
Conclusion: This preliminary analysis suggests that assessment of IFN activity has a role in predicting response to RTX. A novel IFN score (Score-B) was more predictive than classic ISGs (Score-A). These results add to a body of work showing that IFN-Score-B predicts clinically significant outcomes independently of overall IFN activity. Future work will analyse this biomarker in a larger cohort of patients and integrate with other putative clinical and biological predictors of response.

**REFERENCES:**

Acknowledgement: We would like to thank the Medical Research Council, National Institute of Health Research, UK for funding the MASTER-PLANS project.

Disclosure of Interests: Adewonuola Alase: None declared, Zoe Wigston: None declared, Agata Burska: None declared, Elizabeth Hensor: None declared, Md Yuzaili Md Yusof: None declared, John Reynolds: None declared. The Masterplans Consortium: None declared, Miriam Wittmann Consultant for: consultoria honoraria from Abbvie, Celgene, Janssen, L’Oreal, Novartis and Pfizer, Ian N. Bruce Grant/research support from: Genzyme Sanofi, GlaxoSmithKline, Consultant for: AstraZeneca, Eli Lilly, GlaxoSmithKline, ILTCO Pharma, MedImmune, Merck Serono, Speakers bureau: GlaxoSmithKline, UCB Pharma, Edward Vital Grant/research support from: He has received honoraria and research grant from Roche, GSK and AstraZeneca.

**DOI:** 10.1136/annrheumdis-2019-eular.5750

---

OFF-LABEL USE OF RITUXIMAB IN RHEUMATIC DISEASES, A SWISS TERTIARY CENTRE EXPERIENCE

**Alexandre Dumusc, Thomas Huegle, Pascal Zufferey. University Hospital Lausanne (CHUV), Rheumatology, Lausanne, Switzerland**

**Background:** Rituximab (RTX), a monoclonal antibody targeting CD20, is licenced for the treatment of rheumatoid arthritis (RA) for many years and more recently for ANCA-associated vasculitis. RTX is frequently used off-label to treat other auto-immune diseases (AID), especially connective tissue diseases (CTD). There are no published data about off-label use of RTX in AID in Switzerland.

**Objectives:** To describe off-label use of RTX in a real-life setting, when treating AID.

**Methods:** Retrospective cohort study of all patients treated with RTX in the Rheumatology Department between 2005 and 2017. Clinical efficacy of RTX after 12 and 24 months of treatment was evaluated with a semi-quantitative scale (no response (NR), partial (PR) and complete response (CR)). RTX discontinuation rate was also analysed using Kaplan-Meier method and log rank test to evaluate the difference between survival curves. Adverse events (AE), serious AE (SAE) were included in the safety analysis. Occurrences of hypogammaglobulinemia and anti-rituximab antibodies (ADA) were also reported.

**Results:** 178 patients treated with RTX could be identified: 28% for CTD, 63% for RA and 10% for other AID. Rituximab was used off-label in 73% of the patients according to official Swiss indications. No significant differences in terms of clinical response were observed in off-label indication after 12 months (NR:15%/13%, PR:48%/52%, CR:37%/35%). RTX discontinuation rate was also analysed using Kaplan-Meier method and log rank test to evaluate the difference between survival curves. Adverse events (AE), serious AE (SAE) were included in the safety analysis. Occurrences of hypogammaglobulinemia and anti-rituximab antibodies (ADA) were also reported.

**CONCLUSION:** 178 patients treated with RTX could be identified: 28% for CTD, 63% for RA and 10% for other AID. Rituximab was used off-label in 73% of the patients according to official Swiss indications. No significant differences in terms of clinical response were observed in off-label indication after 12 months (NR:15%/13%, PR:48%/52%, CR:37%/35%). RTX discontinuation rate was also analysed using Kaplan-Meier method and log rank test to evaluate the difference between survival curves. Adverse events (AE), serious AE (SAE) were included in the safety analysis. Occurrences of hypogammaglobulinemia and anti-rituximab antibodies (ADA) were also reported.

**Disclosure of Interests:** Alexandre Dumusc: None declared, Thomas Huegle Grant/research support from: AbbVie, Lilly, Novartis and Pfizer, Speakers bureau: AbbVie, Lilly, Novartis and Pfizer, Pascal Zufferey: None declared

**DOI:** 10.1136/annrheumdis-2019-eular.6923

---

THE PLUTO STUDY: INTRA VENOUS BELUMUMAB IN CHILDREN WITH SYSTEMIC LUPUS ERYTHEMATOSUS

**Niccolo Rupperto1, Carlos Abud-Mendoza2, Diego O. Votia3, Inmaculada Calvo4, Deborah M. Levy5, Julia Calderon Gallegos6, Manuel Fernandez7, Vycheslav Chasyreny1, Vladimir Keltsev2, Jordi Anton1, Maria Gastanaga1, Michael Shishov2, Alina Boteanu1, Michael Henrickson2, Damon Bass3, Ken Clark5, Anne Hammer6, Beulah Jt7, Antonio Nino8, David Roth9, Herbert Struemper6, Mei-Lun Wang5, Alberto Martini1, Daniel J Lovell2, Adewonuola Alase1, Zoe Wigston9, Hermine Brunner10, Member of PRINTO, Istituto Gaslini, Genoa, Italy; Member of PRCSG, Cincinnati, United States of America; PRCSG, Philadelphia, United States of America; PRCSG, Research Triangle Park, United States of America; GSK, Stevenage, United Kingdom; GSK, Colleville, United Kingdom; GSK, Research Triangle Park, United States of America**

**Background:** Belimumab (BEL), a monoclonal antibody targeting the B-lymphocyte stimulator, is approved in adults with active systemic lupus erythematosus (SLE). This is the first clinical trial of belimumab in pediatric patients with childhood-onset SLE (cSLE).

**Objectives:** PLUTO, a Phase 2, randomised, double-blind trial (BEL114055; NCT01649765), evaluated the efficacy, safety and pharmacokinetics (PK) of intravenous (IV) BEL vs placebo (PBO), plus standard care (SoC), in cSLE.

**Methods:** Patients with cSLE 5–17 years of age were randomised to BEL 10 mg/kg IV or PBO every 4 weeks, plus SoC. Primary endpoint: SRI4 at Week 52. Major secondary endpoints: PRINTO/ACR 30 and 50 cSLE evaluation criteria for improvement at Week 52; cSLE core response variables at Week 52; and sustained SRI4 and ParentGA (patient well-being) responses (Weeks 44–52). Other endpoints: components of SRI4 at Week 52; and frequency of severe flares using the...