Abstract OP0086 – Figure 1. proportion of patients in quiescence by IMM use in VISUAL III

Conclusions: Exploratory analyses from the VISUAL III trial demonstrated that efficacy in adalimumab-treated patients was sustained or improved through 78 weeks of treatment, irrespective of IMM use. AE rates were consistent with previous VISUAL trials, although numerically higher rates for a subset of AEs were observed in patients taking IMM.

Acknowledgements: AbbVie funded the study and participated in study design, data analysis, and interpretation. AbbVie funded the research and provided writing support. All authors contributed to the development of the content. The authors and AbbVie reviewed and approved the abstract; the authors maintained control over the final content. Kevin Hudson, PhD, of 2theNth, provided medical writing support, which was funded by AbbVie Inc.

Disclosure of Interest: Y. Guex-Crosier Consultant for: AbbVie, Santen, and Novartis, C. S. Foster Grant/research support from: Alcon, Aldeyra, Bausch and Lomb, Clearside Biomedical, Dompe, Icon, Novartis, Santen, Xoma, Aciont, and pSivida, Consultant for: Aldeyra, Bausch and Lomb Surgical, EyeGate, Novartis, pSivida, and Xoma, Speakers bureau: Alcon and Allergan, K. Nakai: None declared, H. Goto Consultant for: AbbVie, K. Douglas Shareholder of: AbbVie, Employee of: AbbVie, S. Pathai Shareholder of: AbbVie, Employee of: AbbVie, M. Kron Shareholder of: AbbVie, Employee of: AbbVie, A. P. Song Shareholder of: AbbVie, Employee of: AbbVie, J. Van Calster Consultant for: consultant for: advisory boards for AbbVie, Allergan, Santen, and MSD, and has served as a consultant for AbbVie, Allergan, and MSD, A. Adán Consultant for: advisory boards for AbbVie, Santen, Allergan, and Novartis

DOI: 10.1136/annrheumdis-2018-eular.2551

OP0087

INCREASED RISK OF ISCHAEMIC HEART DISEASE AND MORTALITY AMONG FMF PATIENTS – PERSPECTIVE FROM A BIG DATABASE

S. Tiosano^{1,2}, R. Shapira^{1,2}, O. Gendelman^{1,2}, D. Comaneshter³, E. Pras^{2,4}, A. D. Cohen^{3,5}, H. Amital^{1,2}, ¹Internal Medicine 'B', Sheba Medical Center, Tel-Hashomer, Ramat-Gan; ²Sackler School of Medicine, Tel-Aviv University; ³Chief Physician's office, Clalit Health Services, Tel-Aviv; ⁴Genetic Institute, Sheba Medical Center, Tel-Hashomer, Ramat-Gan; ⁵Siaal Research Center for Family Medicine and Primary Care, Faculty of Health Sciences, Ben-Gurion University of the Negev, Beer-Sheva, Israel

Background: Familial Mediterranean fever (FMF) is a systemic autoinflammatory monogenic disease. It has been previously reported that FMF patients are prone to develop ischaemic heart disease (IHD),^{1,2} mostly due to increased inflammatory activity and endothelial dysfunction.^{3,4} However, large-scale information regarding the extent and prognosis of IHD among FMF patients is lacking.

Objectives: To check whether an association exists between FMF and IHD, and to assess the long-term prognostic significance of IHD among FMF patients using a big data registry with a 15 year follow-up period.

Methods: Utilising the medical records of Clalit Health Services, the largest HMO in Israel, we extracted a cohort of FMF patients along with their age-and-sex matched controls. Dates of registration in the medical records of FMF, IHD and death, as well as anthropometric information and medical comorbidities were extracted from the database. To compare the distribution of variables across the cohort strata, univariate analysis was performed using Chi-square and student t-test. Multivariate analysis using a logistic regression model was used to find variables associated with IHD. Survival analysis using Cox proportional hazards method and a log-rank test was performed to find variables associated with increased risk of all-cause mortality.

Results: The cohort included 7,670 FMF patients and 7670 age-and-sex matched controls. The mean age of both groups was 39.1, and both consisted 50.1% females. IHD was observed among 491 FMF patients (6.4%) vs 375 controls (4.89%), $p < 0.001$. In multivariate logistic regression, FMF was found to be

independently associated with a diagnosis of IHD (OR 1.44, 95% CI: 1.21 to 1.72). After over 15 years of follow-up, 345 (4.5%) of FMF patients had died, compared to 271 (3.53%) of the controls ($p < 0.001$). In multivariate survival analysis, both FMF and IHD were found to be significantly associated with increased risk to all-cause mortality (HR 1.29, 95% CI: 1.10 to 1.53 and HR 1.57, 95% CI: 1.29 to 1.9, respectively).

Conclusions: IHD is associated with worse prognosis among FMF patients compared to controls. Proper screening methods are recommended to assess whether early identification and treatment may improve life expectancy.

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Disclosure of Interest: None declared

DOI: 10.1136/annrheumdis-2018-eular.4768

OP0088

IMMUNE-RELATED ADVERSE EVENTS OF CANCER IMMUNOTHERAPY – WHEN INFLAMMATORY SIDE EFFECTS ARE ASSOCIATED WITH SURVIVAL: A SINGLE-CENTRE PROSPECTIVE COHORT STUDY

M. Kostine, E. Mauric, L. Rouxel, T. Barnette, R. Veillon, F. Martin, C. Dutriaux, L. Dousset, A. Pham-Ledard, S. Prey, M. Beylot-Barry, A. Daste, M. Gross-Goupil, J. Lallier, A. Ravaud, E. Forcade, B. Bannwarth, M.-E. Truchetet, C. Richez, N. Mehnen-Cetre, T. Schaevebeke, on behalf of the FHU ACRONIM. Bordeaux University Hospital, Bordeaux, France

Background: Immune checkpoint inhibitors (ICI) represent a new standard of care for the treatment of selected advanced cancers and are still being investigated in many other tumour types. By enhancing the T-cell activation, a unique spectrum of inflammatory side effects has emerged, also known as immune-related adverse events (irAEs), including various well-described rheumatic manifestations. Data regarding the association between irAEs and patient outcomes are conflicting.

Objectives: To evaluate the incidence and characteristics of irAEs in patients receiving ICI, as well as the correlation with tumour response and patient survival.

Methods: This was a single-centre prospective observational study including all cancer patients receiving ICIs. The occurrence of irAEs, tumour response and patient outcomes were assessed on a regular basis. Overall survival has been considered from the start of ICI.

Results: From May 2015 to September 2017, 636 patients (70% male, mean age 64 years) have been included in this cohort while receiving anti PD-1 (n=435), anti PD-L1 (n=66) or anti CTLA-4 (n=3) as single agent or as sequential (n=100) or combined (n=32) therapies. Cancer types were mainly melanoma (n=293), non-small cell lung cancer (n=150) and renal carcinoma (n=83). Overall, 274/633 patients (43%) experienced irAEs, either 1 irAE (n=162), 2 irAEs (n=78) or ≥3 irAEs (n=34), with a median exposure time of 52 days³⁰⁻⁹¹ for the first irAE. Dermatological irAEs were by far the most frequent (n=160), followed by digestive