398 The clinically important impact of preschool food oral immunotherapy on parental quality of life

Rishma Chooniedass[1], Lianne Soller, PhD[1], Sandeep Kapur, MD[2], Gregory Rex, MD[2], Mary McHenry, MD[2], Timothy Vander Leek, MD FAAAAI[3], Raymond Mak, MD[1], Tom Gerstner, MD[4], Stuart Carr, MD FAAAAI[3], Edmond Chan, MD FAAAAI[1]; [1]University of British Columbia, [2]Dalhousie University, [3]University of Alberta, [4]University of Manitoba.

RATIONALE: Our group previously showed the safety of peanut oral immunotherapy (OIT) in 270 preschool-aged children (0.4% had severe reactions). The impact of preschool OIT on parental quality of life (QoL) has not been previously described.

METHODS: We enrolled preschool-aged children into OIT. The project was conducted in four clinics across Canada (Halifax, Winnipeg, Edmonton, Vancouver). The OIT protocol used capsules and/or food, and the maintenance dose was 300mg of protein daily. The 17-item Food Allergy Quality of Life– Parental Burden (FAQL-PB) questionnaire was administered to parents at baseline and end of build-up, and Wilcoxon signed-rank test was performed to compare the FAQL-PB scores between timepoints.

RESULTS: Between May/2019-August/2020, 29 patients aged 9–32.3 months (58.6% males) completed OIT (28 peanut, 1 sesame), and FAQL-PB questionnaires. There was a significant improvement in FAQL-PB from baseline to end of build-up with a median change in score of -14 ((IQR: -33.5, -7.5); $p<0.00001$), representing a change of 0.82 in mean total score ($\geq$0.5 is considered a minimal clinically important difference [MCID]).

CONCLUSIONS: Our real-world study found that preschool OIT improves parent QoL from baseline to end of build-up (exceeding the MCID), even though families may be most fearful of potential reactions during this period based on reaction risks described in older children. This reduction in parental burden is most likely associated with the superior safety experienced by families of preschoolers. Future work will involve analyzing QoL at various timepoints during maintenance, to determine whether improvement in QoL holds over time.

399 Mepolizumab Improves Health Related Quality of Life for Patients with Chronic Rhinosinusitis with Nasal Polyps: Data from the SYNAPSE study

Stella Lee, MD[1], Maggie Tabberer, MSc[2], Andrew Trigg, MSc[3], Joseph Han, MD FAAAAI[4], Wytske Fokkens, MD PhD[5], Robert Naclerio, MD FAAAAI[6], Philippe Gevaert, MD[7], Ana Sousa, PhD[2], Peter Howarth, MD[8], Bhabita Mayer, MSc[2], Steven Yancey, MS MBA[9], Robert Chan, MD[10]; [1]University of Pittsburgh School of Medicine, Pittsburgh, Pennsylvania, USA, [2]GSK, Stockley Park, Uxbridge, Middlesex, UK, [3]Adelphi Values Ltd, Manchester, UK, [4]Eastern Virginia Medical School, Norfolk, VA, USA, [5]Amsterdam University Medical Centres, Location AMC Amsterdam, Amsterdam, The Netherlands, [6]Pritzker School of Medicine, University of Chicago, Chicago, IL, USA, [7]Ghent University Hospital, Ghent, Belgium, [8]GSK, Brentford, London, UK, [9]GSK, Respiratory Triangle Park, NC, USA, [10]GSK, Stevenage, UK.

RATIONALE: To report the efficacy of 4-weekly add-on mepolizumab 100 mg SC on health-related quality of life (HRQoL) in adults with Chronic Rhinosinusitis with Nasal Polyps (CRSwNP) .

METHODS: SYNAPSE (NCT03085797), a randomised, double-blind, placebo-controlled, multicentre, 52-week study, enrolled adult patients with highly symptomatic CRSwNP and prior surgery, treated with intranasal corticosteroids. Co-primary endpoints: change from baseline in endoscopic NP score (Week 52) and nasal obstruction visual analogue scale (VAS) score (Weeks 49–52). HRQoL was measured every 4 weeks using the SinoNasal Outcome Test (SNOT-22), assessing symptoms and impact of CRSwNP. Blinded psychometric analysis of SYNAPSE data and prior qualitative research in patients with CRSwNP was conducted to confirm domain structure and meaningful within-patient change thresholds.

RESULTS: Psychometric analyses support a six-domain solution: nasal symptoms, ear/facial symptoms, non-nasal symptoms, fatigue, impact on sleep, and emotional impact supporting the validity of a total score. A threshold of -28 points was defined using anchor-based methods and supported by distribution-based methods. Although substantially greater than previously published thresholds, this value is supported by qualitative patient research. LS mean change from baseline total score at week 52 was -29.5 (SE1.62) for mepolizumab and -15.6 (SE 1.65) for placebo, with 54% and 32% responders respectively (post-hoc analyses). Odds ratio of response was 2.66 95% CI (1.75, 4.04) favouring mepolizumab. Change from baseline in all domain scores was approximately twice as large for mepolizumab compared with placebo, with similar magnitude of improvement across all domains.

CONCLUSIONS: Mepolizumab significantly and meaningfully improves HRQoL in CRSwNP.

FUNDING: GSK [GSK ID:205687/NCT03085797]