20 BIOLOGICS USE IN SLE IN 23 CENTERS – DATA FROM THE INTERNATIONAL REGISTRY FOR BIOLOGICS IN SLE

R F van Vollenhoven,[1] Søren Jacobsen,[2] Daniel Wallace,[3] John G Hanly,[4] Michelle Petri,[5] David A Isenberg,[6] Ann E Clarke,[7] Christian A Pineau,[8] Sasha Bernatsky,[9] Julia F Simard,[10] Sang-Cheol Bae,[11] Manuel Ramos-Casals,[12] Cándido Díaz-Lagares,[12] Guillermo Ruiz-Irastorza,[13] Agustín Martínez-Berriotxoa,[13] Francisco J García-Hernández,[14] Rocío González-León,[14] M Jesús Castillo-Palma,[15] Luis Saez,[16] José Luis Callejas,[17] Javier Rascón,[18] Enrique de Ramón,[19] M Mar Ayala-Gutiérrez,[19] Maite Camps,[19] Melinda Mild,[10] Murat Inanç,[20] Bahar Artim-Esen,[20] Rosalind Ramsey-Goldman,[21] Christine A Peschken,[22] Danilo Squatrito,[23] Lorenzo Emmi,[23] László Kovács,[24] Andrea Doria,[25] Zoltan Szekanecz,[26] Gianfranco Ferraccioli,[27] Elisa Gremese,[28] Emilia I Sato[29] *[1]Karolinska University Hospital, Stockholm, Sweden; [2]Rigshospitalet, Copenhagen, Denmark; [3]Cedars-Sinai/UCLA, Los Angeles, California, USA; [4]Dalhousie University and Capital Health, Halifax, Canada; [5]Johns Hopkins Hospital, Baltimore, Maryland, USA; [6]University College London, London, UK; [7]McGill UHC/RI, Montreal, Canada; [8]McGill Univ Health Center, Montreal, Canada; [9]McGill UHC/RVH, Montreal, Canada; [10]Karolinska Institutet, Stockholm, Sweden; [11]Hanyang University Hospital for Rheumatic Diseases, Seoul, South Korea; [12]Hospital Clínic, Barcelona, Spain; [13]Hospital de Cruces, Bizkaia, Spain; [14]Hospital Virgen del Rocío, Sevilla, Spain; [15]Sevilla, Spain; [16]Hospital Miguel Servet, Zaragoza, Spain; [17]Hospital San Cecilio, Granada, Spain; [18]Hospital Son Dureta, Palma de Mallorca, Spain; [19]Hospital Carlos Haya, Málaga, Spain; [20]Istanbul University, Istanbul Medical Faculty, Istanbul, Turkey; [21]Northwestern University Feinberg School of Medicine, Chicago, Illinois, USA; [22]Univ of Manitoba, Winnipeg, Canada; [23]Careggi Hospital-Florence, Florence, Italy; [24]University of Szeged, Szeged, Hungary; [25]University of Padova, Padova, Italy; [26]University of Debrecen Medical and Health Sciences Center, Debrecen, Hungary; [27]Division of Rheumatology, Catholic University of the Sacred Heart, Rome, Italy; [28]Rheumatology Unit, Catholic University, Roma, Italy; [29]Escola Paulista de Medicina - Universidade Federal de São Paulo, Sao Paulo, Brazil*

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Background and objectives There is only one biologic agent approved for use in SLE, but some are used off-label in various settings. To obtain information systematically regarding this, members of the SLICC group initiated the International Registry for Biologics in SLE (IRBIS). The objective of this study was to analyse the use of biologics in SLE, and assess results achieved with the most commonly used off-label biologic, rituximab (RTX).

Materials and methods IRBIS investigators were asked to provide retrospective data on all patients treated with a biologic for SLE at their center. Standardised case report forms were used to collect demographic, disease-specific and treatment data at the time of biologic initiation and at yearly follow-up. Data from the first 23 reporting centers are presented.

Results Three hundred and fifty-nine patients were treated off-label with RTX, and additional groups of patients were exposed to belimumab (n=44), epratuzumab (n=21), abatacept (n=4), etanercept (n=3) and adalimumab (n=1). For the RTX treated group, age (mean±SD) was 41.3±13.3 and 91% were female. The majority (76%) were Caucasian, and smaller proportions were Southeast Asian, Asian/Indian, African-American, Latino, Afro-Caribbean or other (each <10%). Disease duration when RTX was initiated was 9.2±7.8 years. SLEDAI at start was 11.3±7.6, SLICC-damage index 1.4±1.5 and glucocorticoid dosage 17.0±15.2 mg. Most patients (78%) had been treated with one or two different immunosuppressives (ISs) prior to RTX, and the remaining with three to five ISs. Two dosing regimens were used for RTX: 375 mg/m2x4 (52%) and 1000 mgx2 (48%). The major organ manifestations leading to RTX treatment were lupus nephritis (LN, 48%), haematological (21%), musculoskeletal, skin disease, CNS and other (each <10%). At 1-year follow-up both SLEDAI and GC dose had decreased (4.2±3.5 (n=106) and 7.9±7.0mg (n=89), respectively, paired samples, p<0.0001 for both comparisons). Exclusion of patients started on additional ISs (n=24) did not change SLEDAI or GC dose significantly. SLEDAI at baseline was higher in LN than in non-LN patients but similar at follow-up. Overall, the 1000 mgx2 was more often used but both dosing regimens appeared equally effective in LN.

Conclusions RTX was the off-label biologic most commonly used in this multi-center international lupus cohort and was used for LN as well as for other SLE manifestations. At one-year-follow-up both lupus activity and concomitant glucocorticoid dosage had decreased even when no other IS treatments had been introduced. The two RTX dosing regimes appeared equally effective for LN treatment, but firm conclusions cannot be made from these observational data.