Background: Low immunoglobulin (Ig) levels can occur after rituximab treat-
ment, but the clinical significance is not completely understood. Not all patients
(pts) who develop low Ig levels after rituximab are at an increased risk of seri-
onous infection (SI), but factors such as pre-existing low Ig levels, prior biologic
therapies, history of SI and other disease and age-related factors may increase the
risk.

Objectives: To assess the risk of SI in pediatric pts with prolonged low IgG or
IgM serum concentrations following rituximab treatment for GPA or MPA in a
global clinical trial.

Methods: In the Phase 2a PePRS study (WA25615), pts aged 2 ≥ 18 yrs
with GPA or MPA received 4 weekly intravenous rituximab infusions of 375mg/m²
body surface area and concomitant oral glucocorticoid taper. After 6 months, pts
could receive further rituximab and/or other immunosuppressants at the investi-
gator’s discretion during a minimum 12-month follow-up phase. Pts with IgG/IgM
levels below age-appropriate reference ranges at baseline were excluded. Ig levels
were measured every 4-12 wks. SI occurrence was assessed during/after low
IgG or IgM. Prolonged low Ig was defined as IgG or IgM levels < lower limit of
normal (LLN) reference range for age for a ≥ 4-month period.

Results: All 25 pts completed 4 weekly rituximab infusions and the 6-month
Remission Induction Phase; 24/25 pts completed ≥ 18 months of follow-up. 17
pts (68%) had prolonged low IgG levels in addition to rituximab treatment or after Month 6. 11 pts received concomitant immunosuppressants (cyclophosphamide, azathioprine, mycopheno-
late mofetil) during the study. All pts had a decrease in IgG and IgM mostly after
the first rituximab infusion. There was no consistent trend in IgG or IgM levels over
time and no clear relationship between low IgG or IgM levels and the number of follow-up rituximab treatments. 18 pts (72%) had prolonged low
IgG ≥ 4 months, of whom 5 had IgG levels < LLN at screening and/or baseline; in 7 pts, IgG levels returned to normal range by study end. During or after prolonged low
IgG, 6/18 pts experienced a total of 7 SIs. Three pts received treatment with intravenous Ig, 19 pts (76%) had prolonged low IgM, of whom 5 had
IgM levels < LLN at screening and/or baseline. During or after prolonged low
IgM levels, 6/19 pts experienced a total of 8 SIs. There were no deaths or study
discontinuation due to SI. All pts with prolonged low IgG or IgM had past and/or
current treatment with steroids and/or immunosuppressants as potential contribut-
ory factors. Analysis of SI onset in relation to timing of low Ig was limited
due to protocol-defined time points for Ig assessments.

Conclusion: In pediatric pts with GPA/MPA treated with rituximab, there was no
consistent pattern in IgG or IgM levels over time. The majority of pts with pro-
longed low IgG or IgM did not experience any SIs; no increase in the number of SIs
was observed over time or with multiple rituximab treatments. While no firm
conclusions can be made on a possible relationship between prolonged low IgG or
IgM and risk of SI following rituximab due to study limitations (low pt numbers,
contributory factors. Analysis of SI onset in relation to timing of low Ig was limited
due to protocol-defined time points for Ig assessments.

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SAT0505
PLUTO TRIAL OF INTRAVENOUS BELIMUMAB IN PAEDIATRIC PATIENTS WITH CHILDHOOD-ONSET SYSTEMIC LUPUS ERYTHEMATOSUS (CSLE): PATIENT RESPONSES OVER TIME

N. Rupert,1 L. Mc Cann,2 S. Takai,1 C. Pilkington,4 D. Bass,5 B. Ji,6 A. Hammer,6 M. Okily, G. Eriksson,5 H. Quasny,7 H. Brunner,8 Istituto Giannina Gaslini, Genoa, Italy; 1Alder Hey Children's Hospital, Liverpool, United Kingdom; 2Kagoshima University, Kagoshima, Japan; 3Great Ormond Street Hospital, London, United Kingdom; 4GlaxoSmithKline, Collegeville, United States of America; 5GlaxoSmithKline, Uxbridge, United Kingdom; 6GlaxoSmithKline, Research Triangle Park, United States of America; 7Children's Hospital Colorado, Aurora, United States of America

Background: Belimumab (BEL) is a human monoclonal antibody that specif-
ically inhibits B-cell activating factor (BAFF). PLUTO is an ongoing trial eval-
uating efficacy and safety of intravenous (IV) BEL in children ≥5 years of age
with cSLE. Efficacy, and safety endpoints of PLUTO have been reported; briefly,
numerically more BEL vs PBO pts met the primary and major secondary efficacy
endpoints. We present patient (pt) responses to BEL over time.

Objectives: To evaluate changes in SLE Responder Index (SRI) 4 and SRI
responses, and disease activity over 52 weeks, in paediatric pts receiving BEL,
or placebo (PBO), plus standard SLE therapy (SST).

SAT0504
STING-ASSOCIATED VASCULOPATHY WITH ONSET IN INFANCY (SAVI SYNDROME) CAN MIMIC JUVENILE IDIOPATHIC ARTHRITIS.

M. Lopez Corbeto, E. Moreno Ruzafa1,2, Hospital Universitari Vall d’Hebron, Pediatric Rheumatology, Barcelona, Spain; 3Hospital Universitari Vall d’Hebron, Barcelona, Spain

Background: STING-associated vasculopathy with onset in infancy (SAVI syn-
drome) can mimic Juvenile Idiopathic Arthritis.