, waiting times, and prescription/use of epinephrine auto-injectors.

RESULTS: Data were gathered on 54.4 million injection visits (2008-2016). Three confirmed fatalities from SCIT occurred between 2008-2016. An additional 4 confirmed fatalities occurred between 2016-2017. No infections occurred in 17.3 million injection visits (2014-2016). 25% (68/2016) of SRs occurred at 20-29 minutes. 35% (1311/3711) of SRs were reported to have begun after 30 minutes, including 90 Grade 3/4 SRs; only 7 patients self-administered epinephrine. Practices always prescribing an epinephrine auto-injector (29%) did not have lower rates of Grade 3/4 SRs. There were 7 SRs among 2994 patients on non-commercial SLIT; none self-administered epinephrine. There were 26 SRs among 1761 patients on commercial SLIT; 31 patients on commercial tablets self-administered epinephrine.

CONCLUSIONS: There has been a marked, unexplained increase in SCIT-related fatalities from 2016-2017; investigation is ongoing. Concerns about SCIT-related infections have not been supported by surveillance data. Despite a high number of delayed SRs, it is not clear that prescription of epinephrine auto-injectors for SCIT improves outcomes, in part because of low rates of self-administration. SRs to commercial and non-commercial SLIT were reported.

L8 Introduction of Allergen-Containing Foods: Feeding Infants and Toddlers Study (FITS) 2016

Ms. Marion E. Groetch, MD, MS RDN1, Dr Anna H. Nowak-Wegrzyń, MD, PhD FAAAAI1, Dr Erin Quann, PhD, RD2, Ms. Jami Boscetta, RD, LD, CLC3, Ms. Laura Czerekis, MS, RD4, Dr Sophie Nutten, PhD5, and Dr Ryan Carvalho, MD2; 1Icahn School of Medicine, New York, NY, 2Division of Pediatric Allergy/Immunology, Johns Hopkins University School of Medicine, Baltimore, MD, 3Division of Pediatric Pulmonology, Johns Hopkins University School of Medicine, Baltimore, MD, 4Division of Pediatric Allergy/Immunology, Johns Hopkins University School of Medicine, Baltimore, MD, 5Department of Environmental Health Sciences, Mailman School of Public Health, Columbia University, New York, NY.

RATIONALE: Despite high numbers of delayed SRs, it is not clear that prescription of epinephrine auto-injectors for SCIT improves outcomes, in part because of low rates of self-administration. SRs to commercial and non-commercial SLIT were reported.

METHODS: FITS 2016 is a U.S. cross-sectional survey of 3,224 children 0-48 months old. Twenty-four hour dietary recalls were conducted from June 2015-May 2016 by telephone with parents/caregivers to determine foods/beverages consumed. We analyzed the percentage of children 0-24 months (n=2,624) consuming foods containing nuts, tree-nuts, fish/shellfish, eggs, and milk (excluding breast milk & infant formula). Foods are categorized by their primary ingredient, resulting in exclusion of some allergens used as minor ingredients.

RESULTS: Between 4-5.9 months, no infants ate peanuts, tree-nuts, or fish/shellfish. Few ate eggs (1.5%), milk (2%), cheese (0.8%), and yogurt (2.2%). Among 6-11.9 month olds, 2.4% consumed peanuts or tree-nuts, 1.6% consumed fish/shellfish, 11.3% eggs, 10.2% milk, 9% cheese, and 7.5% yogurt. Between 12-23.9 months, most consumed milk (82.9%) and about 1/4-1/3 had cheese (36.1%), yogurt (23.4%), and eggs (27.2%); some ate nuts/seeds (17%) and peanut butter sandwiches (4%), and fish/shellfish (6.9%).

CONCLUSIONS: The 2016 FITS provides important nationally representative data. Few infants consumed allergen-containing foods prior to 12 months, demonstrating the need to increase awareness about new pediatric recommendations on the introduction of food allergens early during complementary feeding. This is important baseline data to track changes in consumption.

L9 Sensitization and Exposure to Other Indoor Allergens May Attenuate the Clinical Benefit of Mouse Allergen Reduction Among Mouse-Sensitized Urban Children with Asthma

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RATIONALE: Mouse allergen reduction is associated with improvements in symptoms among asthmatic children who are mouse sensitized and exposed; whether concomitant sensitization/exposure to other indoor allergens reduces the effectiveness of mouse allergen reduction is unclear.

METHODS: 350 mouse-sensitized and exposed asthmatic children (5-17y) were enrolled in a clinical trial of integrated pest management + education versus education alone. Symptoms and mouse allergen exposure were assessed every three months. Sensitization was defined as a skin prick test ≥3 mm, mouse allergen reduction as ≥75% decrease in bedroom floor mouse allergen from baseline, and exposure as detected vs. non-detected via previously defined cut-points. Groups were combined for analyses, as they did not differ in exposures or clinical outcomes. Analyses were stratified by allergen sensitized and exposed and interaction terms were created (e.g.: cat sensitized & exposed vs. ≥75% exposure reduction). Regression models included sex, age, race, and type of insurance.

RESULTS: Participants were low-income, urban asthmatic children with persistent asthma (79% African-American, 62% male, 88% Medicaid). The prevalences of sensitization/exposure were: 41% cat, 15% dog, 11% dust mite, 6% rat, 57% any. Participants who were not sensitized/exposed to other indoor allergens had a greater reduction in maximal asthma symptom days in response to mouse allergen reduction than sensitized/exposed participants(OR[95% CI]: 0.69[0.52-0.91] vs. 1.32[1.06-1.64], p=0.0001). Similar associations were seen with exercise-associated symptoms(0.56[0.36-0.87] vs. 1.06[0.72-1.54], p=0.038) and nocturnal symptoms(0.80[0.58-1.11] vs. 1.23[0.91-1.68], p=0.036).

CONCLUSIONS: Mouse sensitized/exposed asthmatic children who are sensitized/exposed to additional allergens in the home do not appear to experience an improvement in daily symptoms with mouse allergen reduction.
**L10** Associations between Total and Speciated Pollen Counts and Several Morbidity Measures in the Contiguous United States from 2008 to 2015

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**RATIONAL:** Pollen allergies cause substantial morbidity, yet knowledge of specifics regarding the timing and magnitude of risks associated with pollen exposure across the US is limited.

**METHODS:** We combined a previously-assembled daily time series database of speciated pollen counts from 36 US stations from 2003 to 2016 with claims data from Truven Health Analytics MarketScan Research databases from 2008-2015. We identified the Metropolitan Statistical Area (MSA) for the stations and extracted daily MSA-specific health information. We divided exposure metrics at 50th, 75th, 90th, and 95th percentiles and used case-crossover methods to examine odds of outpatient visits for asthma and allergic rhinitis, emergency department (ED) visits for asthma, and allergy medications refills for high versus low exposure quintiles.

**RESULTS:** Combined data covered the US with some gaps in the Midwest and Southwest. We found increased odds of outpatient visits for allergic rhinitis and asthma, ED visits for asthma, and medication purchases in association with high exposures to total pollen and several highly allergenic genera. Odds ratios ranged from 1.05 (95% CI 1.00-1.11) to 1.08 (1.04-1.33) for total pollen count 1-3 day moving averages for the various endpoints. Relationships were generally consistent across US ecozones.

**CONCLUSIONS:** Counts of total and allergenic pollens are moderately and consistently associated with several morbidity measures across the US. These results are consistent with more localized studies and extend the catalogue of quantitative estimates of pollen disease burden in the US. Results have implications for clinical management, public health surveillance, disease burden estimates, and health impact forecasting.

**L11** Healthy Caregivers and Atopic Dermatitis Patients Share Similar Skin Microbiome

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**RATIONAL:** Atopic dermatitis (AD) is a chronic inflammatory skin disorder characterized by an imbalanced skin microbiome (dysbiosis). The extent to which skin microbiome characteristics in eczema children are shared by healthy caregivers is currently unknown. We hypothesize that there is a unique microbiome signature which is shared by AD subjects and their caregivers and aim to characterize the skin microbiome characteristics of AD subject-caregiver dyads.

**METHODS:** D-Squame discs were used to sample the volar forearm (VF), antecubital fossae (AF), cheek (Ch) and lesional skin of AD subjects (0–10 years) and their healthy primary caregivers. We performed shotgun metagenome sequencing to evaluate microbial abundance profiles. All data analyses were performed in R using the phyloseq and vegan packages.

**RESULTS:** As expected, the lesional skin of AD subjects had reduced alpha diversity compared to other body sites sampled (VF; P=0.002, AF; P=0.008 and Ch; P=0.004). AD subject-caregiver pairs living in the same household had more microbial community similarity, compared to hypothetical pairs not living in the same household, at the VF (0.40 versus 0.66; P=0.002) and AF (0.62 versus 0.78; P=0.05), according to Bray-Curtis dissimilarity indices. Propionibacterium, Staphylococcus and Micrococcus were the predominant bacterial genera identified in both AD subjects and their caregivers.

**CONCLUSIONS:** Healthy caregivers share a similar skin microbiome with AD subjects, which could be transmittable through close physical contact, potentially preventing the adequate clearance of pathogenic bacteria from treated patients. Further research into the mechanisms of skin microbiome transmissibility and development of preventive interventions are needed.

**L12** Safety of 300IR 5-Grass Tablet in Children with Grass Pollen-Induced Allergic Rhinoconjunctivitis: Results of an Observational, Post-Marketing Safety Study

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**RATIONAL:** We report safety data of 300IR 5-grass pollen tablet* from a post-marketing study conducted in grass pollen-allergic children in Europe.

**METHODS:** This multicenter, observational study included allergy immunotherapy-naive children 5 to 9 years old with grass pollen-induced allergic rhinitis (AR) with/without conjunctivitis prescribed with 300IR tablet daily. Patients whose parent/legal guardian provided written consent were followed for safety and tolerability during the first 30 treatment days. Adverse reactions (ADRs) were analyzed descriptively.

**RESULTS:** 307 children (mean age: 7.1 years, SD: 1.42) were enrolled in 2015-2016: 71% were males, 70% polysensitized. The mean duration of their AR was 2 years. 76% had conjunctivitis, 36% had asthma. Over the first treatment month, 173 (56%) patients reported ADRs, most frequently application-site reactions (e.g., throat irritation, oral pruritus, oral paresthesia), mild in 73% of ADRs, moderate in 24%. ADRs occurred in 20% patients on Day 1, 14% on Day 2, 34% within Day 3-Day 10. 16 (5.2%) patients discontinued due to ADRs: application-site reactions in 3.3%. Two patients reported serious reactions. One experienced oral pruritus, mild urticaria and asthmatic attack (grade II anaphylaxis, Day 5), received oral antihistamine/inhaled salbutamol and resumed treatment. The other developed severe lip and eye swelling (angioedema, Day 26) resolved within six hours with IV antihistamine/corticosteroid. She was hospitalized overnight. No epinephrine use nor ICU was reported.

**CONCLUSIONS:** Over the first treatment month, the safety profile of the 300IR tablet in 5 to 9-year-old children was consistent with that previously observed in pre- and post-marketing settings. *The US indication is for patients 10-65.
**L13** Correlation between Overall Allergy Symptom Visual Analog Scale (VAS) Scores and Total Symptom Scores (TSS) in Subjects with Ragweed-Induced Allergic Rhinitis in an Environmental Exposure Chamber (EEC)

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**RATIONALE:** The severity of allergic rhinitis is typically measured by TSS, scored on a Likert scale (0-3). However, VAS are increasingly being used in clinical trials. In the present study, we evaluated the correlation between an overall allergy symptoms VAS (0-100 mm) and TSS of allergic rhinitis subjects in the EEC over separate visits.

**METHODS:** A total of 78 subjects with allergic rhinitis were exposed to ragweed allergen in the EEC and subsequently every 13 (+5) days thereafter for a total of 3 visits. During the EEC visits, subjects recorded their individual nasal and ocular symptoms to achieve a TSS as well as their overall allergy symptoms on a V AS using an electronic diary (ePDAT®) prior to EEC entry and every 30 minutes over a 2 hour period.

**RESULTS:** Both TSS and VAS increased and peaked over time showing similar trends between all 3 visits. The average TSS and V AS showed a highly positive correlation at all 3 visits (Visit 1: \( r = 0.7765 \), Visit 2: \( r = 0.6433 \), Visit 3: \( r = 0.7316 \), all p-values < 0.0001). When the correlation between TSS and V AS scores were analyzed over time, once again, high correlations were seen (Visit 1: \( r = 0.9948 \), Visit 2: \( r = 0.9873 \), Visit 3: \( r = 0.9863 \), all p-values < 0.0001).

**CONCLUSIONS:** These findings suggest that VAS can also be used as an alternative to total scores of individual nasal and ocular symptom scores correlating with disease severity and detecting symptom variation in allergic rhinitis individuals.

**L14** Repeatability of Total Nasal Symptom Scores (TNSS) in Allergic Rhinitis Individuals Using an Electronic Diary during Environmental Exposure Chamber (EEC) Visits

Dr Erin Beattie, MSc, PhD, Dr Cherrie Small, MSc, PhD, Dr Holly Lorentz, PhD, Ms. Victoria Nelson, MSc, Dr Peter R. Couroux, MD, and Dr Anne Marie Salapatek, MSc, PhD; Inflamax Research Limited, Mississauga, ON, Canada.

**RATIONALE:** EECs are used in allergic rhinitis models to assess clinical nasal symptom responses while circumventing the variability observed in outpatient field studies. In the present study, we evaluated the repeatability of TNSS during repeated exposure to the ragweed allergen during separate EEC visits.

**METHODS:** Seventy-eight subjects with allergic rhinitis were exposed to ragweed pollen in the EEC at an interval of 27 (+5) days between visits. During the EEC visits, subjects recorded their total nasal symptoms using an electronic diary (ePDAT®) prior to EEC entry and every 30 minutes over a 2 hour period.

**RESULTS:** The mean TNSS levels at both Visits 1 and 2 increased and peaked at similar levels with average maximum TNSS scores (1st visit = 8.86 ± 0.22; 2nd visit = 8.37 ± 0.24). Consistent pollen levels were observed throughout the EEC visits. A highly significant correlation was shown of the overall average TNSS over time between Visits 1 and 2 (\( r = 0.9964, p = 0.0003 \)). The average TNSS of each subject over both EEC visits showed a correlation coefficient of \( r = 0.5722, p<0.0001 \). In addition, a Bland-Altman plot had a mean difference of 0.6667 and 95% limits of agreement between -5.713 and 7.047 indicating a good clinical agreement between the two visits.

**CONCLUSIONS:** The ability of the EEC to elicit repeatable nasal symptoms at clinically significant levels in allergic rhinitis individuals will be a positive step forward in the evaluation of treatment outcomes and allergic rhinitis efficacy trials.

**L15** A Randomized, Double-Blind, Placebo-Controlled, Ascending Dose Phase 1 Study of AK002, a Novel Siglec-8 Selective Monoclonal Antibody, in Healthy Subjects

Dr Henrik S. Rasmussen, MD, PhD, Alan T. Chang, Dr Nenad Tomasevic, PhD, and Dr Christopher Bebbington, PhD; Allakos, Inc., San Carlos, CA.

**RATIONALE:** Eosinophils and mast cells play a significant role in chronic allergic and inflammatory diseases such as eosinophilic gastrointestinal diseases, urticaria, mastocytosis, allergic conjunctivitis, atopic dermatitis, and asthma. The Siglec-8 receptor is selectively present on eosinophils, mast cells, and basophils. Animal and in-vitro experiments have demonstrated that anti-Siglec-8 antibodies directly deplete eosinophils and inhibit mast cells. This study evaluated AK002, a novel humanized non-fucosylated IgG1 monoclonal antibody to Siglec-8, in healthy subjects – the first completed AK002 study in humans.

**METHODS:** This study was a Phase 1, randomized, double-blind, placebo-controlled, single and multiple-dose study. 51 healthy subjects were randomized (4 AK002 to 2 placebo) in 7 AK002 dose level cohorts (0.001, 0.003, 0.01, 0.03, 0.1, 0.3, and 1.0 mg/kg given intravenously). Pharmacokinetics (PK), pharmacodynamics (PD), and safety were assessed.

**RESULTS:** All AK002 dose groups recorded complete depletion of blood eosinophils by the first post-dosing timepoint (1 hr). Duration of eosinophil depletion increased with dose level and was sustained up to 84 days after a single dose of 1.0 mg/kg. Eosinophil levels were not significantly changed on placebo. AK002 had an 18-day half-life at 1.0 mg/kg. Mild to moderate infusion reactions occurred and resolved quickly; 1 serious adverse event occurred and resolved without sequelae within 1 day.

**CONCLUSIONS:** AK002 rapidly depleted blood eosinophils after a single dose. AK002’s PK, PD, and tolerability suggest an acceptable profile for chronic administration with monthly to quarterly dosing. These results suggest that AK002 should be evaluated as acute and chronic treatment in eosinophil and mast cell driven diseases.
L16 Esophageal IgG4 and Eosinophilic Inflammation Correlate in Subjects Undergoing Peanut Oral Immunotherapy

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RATIONALE: Peanut oral immunotherapy (PN-OIT) is associated with increases in serum peanut-specific IgG4. Recent studies suggest that eosinophilic esophagitis (EoE), a potential complication of PN-OIT, is associated with marked tissue deposition of IgG4. We sought to examine the IgG4 and eosinophil responses to PN-OIT in gastrointestinal biopsies.

METHODS: We performed serial esophagogastroduodenoscopies (EGD) in adults undergoing PN-OIT. Biopsies were obtained from the esophagus, stomach, and duodenum at baseline, 1, and 2yrs. Immunohistochemical staining for IgG4 and eosinophil peroxidase (EPX) were performed. Deposition of IgG4/mm² and EPX/mm² in serial hpf were quantified using automated image analysis.

RESULTS: EGD’s were performed at baseline (n = 21), 1yr (n = 10) and 2yrs (n = 5) during PN-OIT. At baseline, 48% of subjects had gastrointestinal eosinophilia (esophagus ≥15 eos/hpf; stomach ≥30 eos/hpf; and duodenum ≥52 eos/hpf). EPX/mm² correlated strongly with eos/hpf in all biopsies (r = 0.89, p < 0.0001) and with IgG4/mm² at baseline (r = 0.38, p = 0.004), 1yr (r = 0.36, p = 0.05) and 2yrs (r = 0.72, p = 0.003). Importantly 4/8 subjects with <15 eos/hpf at baseline developed esophageal eosinophilia; one met clinicopathologic criteria for EoE and 2 had histologic resolution by 2yrs. This trial is ongoing and only the subject with OIT-induced EoE has withdrawn.

CONCLUSIONS: This is the first study examining tissue IgG4 deposition in serial gastrointestinal biopsies (including baseline) during PN-OIT. Similar to EoE, PN-OIT subjects demonstrate esophageal IgG4 deposition correlating with eosinophilic inflammation. Further studies are needed to clarify the relationship between IgG4, EoE, and PN-OIT.

L17 Fixed-Dose Combination Intranasal Azelastine-Fluticasone Propionate Versus Oral Loratadine with Intranasal Fluticasone Propionate: Assessment of Onset of Action in the Treatment of Allergen-Induced Allergic Rhinitis Symptoms

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RATIONALE: Research has shown that a formulation of azelastine hydrochloride – fluticasone propionate in a single device (MP-AzeFlu) effectively treats allergic rhinitis (AR), but its onset of action (OOA) requires further investigation. This study compared MP-AzeFlu with 2 sequential monotherapies of oral loratadine and intranasal fluticasone propionate (LORA/INFP).

METHODS: In this single-center (Ontario, Canada), randomized, double-blind, double-dummy, 3-period cross-over trial, AR was induced in asymptomatic, ragweed-sensitive patients by ragweed pollen challenge in an environmental exposure chamber. Patients receiving single-dose MP-AzeFlu, LORA/INFP, or placebo were monitored for 4 hours. Primary outcome was OOA (ie, first time point with greater efficacy change from baseline vs placebo and durable until last time point [240 min]) measured by total nasal symptom score (TNSS). Secondary measures included OOA assessed by total ocular symptom score (TOSS) and effect on individual nasal (itchy and runny nose, nasal congestion, and sneezing) and ocular (itchy, watery, and red eyes) symptom scores.

RESULTS: Of the 82 patients in the full-analysis set, 78 completed treatment. TNSS was significantly reduced vs placebo from 5 min (MP-AzeFlu) and 150 min (LORA/INFP) by end of assessment (all P<0.05); similarly, OOA for TOSS was 10 min (MP-AzeFlu) and 120 min (LORA/INFP). All individual nasal and ocular symptoms contributed to these effects; generally, first time point with greater efficacy change from baseline vs placebo for individual symptoms was 5-15 min (MP-AzeFlu) and 120-180 min (LORA/INFP).

CONCLUSIONS: Overall, MP-AzeFlu had rapid onset of action (5 min) and was more effective than LORA/INFP.

L18 Validation and Use of the Anaphylaxis Score Assisting Providers (ASAP)

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RATIONALE: Early recognition and treatment of anaphylaxis decreases morbidity and mortality, but challenges emergency providers.

METHODS: The Anaphylaxis Score Assisting Providers (ASAP) http://www.seattlechildrens.org/pdf/anaphylaxis-pathway.pdf (p.8) identifies patients with suspected anaphylaxis who warrant treatment with epinephrine (score ≥5). It incorporates features of existing scores, diagnostic criteria, food challenge stopping rules and care plans. Preliminary validation of the ASAP was performed retrospectively on 60 patients 0-21 years prior to clinical use. Following introduction into a clinical information system and use with standardized emergency anaphylaxis care, we evaluated score concordance with epinephrine use within 30 minutes, for patients with an ICD-based definition of anaphylaxis and/or ASAP use, evaluated in a children’s hospital urgent care (UC) or emergency department (ED).

RESULTS: In pre-use analysis, compared with a clinical diagnosis of anaphylaxis, the ASAP demonstrated significantly better sensitivity than NIAD/FAAN criteria, 85% versus 58% (p-value = 0.002), with comparable specificity, 89% versus 93% (p-value = 0.42). In clinical use, 61 of 64 patients with an ICD-based definition of anaphylaxis received epinephrine, 20 pre-arrival (3 UC, 17 ED) and 41 after arrival only (13 UC, 28 ED). Initial score and epinephrine use were concordant in 41 (93%) without pre-arrival epinephrine, and 13 (65%) with pre-arrival epinephrine. Initial score was ≥5 in 41 (10%) other patients scored (no epinephrine given). Test characteristics were: sensitivity 93% (95% confidence interval (CI) 80-98%), specificity 86% (95% CI 75-93%), positive predictive value 80% (95% CI 69-86%), negative predictive value 95% (95% CI 86-98%).

CONCLUSIONS: The ASAP shows promise as a clinically useful anaphylaxis scoring tool.

AB404 Abstracts

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**L19 Reactions to Peanut during a Double-Blind Placebo Controlled Food Challenge (DBPCFC) for Enrollment in a Randomized Trial**

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**RATIONALE:** Few studies have comprehensively examined reaction characteristics in a large cohort. We describe symptoms and eliciting doses during DBPCFC in children with peanut allergy. Predictors of cumulative reaction-eliciting dose and severity were also examined.

**METHODS:** Children underwent a DBPCFC (4950mg peanut protein). Demographics, peanut sIgE, peanut skin prick test (SPT) and reaction characteristics were recorded. Associations between variables were investigated by correlation, linear and logistic regression analyses.

**RESULTS:** 112 children completed DBPCFC; 7 did not react, 103 reacted to peanut; 2 reacted to both peanut and placebo. The median cumulative reaction-eliciting dose was 1200mg (IQR 560–2450), 23.4% reacted to 1240 mg and 51.4% to ≥1200mg. Abdominal pain (68%) and vomiting (59.2%) were the most frequent symptoms. Anaphylaxis occurred in 21.4%. There was no association between reaction-eliciting dose and reaction severity. Peanut sIgE and SPT were negatively correlated to reaction-eliciting dose (p<0.001) but sIgE was the only predictor on regression analysis (p=0.002). Peanut sIgE and SPT were not associated with and did not predict reaction severity.

**CONCLUSIONS:** Reaction-eliciting dose varied widely in this cohort of peanut allergic children, with the majority (76.6%) reacting to ≥560mg peanut protein. Severity of reaction was not related to dose at reaction and is difficult to predict. DBPCFC were equivocal or negative in 8.7% of children, supporting inclusion of DBPCFC at study entry to confirm eligibility in food immunotherapy trials.

**L20 Impact Of Omalizumab On Patient Reported Outcomes In Chronic Idiopathic Urticaria: Results From XTEND-CIU, A 48-Week, Randomized, Placebo-Controlled Study**

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**RATIONALE:** Chronic idiopathic urticaria (CIU) is reported to have a major impact on quality of life (QOL) comparable to that experienced by patients with coronary artery disease awaiting bypass surgery. Patients with CIU often experience sleep deprivation, psychiatric comorbidity, and work-activity impairment. In the double-blind phase of the XTEND-CIU study, we explored the effects of CIU on QOL and the potential of omalizumab to improve these measures.

**METHODS:** XTEND-CIU enrolled 206 patients ≥12 years of age with CIU who were symptomatic despite standard H1 antihistamine treatment. Following a 24-week open-label period, patients were randomized to either placebo or omalizumab for an additional 24 weeks. Patients completed the following patient-reported outcome measurements: Insomnia Severity Index (ISI), Work Productivity and Activity Impairment Questionnaire (WPAI), and Generalized Anxiety Disorder 7 item (GAD-7) Scale.

**RESULTS:** At baseline, patients reported severe negative effects on QOL due to CIU. During the double-blind phase (week 24 to 48), patients randomized to receive omalizumab exhibited significantly better ISI scores (mean (SD) change of 1.4 (6.0) vs. 8.8 (11.2), p<0.0001) and overall WPAI activity impairment (mean (SD) change of 6.6 (22.3) vs. 33.0 (38.0), p<0.0001) compared to placebo. Anxiety scores decreased in all patients throughout the 48-week study, and the change in mean (SD) GAD-7 was not statistically significant between groups during the double-blind period (1.19 (3.7) vs. 1.65 (4.6), p=0.5360).

**CONCLUSIONS:** This long-term study demonstrates that patients continuing omalizumab treatment for 48 weeks exhibited significantly better patient-reported outcomes, other than anxiety, when compared to patients withdrawing treatment after 24 weeks.

**L21 Asian Migrants Have a Different Profile of Allergy and Anaphylaxis Than Australian-Born Children: A State-Wide Survey**

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**RATIONALE:** Children of Asian background who are born in Australia have higher rates of eczema and nut allergy than non-Asian children. However, less is known about other allergy and anaphylaxis in this group.

**METHODS:** We used data from the 2010 School Entrant Health Questionnaire, which was completed for 57,005 students (85.8% response rate) at age 5 in Victoria, Australia. Analyses were conducted using logistic regression with results presented as odds ratios (OR) and 95% confidence intervals (CIs).

**RESULTS:** Asian children born in Australia were more likely to have food allergy (OR 2.33, 95%CI 1.96-2.77) and eczema (OR 2.04, 95%CI 1.74-2.41), but less likely to have asthma (OR 0.87, 95% CI 0.74-1.02) compared to non-Asian children. By contrast, children born in Asia had a lower risk of food allergy (OR 0.33, 95%CI 0.20-0.55), eczema (OR 0.41, 95%CI 0.28-0.62) and asthma (OR 0.29, 95% CI 0.21-0.40). Triggers of anaphylaxis differed by ethnicity and country of birth. Asian children born in Australia had a higher risk of food-induced anaphylaxis (OR 1.50, 95% CI 1.16-1.94), including anaphylaxis to peanut, tree nuts, soy, wheat and seafood (fish/shellfish), and non-food anaphylaxis (OR 2.50, 95% CI 1.75-3.57) compared to non-Asian children. Interestingly, children born in Asia had a lower risk of food-induced anaphylaxis overall (OR 0.28, 95%CI 0.14-0.56) including anaphylaxis to milk, peanut and tree nuts, but higher risk of anaphylaxis to soy, wheat and non-food anaphylaxis (OR 2.28, 95%CI 1.41-3.69).

**CONCLUSIONS:** Patterns of allergy & anaphylaxis and its triggers differed according to both ethnicity and country of birth.
**L22**

**Evaluation of the in Vitro Penetration of Fluticasone Propionate (FP) from Azelastine Hydrochloride-Fluticasone Propionate Nasal Spray (MP-AzeFlu) & Fluticasone Propionate Nasal Spray through EpiAirway™606 Tissues Using Vertical Diffusion Cells**

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**RATIONALE:** MP-AzeFlu has demonstrated superior efficacy vs FP in treating allergic rhinitis. In addition, pharmacokinetic studies have suggested that MP-AzeFlu may yield higher FP blood levels than a nasal spray containing FP alone. This study used normal human-derived tracheal/bronchial epithelial cells mounted in a vertical diffusion cell system to evaluate in vitro penetration of FP from MP-AzeFlu vs FP nasal spray into and across EpiAirway™606 tissues from aqueous suspension.

**METHODS:** Donor solutions containing MP-AzeFlu (3.65 μg; n=8), FP nasal spray (5 μg; n=8), MP-AzeFlu placebo (n=1), and Lucifer yellow (280 μM; n=1) were applied to the ciliated apical surface (top) of EpiAirway™606 tissues equilibrated at 37°C. Aliquots from the receiver solution (bottom) of each sample were taken at 1, 2, 4, 6, 18, and 18.5 hrs to assess tissue integrity.

**RESULTS:** FP penetrated through and into tissues in all cells dosed with MP-AzeFlu or FP nasal spray, with no indications of compromised tissue integrity. Both MP-AzeFlu and FP nasal spray demonstrated similar drug accumulation profiles for FP, indicating 2.5% drug delivery. After correcting for differences in FP concentration in each product, FP permeability was similar between treatments at 18 hrs but was significantly higher during 0–6 hrs with MP-AzeFlu compared with FP nasal spray (P=0.135).

**CONCLUSIONS:** While absolute amounts of FP were similar between treatments, FP permeation occurred more quickly with MP-AzeFlu than with FP nasal spray, suggesting earlier time to maximum FP plasma concentration with MP-AzeFlu.

**L23**

**Predicting Peanut Allergy in an Unbiased Allergy Clinic Population Using Peanut Specific IgE Levels Measured in Two Independent Assays: ImmunoCAP and Immulite 2000**

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**RATIONALE:** Prior studies establishing diagnostic decision points associated with high probability of failing a double-blind, placebo-controlled oral food challenge (DBPCOFC) utilized selected, highly atopic populations, and food allergy was not consistently confirmed via OFC. We assessed the performance characteristics of two diagnostic tests to predict peanut allergy (PA) determined by DBPCOFC in children representing a more general allergy clinic population.

**METHODS:** Patients with a history of physician-diagnosed PA and positive skin prick test and/or detectable serum specific IgE (sIgE) by ImmunoCAP were recruited for this prospective study. Patients with severe atopic dermatitis or asthma were excluded. Subjects had ImmunoCAP and IMMULITE sIgE levels drawn and underwent graded, DBPCOFC to peanut. A fitted logistic regression model expressed the probability of an allergic reaction; 95% positive predictive values (PPVs) and 50% negative predictive values were calculated. Receiver operating curves were constructed and area under the curve computed to compare each test’s ability to predict clinical PA.

**RESULTS:** 51 subjects, ages 3–20 years (median=8) underwent peanut DBPCOFC; 30 subjects failed (58.8%). IMMULITE peanut sIgE and ImmunoCAP Ara h 2 component testing performed similarly and were superior to ImmunoCAP crude peanut sIgE in predicting PA. Our resultant 95% PPV for PA via ImmunoCAP (80.3 kU/L) is higher than previously published values.

**CONCLUSIONS:** These results, generated from a unique population, proved valuable for the diagnosis of PA in a general allergy clinic population. This suggests that sIgE to Ara h 2 by ImmunoCAP or peanut sIgE by IMMULITE may be the most accurate tests for diagnosing and predicting PA.

**L24**

**Implementing Health Care Research Technology to Improve Asthma Management**

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**RATIONALE:** Research looking at the use of technology to improve asthma adherence and outcomes has shown promise. Few studies have looked at the implementation of such research on larger asthma populations.

**METHODS:** A Speech Recognition (SR) program was implemented for the total KPCO patient population of 480,142, of which 36,356 had asthma. To be included in this analysis, patients had to have a diagnosis of persistent asthma, filled 1 or more ICS prescriptions in the prior 6 months, and remain continuously enrolled with Kaiser Permanente for a two-year period (10/23/12-10/23/14). We compared adherence and exacerbation events one year prior to the intervention and one post intervention for 4,510 adults ages 19–64. Documentation of an exacerbation event was defined as a hospitalization, emergency room visit, or course of prednisone where asthma was the principal diagnosis.

**RESULTS:** Patient adherence, defined as portion of days covered (PDC), improved from 39.5% to 41.1% (P-value: 0.0001). There was no difference in asthma outcomes. The implementation of the SR program was found to have had a significant impact when evaluated using the dimensions of the RE-AIM framework. The initial cost of developing the SR system using internal resources was $11,000. Using an external vendor, it would have cost $24,000.

**CONCLUSIONS:** We showed that an SR reminder system was relatively easily adopted and implemented in our organization, at a low cost, that was easy to maintain and allowed us to reach a greater population in an effort to improve asthma medication adherence.
Feasibility Survey for a Food Allergy Control Tool

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RATIONALE: There is currently no validated clinical assessment tool for the management of food allergy. This study aimed to determine whether a Food Allergy Control Tool (FACT) fulfills a clinical need, whether primary care providers (PCPs) and allergists would use a FACT, and what content should be included in a FACT.

METHODS: 53 allergists and 57 pediatricians from various geographic regions and clinical practice settings were invited to complete an anonymous, 13-question online survey. The survey contained a sample FACT that assessed potential domains of food allergy control such as reaction rate/severity, emergency medication/plan, reducing cross-contamination, and quality of life concerns.

RESULTS: The response rate was 62% for allergists and 40% for pediatricians. All responders indicated that they would use the FACT in some capacity. 45% of allergists and 22% of pediatricians would use the FACT for all food allergy (FA) patients, while 33% and 43% respectively, would use the FACT for most FA patients. Allergists and pediatricians felt the FACT would be useful for allergists (85%, 87%), patients (91%, 78%) and PCPs (55%, 70%). Both groups felt the FACT should include the number/severity of reactions, the use of emergency medication/anaphylaxis plan, and accidental ingestion precautions. Allergists also prioritized psychosocial concerns. Pediatricians also prioritized comorbid conditions.

CONCLUSIONS: Our pilot survey indicates that allergists and pediatricians would utilize a FACT and perceive a benefit of such an instrument. The FACT should assess reaction prevention/management including emergency medications and an anaphylaxis plan. These results suggest the need for a standardized, validated FACT.

A 10 Year Cost Comparison of Non-Penicillin Antibiotics to Treat Bacterial Rhinosinusitis, Group A Strep, and Otitis Media Versus Penicillin Skin Testing, Allergy Consultation and Penicillin Antibiotics

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RATIONALE: The use of non-penicillin antibiotics to treat bacterial rhinosinusitis, group A strep, and otitis media has been shown to be associated with bacterial resistance leading to treatment failure and increased costs. We hypothesized that PCN skin testing (PST), allergy consultation, and a PCN prescription would be more cost effective than prescriptions for non-penicillin antibiotics when looking at recurrent infection treatment over 10 years.

METHODS: A cohort of 503 PCN allergic patients were identified by a pharmacist from October 2006 to November 2007. This cohort was followed for 10 years to determine which antibiotics were prescribed with note of the diagnosis by review of their medical record. The prices were examined by the cost to the institution. Costs of antibiotics, PST, and allergy consultations were obtained from the Mayo Clinic billing department.

RESULTS: In each disease process, patients were treated with an average of 2.7 prescriptions for sinusitis, 2.07 for otitis media, and 2.54 for GAS. The average cost of allergy consultation, PST, and PCN prescriptions was $125.12 in comparison to non-penicillin prescriptions over the 10 years which was $31.41; Average of $14.60 for sinusitis, $29.18 for otitis media, and $50.45 for GAS. The only patients that benefit from PST and consultation in a direct cost comparison were patients in the GAS subgroup that had received a prescription for erythromycin.

CONCLUSIONS: In patients with reported PCN allergy, it is more cost effective to prescribe non-penicillin drugs than to provide allergy consultation and PST for recurrent bacterial rhinosinusitis, group A strep, and otitis media.

Clinical Efficacy of a Recombinant Grass Pollen Vaccine One Year after a 4 Month Treatment Course

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RATIONALE: Immediate and sustained clinical efficacy of a recombinant grass pollen vaccine (BM32) consisting of IgE epitope peptides of Phl p 1, 2, 5 and 6 was evaluated in terms of optimized treatment schedule of a 4 month pre-seasonal treatment in grass pollen allergic patients (NCT02643641).

METHODS: Four treatment schedules (3, 4, 5 times active vs. Placebo) of BM32 were evaluated during grass pollen seasons 2016 and 2017. Symptom Scores (SS), Medication Scores (MS) and Combined Scores (SMS) of actively treated subjects were compared to placebo. In 2016 scores were correlated with symptoms (TNSS) in the challenge chamber. Symptoms and medication intake were reported daily during entire grass pollen season. SS was reported on a four point scale comprising 4 nasal symptoms (runny nose, blocked nose, sneezing, itchy nose) and 2 ocular symptoms (itchy/red eyes, and watery eyes). It was calculated as the sum of scores divided by 6. In the MS score values were assigned to categories of medication and calculated as predefined in the protocol.

RESULTS: 124 subjects were included in the full analysis set. The mean daily SMS during the pollen peak immediately after treatment with 3, 4 or 5 injections of BM32 improved by 15%, 3% and 25 % vs. Placebo. During the grass pollen peak 2017 no further treatment effect could be demonstrated. Correlation coefficient of TNSS in the challenge chamber and SS during season 2016 was 5.

CONCLUSIONS: Five active injections demonstrated the best immediate clinical efficacy, but no sustained effect. BM32 was safe and well tolerated.
Effects of Reslizumab on Nasal Polyp Inflammation in Aspirin Exacerbated Respiratory Disease

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RATIONALE: Targeting IL-5 can improve clinical symptoms in Chronic Rhinosinusitis with Nasal Polyps (CRSwNP). The mechanisms by which anti-IL-5 drugs exert their clinical effects remain unclear. This is the first study, to our knowledge, to assess the inflammatory environment in NP before and during Reslizumab treatment in the same patient with Aspirin Exacerbated Respiratory Disease (AERD).

METHODS: NP tissue and blood were collected from an AERD patient pre-Reslizumab and then 8 months post-Reslizumab initiation. Gene expression, protein levels, and cellular infiltrates were assessed using RT-PCR, ELISA, flow cytometry, and immunohistochemistry. NP and blood isolated from AERD patients not taking Reslizumab served as comparators.

RESULTS: On Reslizumab, the patient’s asthma improved, but sinonasal disease required revision surgery. NP ECP protein levels and CCR3 and CLC gene expression levels were reduced by 90-fold, 25-fold, and 300-fold respectively post-Reslizumab compared to pre-Reslizumab. Few peripheral eosinophils were detected post-Reslizumab. NP eosinophils (CD45+Siglec8+FcERI-) were detected post-Reslizumab (1,801 cells/mg tissue) at similar levels to AERD controls (7,645±675). NP basophils were elevated post-Reslizumab (515 cells/mg tissue), with lower 2D7 intensity (MFI 1,986±675).

CONCLUSIONS: In this patient, Reslizumab reduced peripheral eosinophilia and markers of eosinophil activation and granular proteins in NP. However, revision sinus surgery was required suggesting that other cell types (including basophils) may play an important role in AERD pathogenesis in this individual.

Efficacy and Safety of Mepolizumab in Uncontrolled Patients with Severe Eosinophilic Asthma Following a Switch from Omalizumab (OSMO Study): Asthma Control, Quality of Life and Lung Function Outcomes

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RATIONALE: Mepolizumab and omalizumab are indicated in distinct asthma phenotypes, although some patients with severe eosinophilic asthma (SEA) are eligible for both biologics. We investigated asthma control in patients not optimally controlled with omalizumab, who switched directly to mepolizumab.

METHODS: OSMO was a multi-center, open-label, single-arm, 32-week study in patients with SEA and ≥2 exacerbations in the past year despite regular high-dose inhaled glucocorticoids plus other controller(s) and omalizumab (for ≥4 months) (204471/NCT02654145). At baseline, patients with poor asthma control (Asthma Control Questionnaire-5 [ACQ-5] score ≥1.5) discontinued omalizumab to receive subcutaneous mepolizumab 100 mg every 4 weeks (last dose: Week 28). Endpoints included (at Week 32): mean change from baseline in ACQ-5 (primary) and St. George’s Respiratory Questionnaire (SGRQ) total score, pre- and post-bronchodilator forced expiratory volume in 1 second (FEV1) (all analyzed using Mixed Model Repeated Measures with covariate adjustment); and responder analysis of ACQ-5 and SGRQ. Exacerbation and safety outcomes will be reported elsewhere.

RESULTS: In the intent-to-treat population (n=145), over the treatment period, least squares (LS) mean (standard error [SE]) ACQ-5 score improved by −1.45(0.11) points, with 77% experiencing the minimal clinically important difference (MCID) of ≥0.5-point reduction. LS mean (SE) SGRQ total score improved by −19.0(1.6) points; 79% experienced MCID of ≥4-point reduction. LS mean (SE) pre- and post-bronchodilator FEV1 increased by 159(41) mL and 120(36) mL, respectively, at Week 32.

CONCLUSIONS: In uncontrolled patients with SEA, switching directly from omalizumab to mepolizumab resulted in clinically significant improvements in asthma control, health status, and lung function.

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RATIONALE: Patients with severe eosinophilic asthma (SEA) not optimally controlled with omalizumab may benefit from mepolizumab treatment. We investigated exacerbation and safety outcomes in patients with SEA not optimally controlled with omalizumab who were switched directly to mepolizumab.

METHODS: OSMO was a multi-center, open-label, single-arm, 32-week study in patients with uncontrolled SEA and a history of >2 exacerbations and exacerbations requiring ED visits/hospitalizations over 32 weeks, ratio to baseline of blood eosinophil counts at Week 32, adverse events (AEs) and immunogenicity. Patient reported outcomes and lung function will be reported elsewhere.

RESULTS: In the intent-to-treat population (n=145), clinically significant exacerbations and exacerbations requiring ED visits/hospitalizations were less frequent during the study (1.18 and 0.19 events/year, respectively) compared with the 12 months prior to screening (3.26 and 0.63 events/year, respectively), a reduction of 64% and 69%, respectively (both p<0.001). Blood eosinophil counts decreased 76% from baseline to Week 32. Overall, 124 (86%) patients experienced AEs; 16 (11%) experienced serious AEs. Post-baseline, anti-drug antibodies were present in 11 (8%) patients; no neutralizing antibodies were detected.

CONCLUSIONS: In patients with SEA not optimally controlled with omalizumab, when switched directly to mepolizumab there were clinically meaningful reductions in asthma exacerbations and ED visits/hospitalizations, with no new safety issues reported.

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**Effect of Epicutaneous Immunotherapy on Inducing Peanut Desensitization in Peanut-Allergic Children: Topline Peanut Epicutaneous Immunotherapy Efficacy and Safety (PEPITES): Randomized Clinical Trial Results**

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**RATIONALE:** Epicutaneous immunotherapy was shown in a multicenter Phase 2 trial to provide therapeutic benefit for children with peanut allergy.

**METHODS:** This was a Phase 3, double-blind, placebo-controlled trial of peanut epicutaneous immunotherapy with peanut-patch (VP250μg) in children 4-11 years (N=356), with positive double-blind, placebo-controlled food challenge (DBPCFC) to eliciting dose (ED) ≤300mg peanut protein, randomized 2:1 to VP250μg containing 250μg peanut protein or placebo-patch daily for 12 months. Primary endpoint was difference in response rates between VP250μg and placebo-patch groups (lower bound of 95% CI >15%), defined as subjects with peanut protein ED≥300mg (baseline ED≥10mg) or ≥1000mg (baseline ED>10mg) at Month 12 DBPCFC. Additional endpoints: Cumulative Reactive Dose (CRD), safety, and serological markers of immunological changes.

**RESULTS:** Response rates showed 35.3% and 13.6% in VP250μg and placebo-patch groups, respectively, reached prespecified criteria (p=0.00001). Difference in response rates (21.7%; 95% CI=12.4-29.8%) was significant, but prespecified primary endpoint was not met. Baseline median (mean) CRD in both groups was ~144mg (210mg) peanut protein. At Month 12, median (mean) CRD was 444mg (905mg) for VP250μg and 144mg (361mg) for placebo groups. CRD change from baseline between groups was significant (p<0.001). Mild or moderate application site reactions were the most common adverse events. Serious adverse events were balanced between groups. Change in IgE and IgG4 markers were marked and consistent with data previously observed during Phase 2.

**CONCLUSIONS:** Twelve months of VP250μg resulted in statistically significant difference in response rate and increase in CRD as compared to placebo, a favorable safety/tolerability profile and changes in serological markers.
**L34**

Observational Study to Determine the Tolerability of Intravenous Immunoglobulin 5% for the Treatment of Patients Diagnosed with Primary Immunodeficiency Disorders

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**RATIONALE:** Intravenous immunoglobulin (IVIG) is relatively safe, with headaches and fatigue being common side effects. Recently, a subset of patients with common variable immunodeficiency (CVID) and low C1 esterase inhibitor (C1-INH) and/or low C1-INH function (C1-INHF) has been identified. Preliminary data indicates that low C1-INH levels may play a role in adverse drug reactions (ADRs) noted in a subset of CVID patients receiving IVIG. We designed this observational study to determine if 5% IVIG may be an alternative for patients who experience ADRs on 10% IVIG.

**METHODS:** Patients who had previously received 10% IVIG completed 6 infusion visits using 5% IVIG. At each visit, ADRs and data from patient diaries were recorded. Immune-biomarkers, including C1-INH/C1-INHF levels, were also evaluated.

**RESULTS:** Fifteen subjects completed the study; 12 with CVID and 3 with hypogammaglobulinemia. Switching to 5% IVIG reduced the number of ADRs by 40%. There were also reductions in mean fatigue index, headache score, and neuropathic pain score from IVIG 10% to 5%. Patients experienced an increase in physical function, greater energy, less fatigue, higher emotional rating and an increase in social function. The mean C1-INH/C1-INHF on 10% decreased from 31 to 27 mg/dL (normal 21-29 mg/dL) and from 91% to 89% (normal >67%) while on 5% the mean C1-INH/C1-INHF decreased from 27 to 21 mg/dL and from 89% to 76%.

**CONCLUSIONS:** This study demonstrated that C1-INH/C1-INHF level changes play a role in the incidence of ADRs for IVIG therapy; and a subset of patients may be more susceptible to C1-INH/C1-INHF downregulation by IVIG 10%. Further studies are necessary.

**L35**

Improved Asthma Control in High-Utilizer Pediatric Population Delivered by Certified Asthma Educator in an Urban Clinic

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**RATIONALE:** Asthma is a leading chronic illness among children in the United States and poor childhood asthma outcomes are associated with lack of parental knowledge regarding asthma treatment, emphasizing the need for adequate asthma education for caregivers. We hypothesized that tailored asthma education would improve asthma control.

**METHODS:** Breathe California’s All About Asthma Program is a bilingual, tailored, NHLBI-NAEPP guidelines-based education intervention for families of high-utilizer asthmatic children, who receive primary care through a pediatric clinic in San Francisco’s Mission District. Through this multi-session one-on-one educational intervention with a Certified Asthma Educator, the program aimed to increase knowledge and confidence of 120 caregivers in caring for their asthmatic children, and improve asthma control in low-income Hispanic/Latino children. The intervention utilized two measurement tools administered multiple times over 12 months, an Asthma Control Test (ACT) and a Knowledge, Confidence and Behavior Survey.

**RESULTS:** Caregivers increased their average asthma knowledge score, using a 5-point scale, from 1.92 at baseline to 4.25 post-intervention. They also increased their average asthma care confidence score from a 2.20 at baseline to a 4.11 post-intervention. Ninety percent of children whose caregivers participated in the program also experienced marked improvement in the control of their asthma, as indicated by an increased ACT score >19.

**CONCLUSIONS:** Tailored asthma education is associated with improved asthma control and improved knowledge and confidence in caring for high-need urban asthmatic children when delivered by a Certified Asthma Educator.