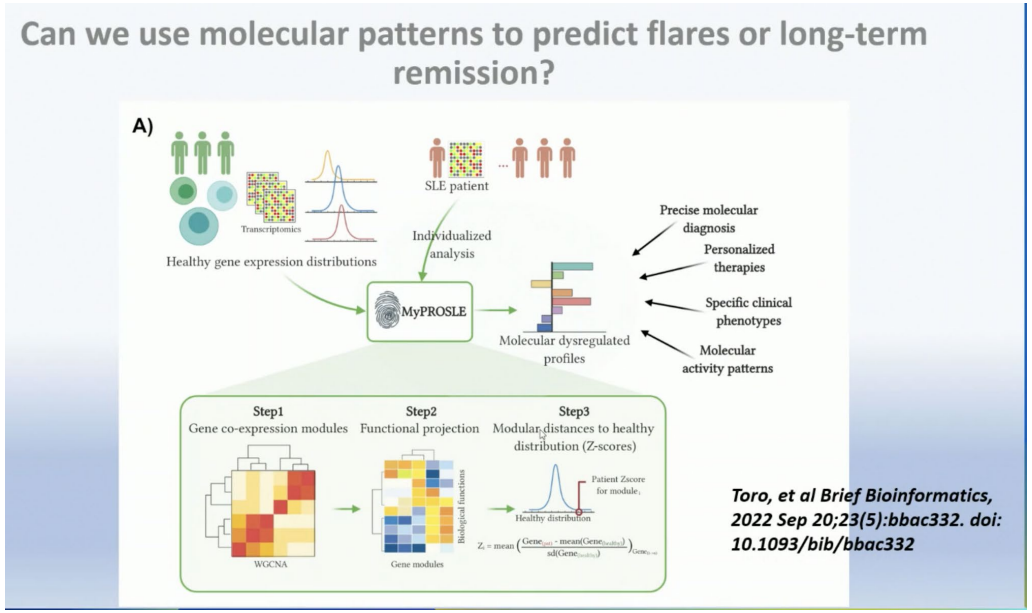
EULAR 2023
SLE/Sjögren Syndrom

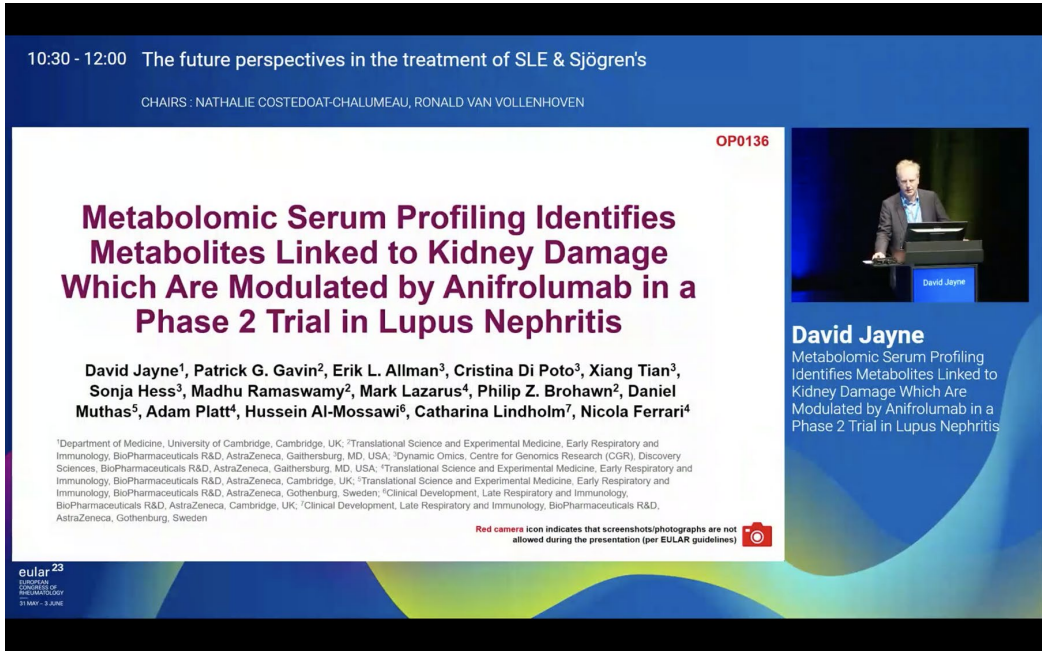
Thomas Daikeler

USB

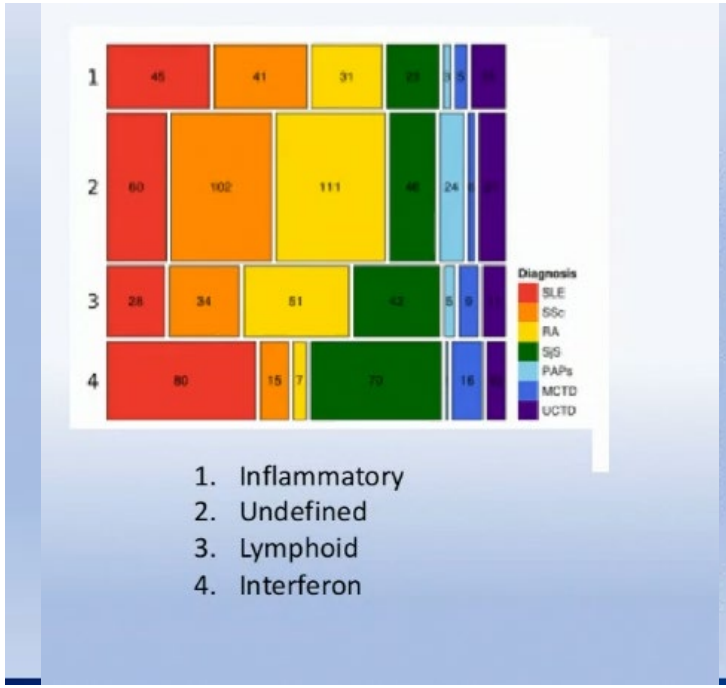
Omics in SLE


14:15 - 15:30 Precision medicine in SLE: where are we?
CHAIRS : DIMITRIOS BOUMPAS, JOSE M PEGO-REIGOSA
Which cells Differentiate Patients that Belong to Different transcriptome groups?
Marta Alarcon-Riquelme
The molecular mechanisms behind lupus: a way to solve the disease heterogeneity?
eular 23

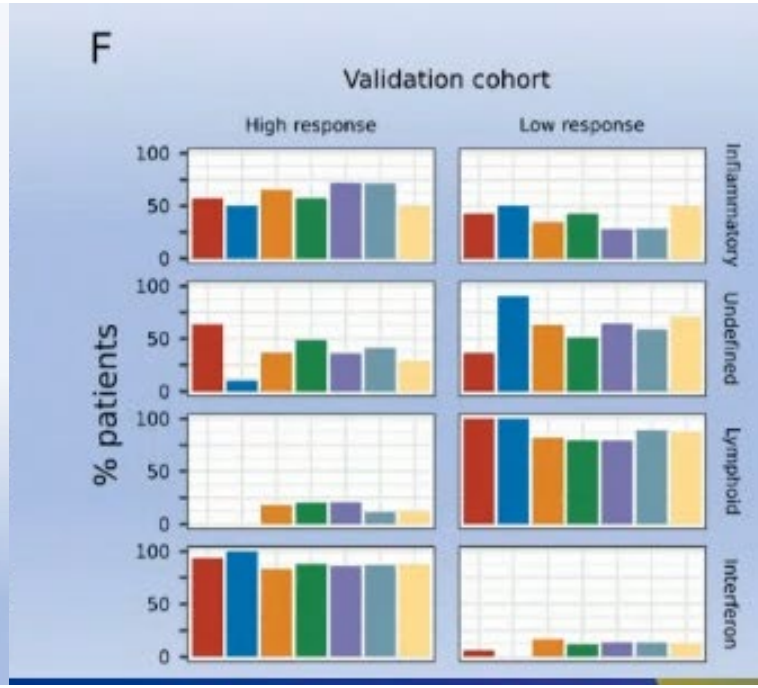

Can we use molecular patterns to predict flares or long-term remission?
A)
SLE patient
Transcriptomics
Healthy gene expression distributions
Individualized analysis
MyPROSLE
Molecular dysregulated profiles
Precise molecular diagnosis
Personalized therapies
Specific clinical phenotypes
Molecular activity patterns
Step1
Gene co-expression modules
Step2
Functional projection
Step3
Modular distances to healthy distribution (Z-scores)
WGCNA
Gene modules
Biological functions
Patient Zscore for module
Healthy distribution
Toro, et al Brief Bioinformatics, 2022 Sep 20;23(5):bbac332. doi: 10.1093/bib/bbac332


10:30 - 12:00 The future perspectives in the treatment of SLE & Sjögren's
CHAIRS : NATHALIE COSTEDOAT-CHALUMEAU, RONALD VAN VOLLENHOVEN
OP0136
Metabolomic Serum Profiling Identifies Metabolites Linked to Kidney Damage Which Are Modulated by Anifrolumab in a Phase 2 Trial in Lupus Nephritis
David Jayne[1], Patrick G. Gavin[2], Erik L. Allman[3], Cristina Di Poto[3], Xiang Tian[3], Sonja Hess[3], Madhu Ramaswamy[2], Mark Lazarus[4], Philip Z. Brohawn[2], Daniel Muthas[5], Adam Platt[4], Hussein Al-Mossawi[6], Catharina Lindholm[7], Nicola Ferrari[4]
Red camera icon indicates that screenshots/photographs are not allowed during the presentation (per EULAR guidelines)
David Jayne
Metabolomic Serum Profiling Identifies Metabolites Linked to Kidney Damage Which Are Modulated by Anifrolumab in a Phase 2 Trial in Lupus Nephritis
eular 23

Klassifikation via Dominanz der Immunantwort



1. Inflammatory
2. Undefined
3. Lymphoid
4. Interferon



E,F: Degree of response of Autoimmune diseases of the IFN cluster

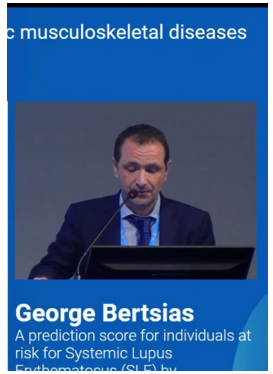
Discovery: 86.2%

Validation: 86.2%

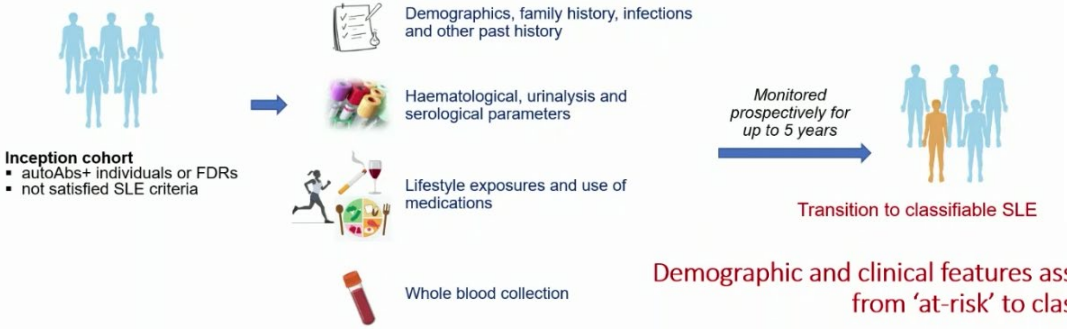
In collaboration with X

Marta Alacon Riquelme
Precision medicine in SLE

Welche Patienten mit LUPUS Stigmata (aber noch kein SLE) Entwicklen eine LUPUS



Methodology: evaluation at baseline and every 4 to 12 months depending on the disease status



Transition to classifiable SLE (median follow-up 21 months)

SLE classified	No. (%)
by the ACR-97 and/or the EULAR/ACR-19 criteria	52 (22.1%)

Demographic and clinical features associated with the transition from 'at-risk' to classfied SLE

Baseline features	Progression to SLE (ACR 1997 and/or EULAR/ACR 2019 criteria)	
	Hazard ratio (95% CI)	P value
FDR(s) with SLE (yes)	2.21 (1.07–4.54)	0.031
Smoking		
Never smoker	1.00	
Smoker – active	1.23 (0.56–2.72)	0.610
Smoker – past	2.15 (1.17–3.96)	0.014
Mediterranean score (0 to 8)	0.88 (0.76–1.02)	0.090
Malar rash	1.76 (0.92 – 3.36)	0.087
Photosensitivity	2.37 (1.35 – 4.17)	0.003
Mucosal ulcers	1.87 (0.84 – 4.16)	0.125
Serositis	4.87 (1.17 – 20.24)	0.029
Non-scarring alopecia	1.85 (0.92 – 3.71)	0.082
Autoimmune hemolysis	2.56 (0.62 – 10.56)	0.193
Thrombocytopenia	0.22 (0.03 – 1.61)	0.136
Low C3 and low C4)	2.13 (0.77 – 5.93)	0.148
Raynaud's	0.52 (0.27 – 1.02)	0.057

Transition to SLE:

- ✓ Increased *IFI27, OTOF, IFI44L* expression
- ✓ Deregulation of response to type I IFN

14:15 - 15:30 Precision medicine in SLE: where are we?

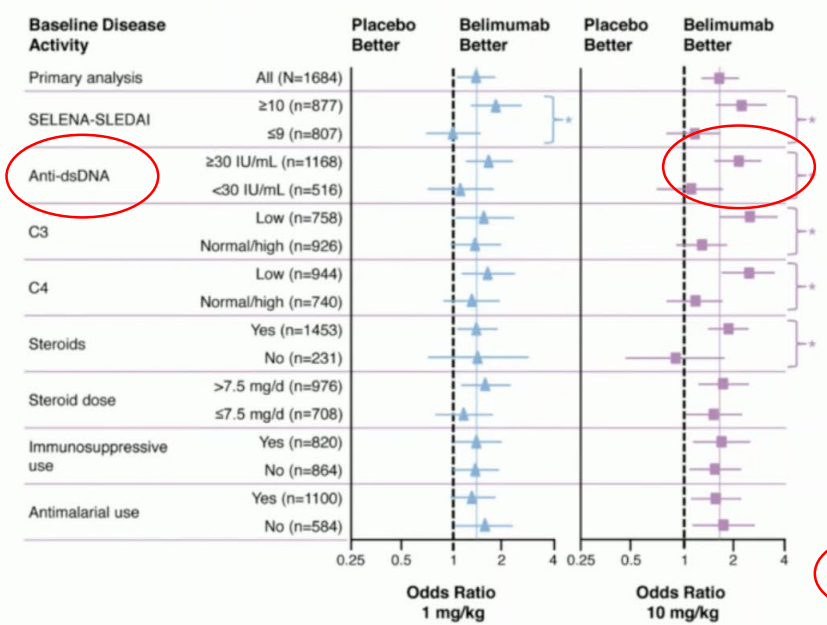
CHAIRS : DIMITRIOS BOUMPAS, JOSE M PEGO-REIGOSA

How can we choose between belimumab and anifrolumab for non-renal SLE?

UNIVERSITY OF LEEDS

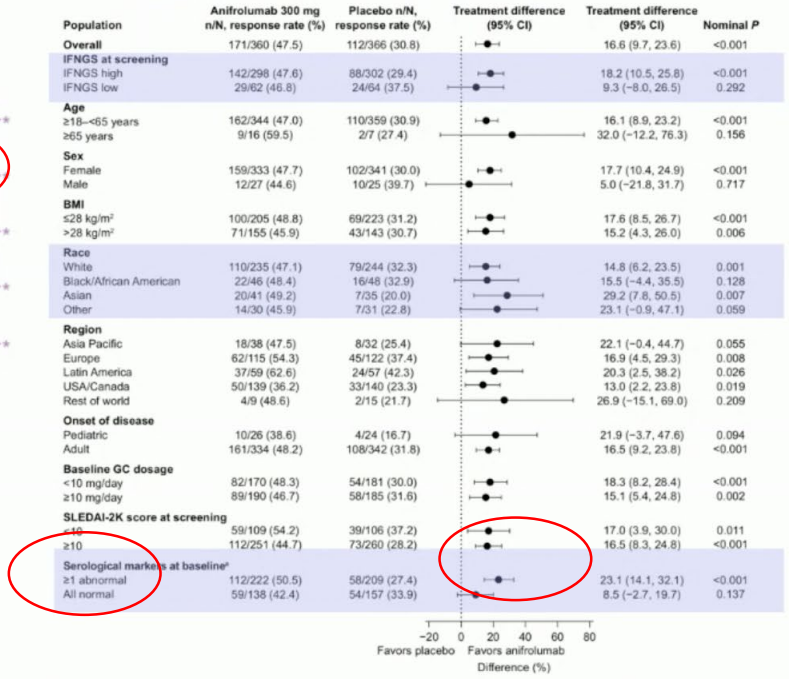
Belimumab

Vollenhoven et al. ARD 2011



Anifrolumab

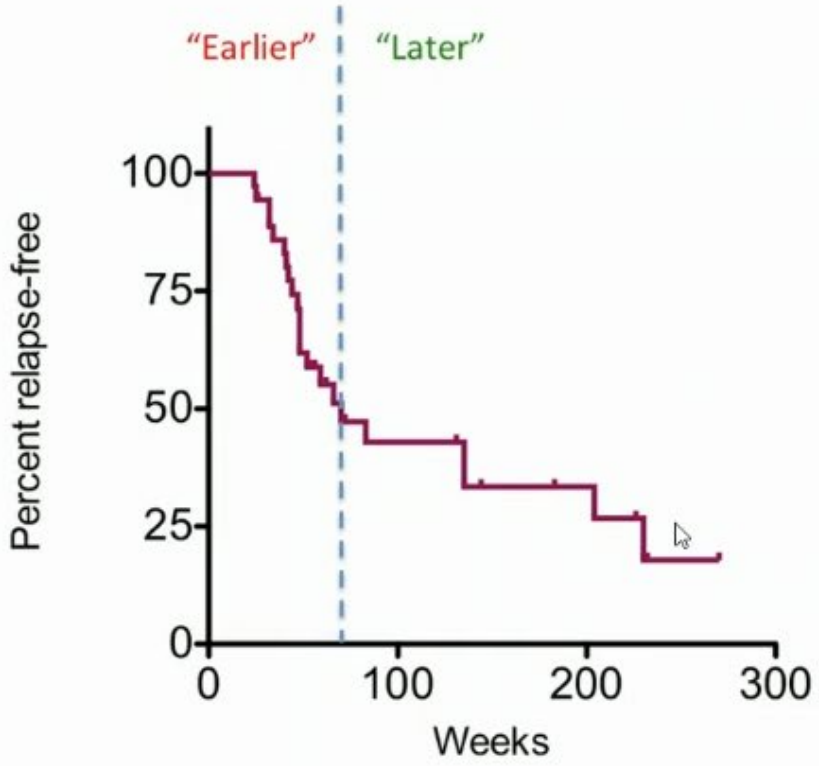
Vital et al. ARD 2022

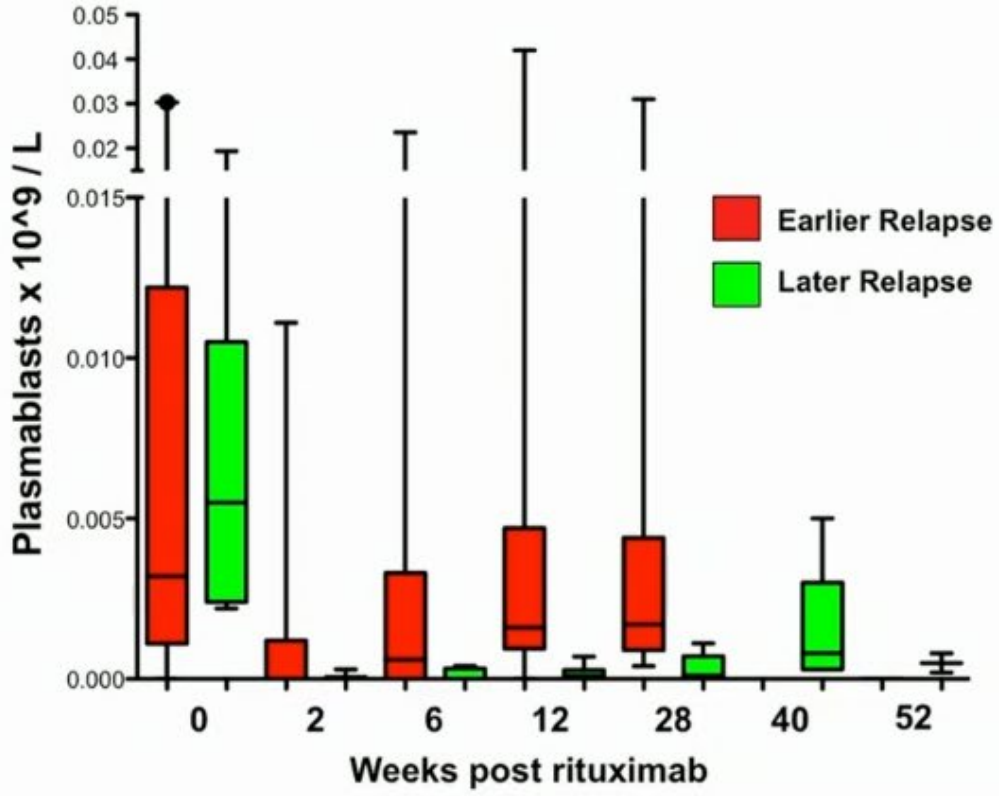


Edward Vital

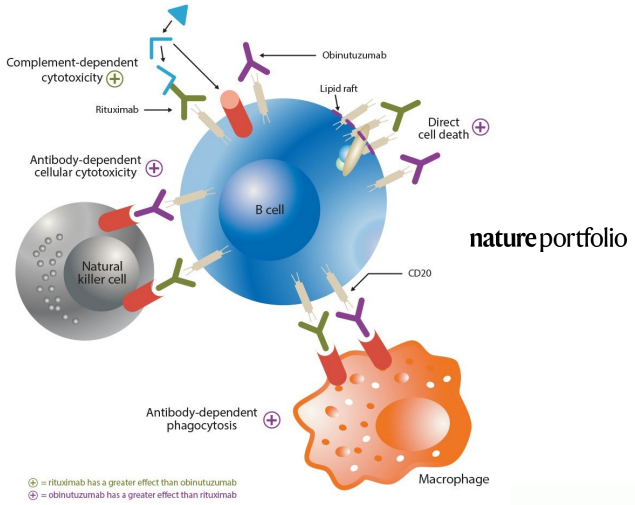
Precision medicine in SLE: what is the role of drugs mechanisms of action in the identification of the right therapy?

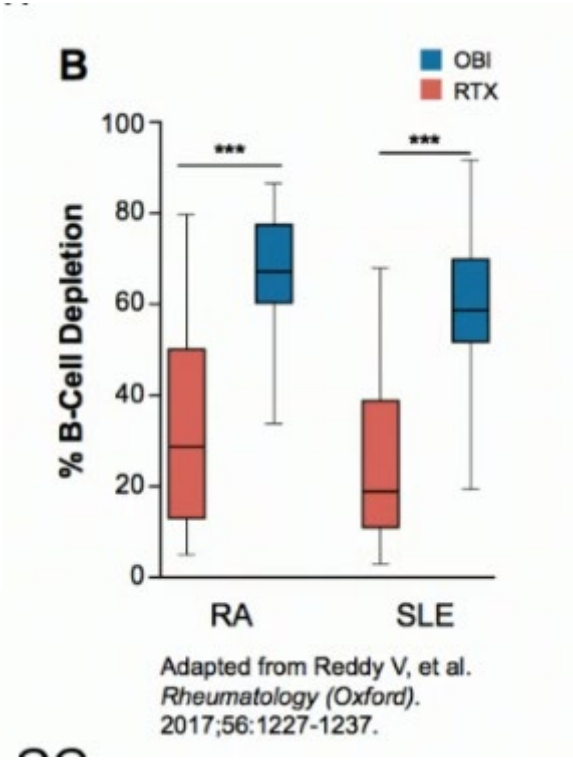
Focus on B-cell Depleting Therapy

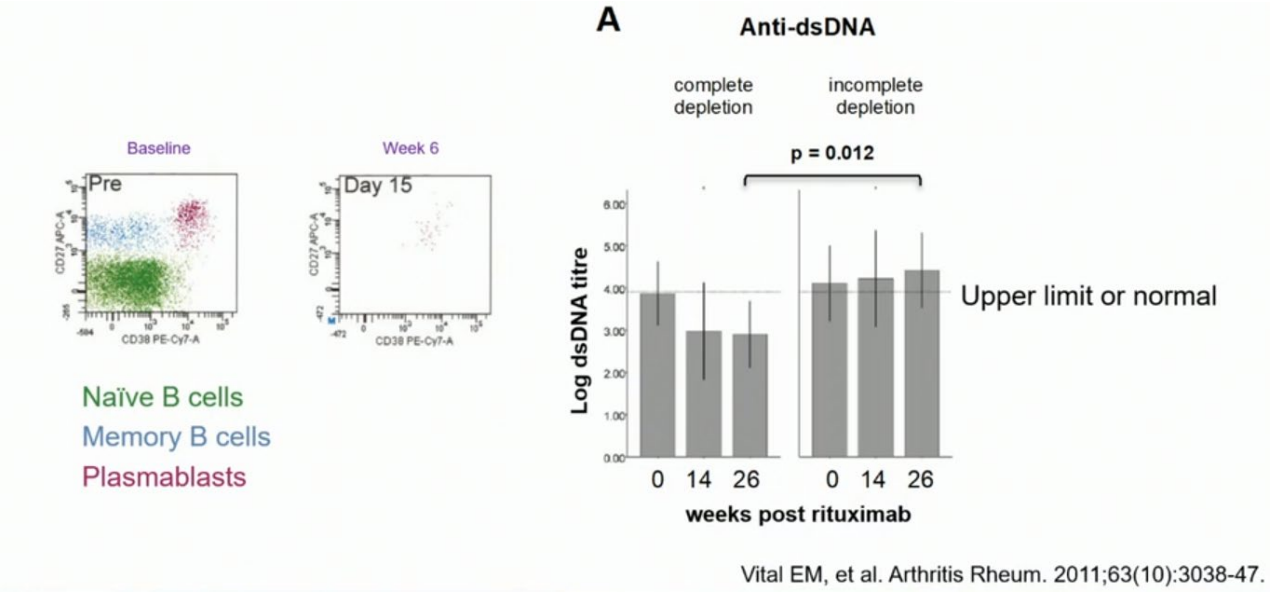


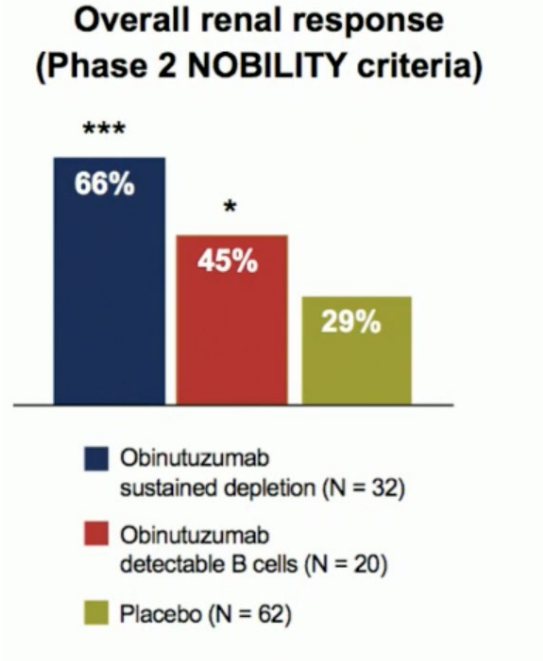


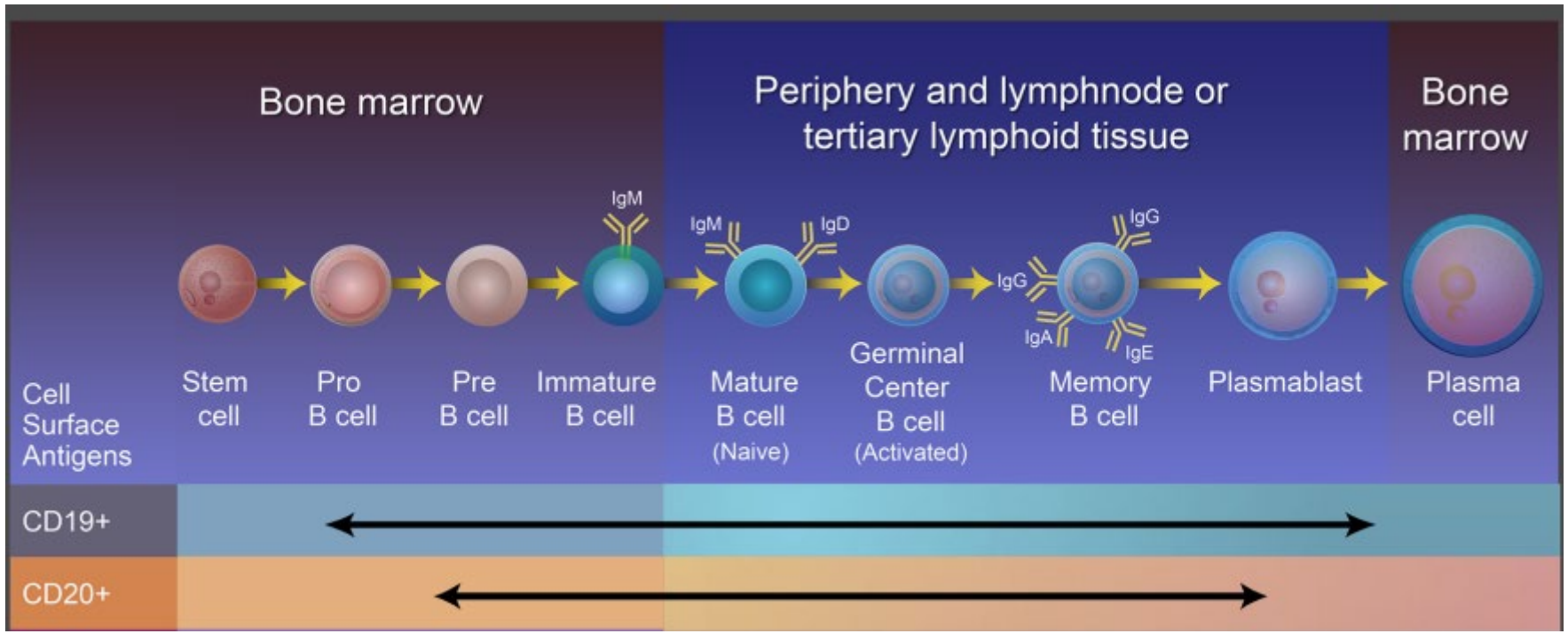
Die Tiefe der B-Zell Depletion ist Entscheidend







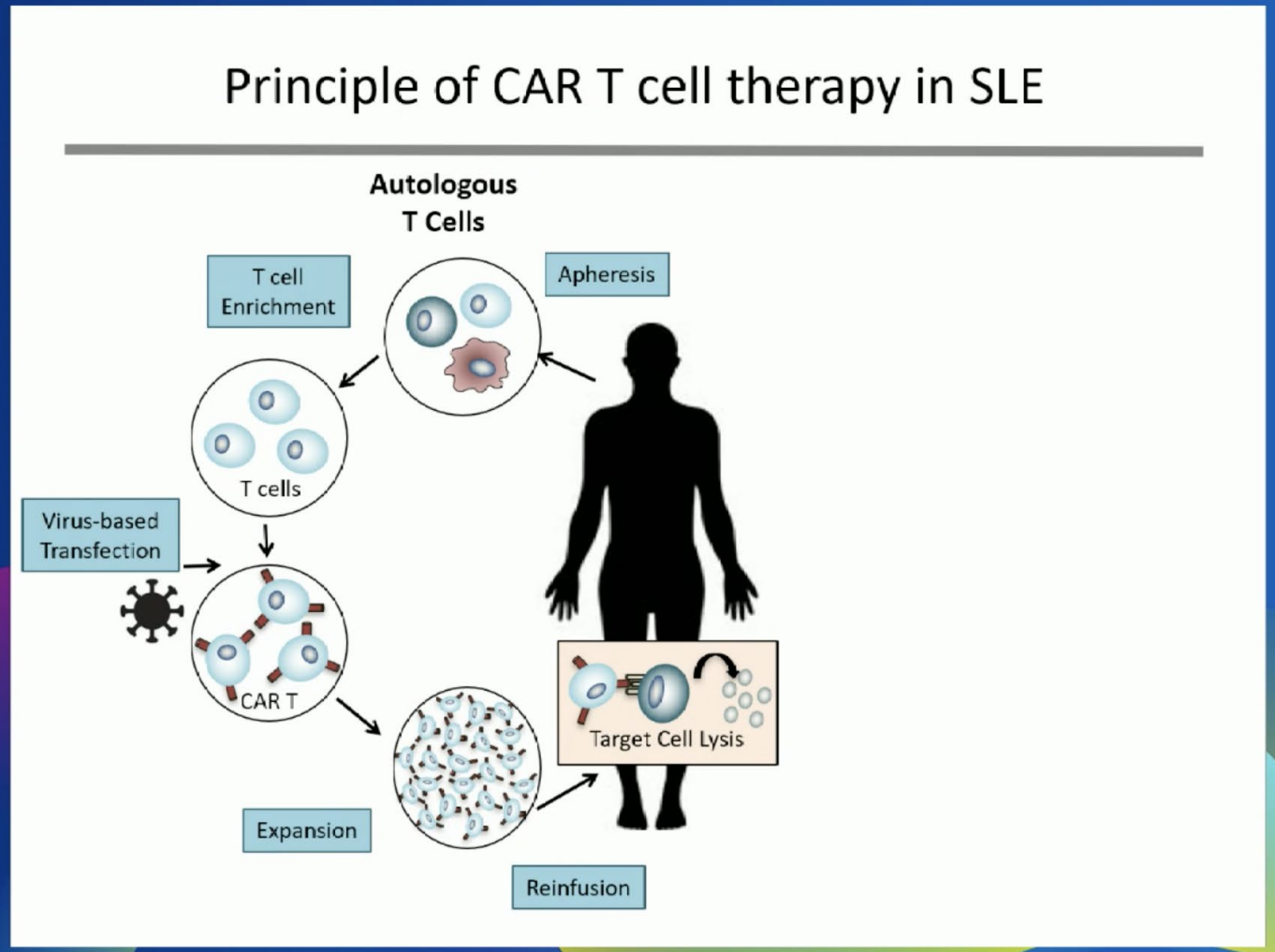




Neurotherapeutics (2022)

10:30 - 12:00 The future perspectives in the treatment of SLE & Sjögren's

CHAIRS : NATHALIE COSTEDOAT-CHALUMEAU, RONALD VAN VOLLENHOVEN



Georg Schett

LONG TERM SAFETY AND EFFICACY OF CAR-T CELL TREATMENT IN REFRACTORY SYSTEMIC LUPUS ERYTHEMATOSUS - DATA FROM THE FIRST SEVEN PATIENTS

10:30 - 12:00 The future perspectives in the treatment of SLE & Sjögren's

CHAIRS : NATHALIE COSTEDOAT-CHALUMEAU, RONALD VAN VOLLENHOVEN

First 7 patients with treatment-refractory SLE

	Pat #1	Pat #2	Pat #3	Pat #4	Pat #5	Pat #6	Pat #7
Age (ys)	22	23	22	24	18	33	33
Sex (F/M)	F	M	F	F	F	F	F
Disease Duration (ys)	4	1	6	9	3	18	1
Baseline SLEDAI (score)	16	16	10	8	9	16	10
Baseline C3 (mg/dL)	49	43	56	88	68	33	49
Baseline anti-dsDNA (U/mL)	5600	2060	479	4	52	1335	680
Kidney Bx Result	III	III	IV	I	V	IV	IV
Proteinuria (/g creatinine)	2015	3080	6539	8096	88	2025	5044
N organs involved	4	3	5	6	4	6	3
N failed treatments	7	5	4	7	5	15	7
Treatments	GLC HCQ MMF BEL TAC CX RTX	GLC HCQ MMF BEL CX	GLC HCQ MMF BEL	GLC HCQ MMF BEL AZA MTX LEF	GLC HCQ MMF BEL AZA	GLC HCQ MMF BEL TAC CX RTX AZA CYA MTX LEF IVIG BORT UPA IA	GLC HCQ MMF BEL TAC CX RTX

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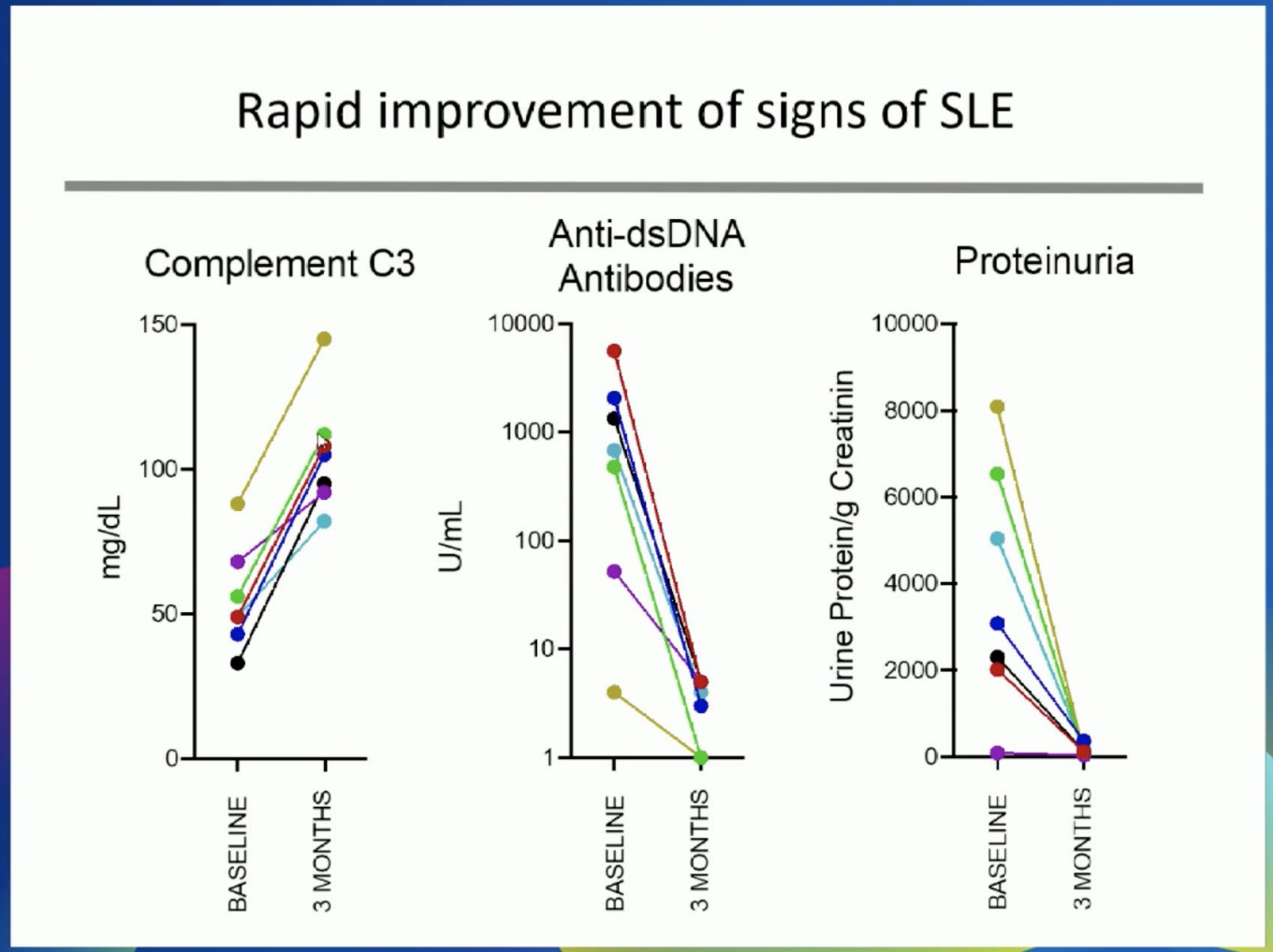


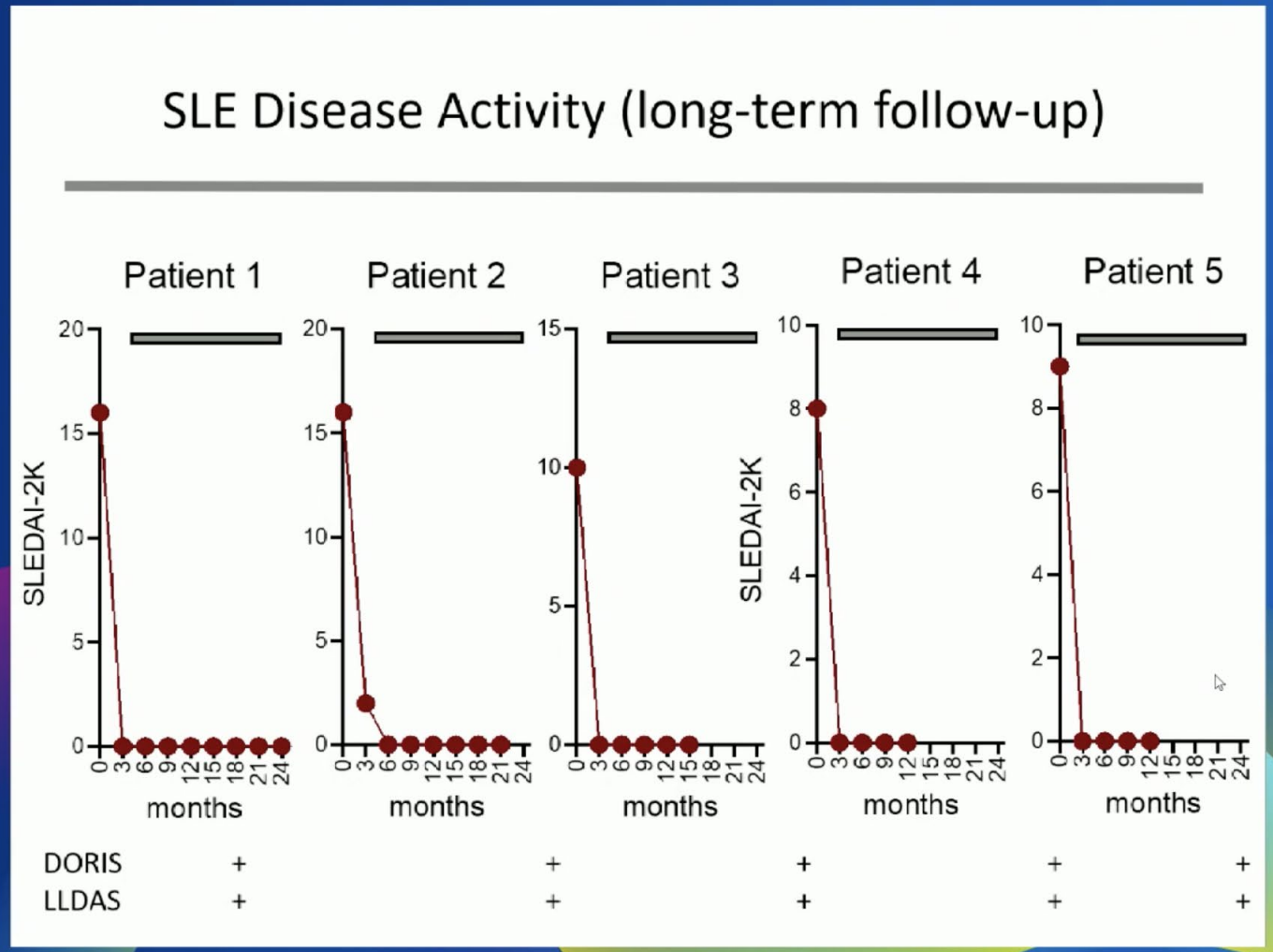
Georg Schett

LONG TERM SAFETY AND EFFICACY OF CAR-T CELL TREATMENT IN REFRACTORY SYSTEMIC LUPUS ERYTHEMATOSUS - DATA FROM THE FIRST SEVEN PATIENTS

eular 23
EUROPEAN CONGRESS OF RHEUMATOLOGY
31 MAY – 3 JUNE

10:30 - 12:00 The future perspectives in the treatment of SLE & Sjögren's

CHAIRS : NATHALIE COSTEDOAT-CHALUMEAU, RONALD VAN VOLLENHOVEN



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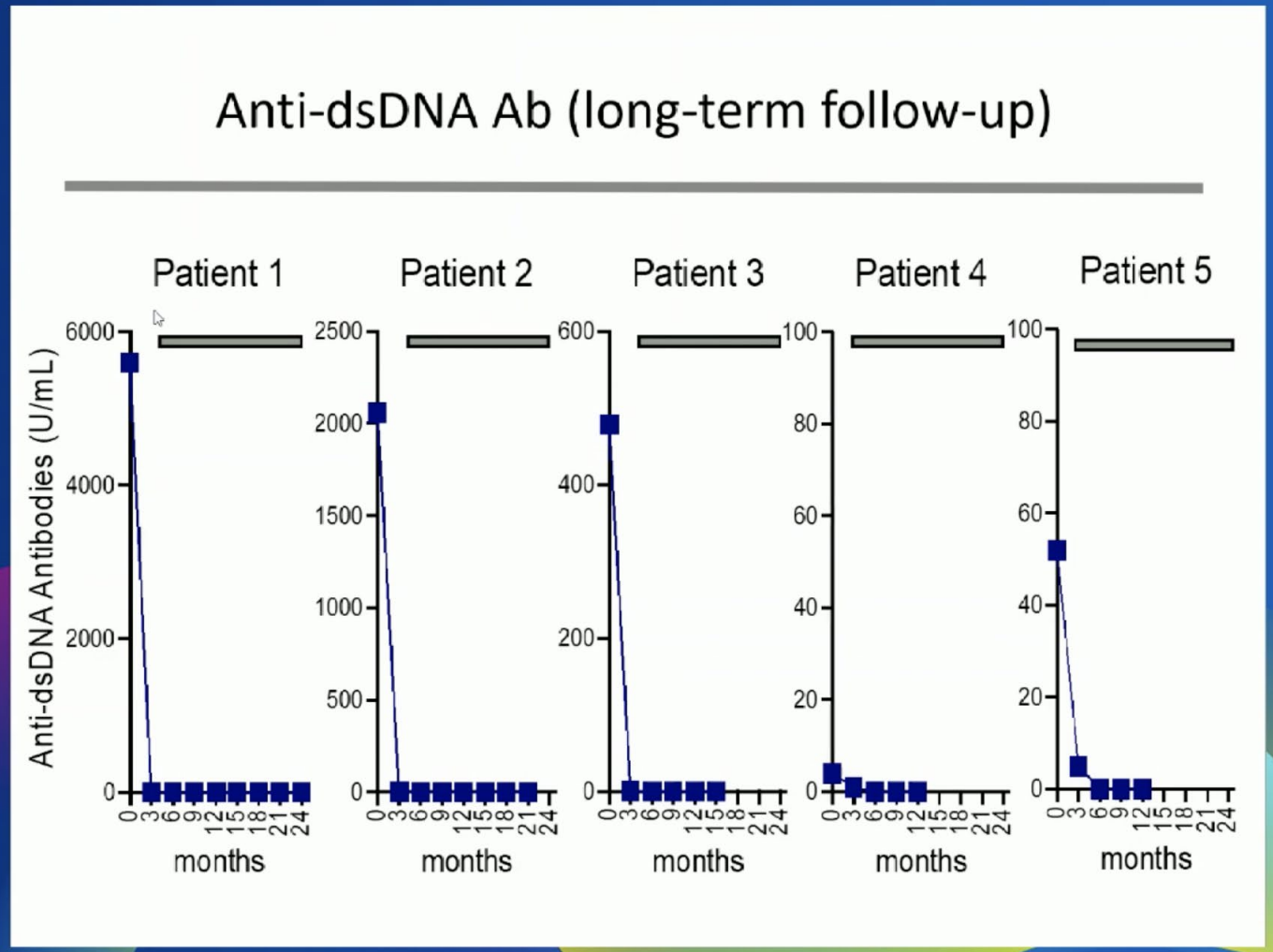

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Infections after CD19 CAR T cell therapy in SLE

	0-3 months	4-6 months	6-12 months	>12 months
Patient 1	Urogential	0	0	Flu-Like
Patient 2	0	0	COVID19	0
	0	0	Rhinitis	0
Patient 3	COVID19	0	Tonsillitis	COVID19 (P)
				Herpes Zoster(A)
Patient 4	0	0	0	0
Patient 5	0	COVID19 (P)	0	
Patient 6	0	COVID19 (P)	COVID19 (P)	
	0	RSV	Conjunctivitis*	
Patient 7	0	0		

RSV, respiratory syncytial virus; (P) paxlovid treatment; (A) acylcovir treatment

mild course moderate course severe course

Georg Schett

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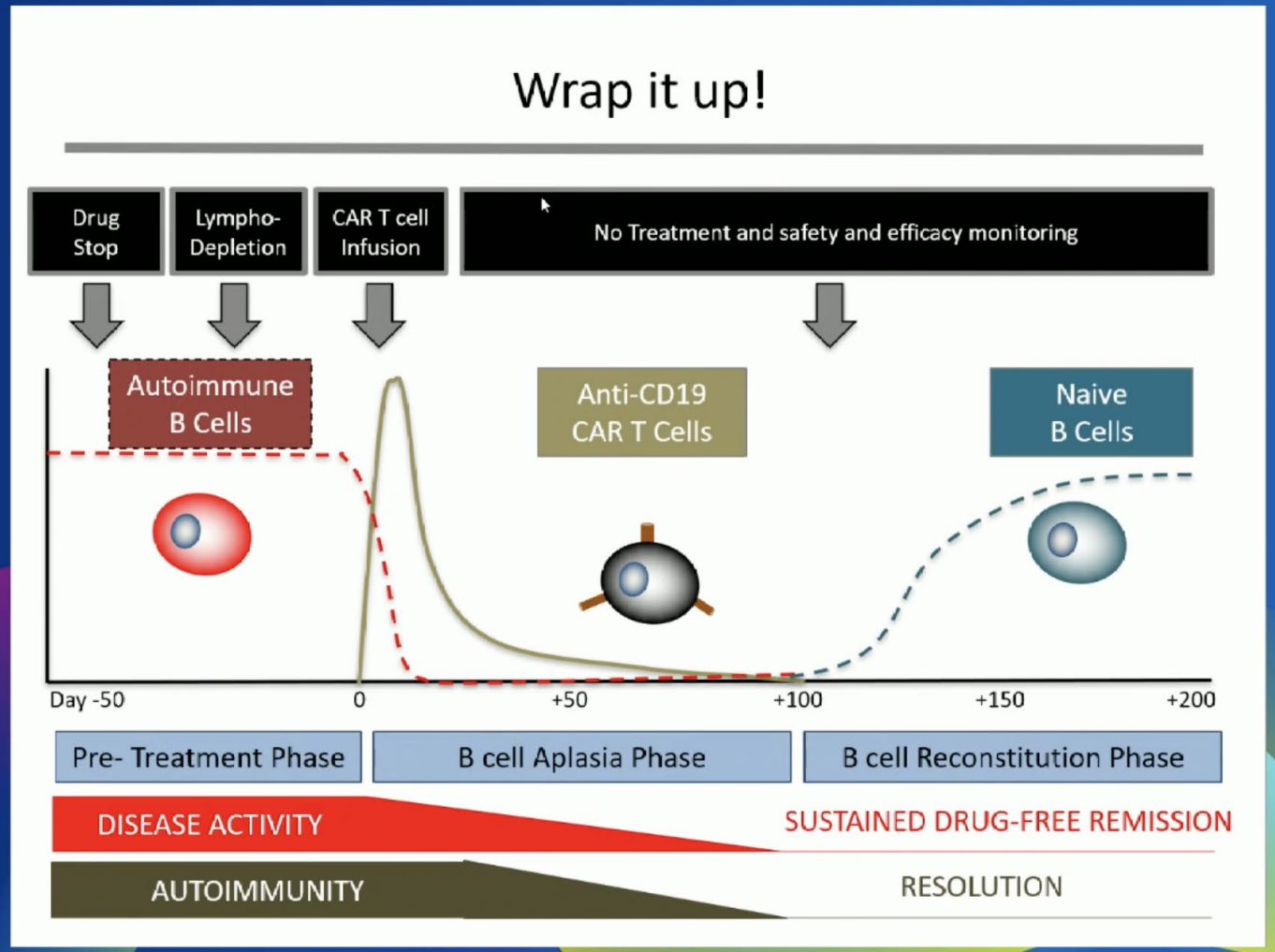

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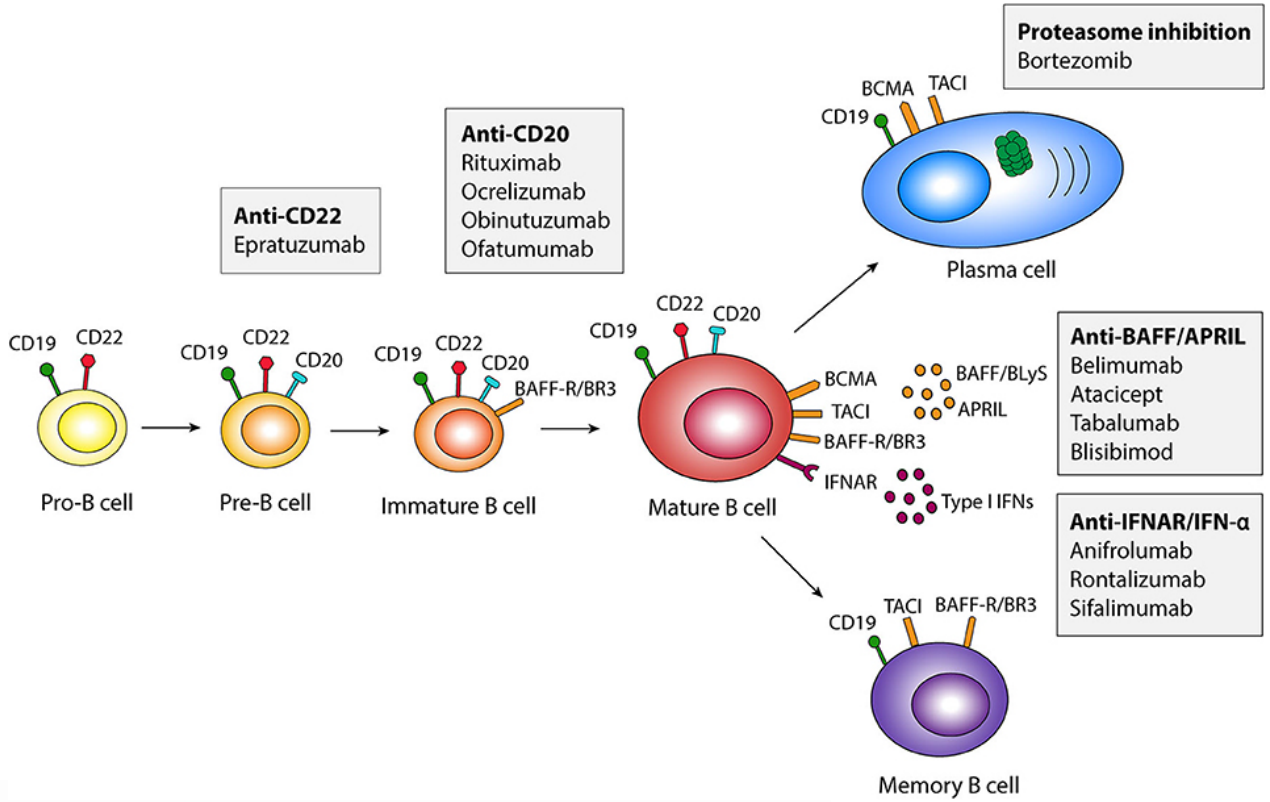


Frontiers 2020

Logical Biologic Sequencing after rituximab

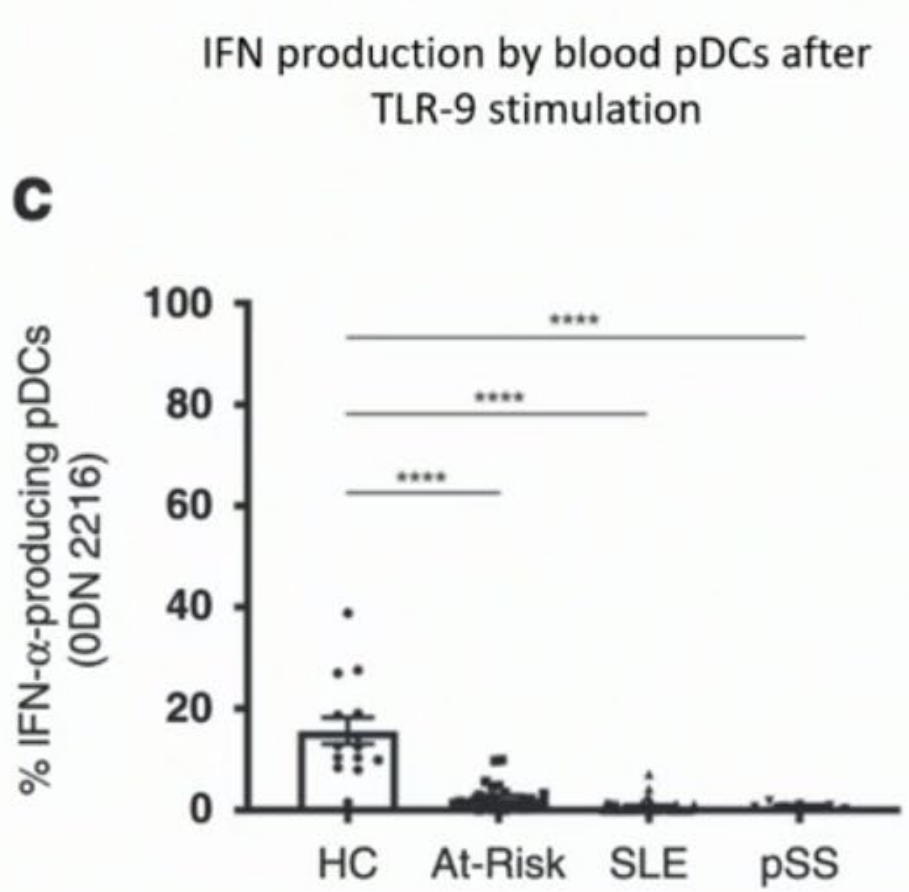
- RTX → OBI for secondary non-response
- RTX → BEL for response with early relapses
- RTX → Bortezomib for plasma cell-mediated disease
- RTX → ANI for primary non-response with skin disease

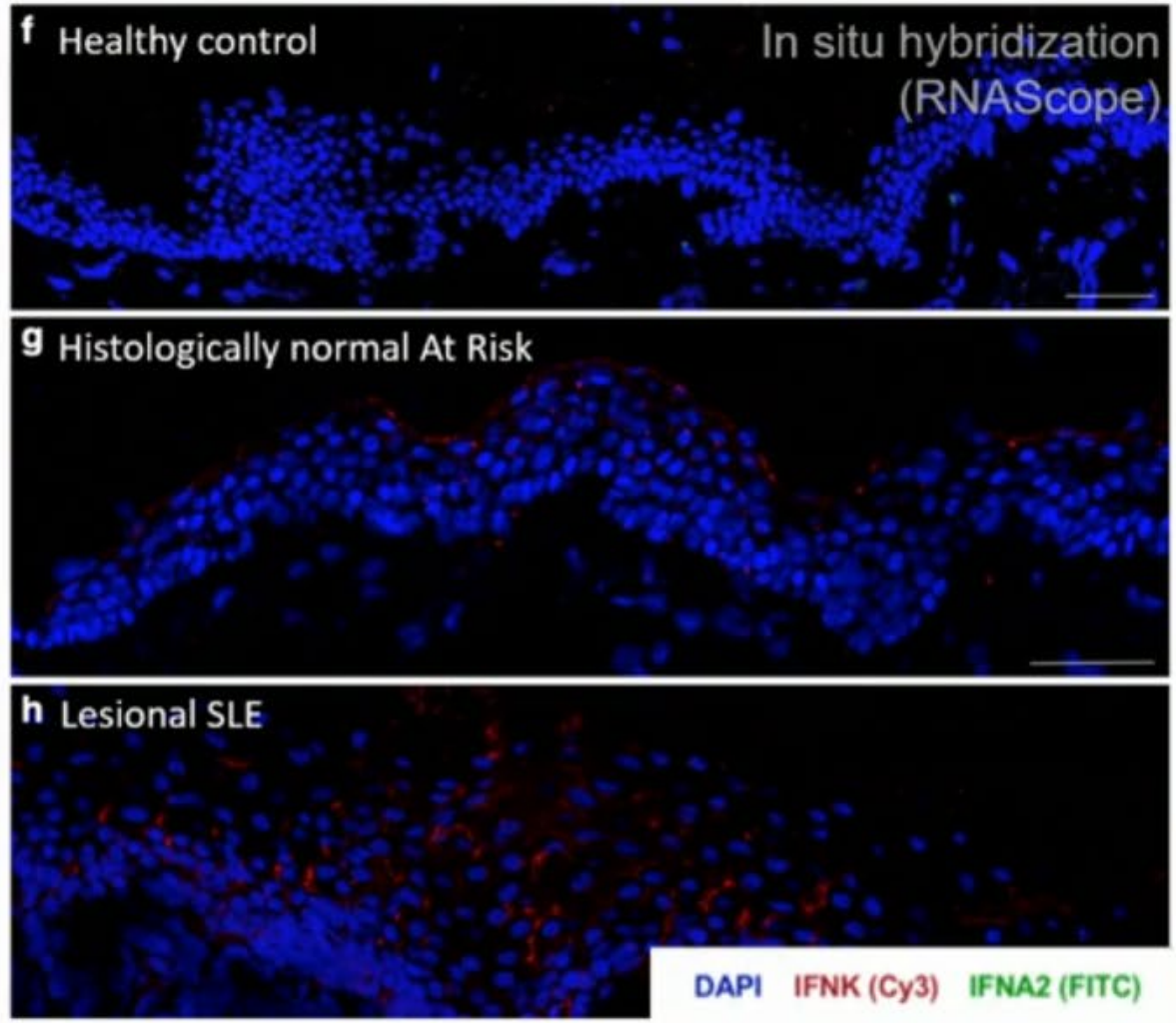
Oder CD 38 abs

Car T-cells/Autologe HSCT

Ed vital Precision medicine SLE/SS

IFN production shifts from circulating immune cells to target organs prior to onset of SLE

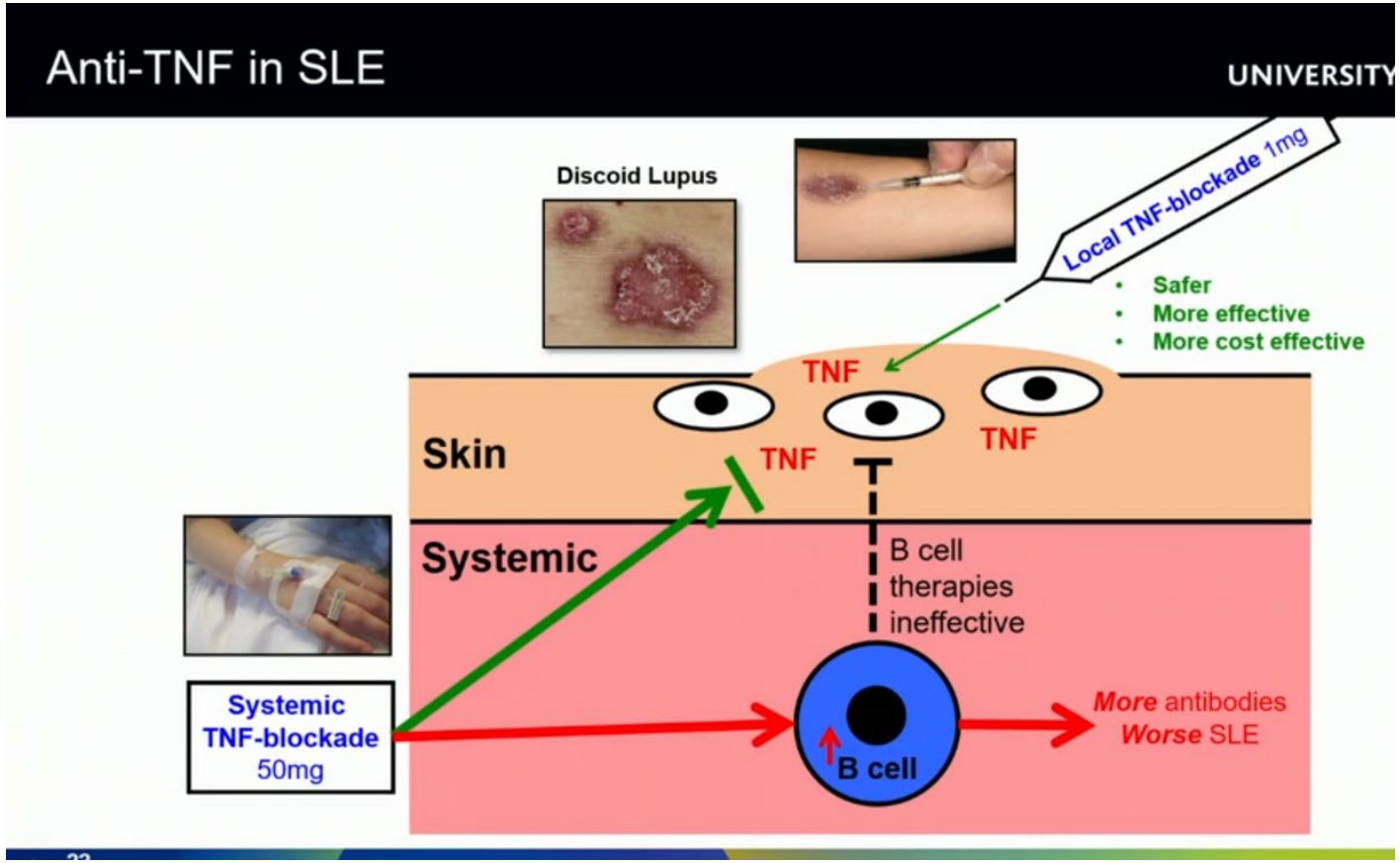




Psarras et al. Nature Communications volume 11, 6149 (2020)

Anti-TNF in SLE

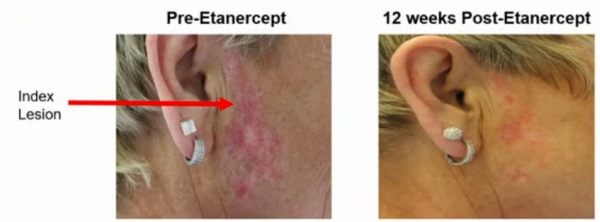
UNIVERSITY



Primary Endpoint = ≥ 6 patients achieving a decrease of 20% from baseline at Week 12 (ML-SADDLE 20)

TARGET-DLE (Full-set Analysis)
ML-SADDLE 20 Response rate:
14/25 (56%)

Secondary Endpoints	Pre-ETN	Post-ETN	p-value
Physician VAS, mean (SD) mm	53.1 (16)	23.2 (20)	<0.001
Patient VAS, mean (SD) mm	56.9 (28)	29.7 (28)	0.001
DLQI, mean (SD)	11.4 (7)	6.5 (6)	<0.001
Laser Doppler Imaging, mean (SD), PU	495.1 (224)	376.2 (223)	0.018
Infrared thermography, mean (SD), °C	1.92 (1.17)	1.08 (1.05)	0.005



Biopsy micro-array: CXCL13 signature predicts response

Yusof et al. Under review

Haematopoietic immunity

- Autoreactive B cells and autoantibodies

Tissue immunity

- Antigen generation, danger signals and innate immune functions of target organs themselves

Non-haematopoietic immunity may explain:

- Differing organ manifestations
- Resistance to therapy
- Relapse after B cell therapies

Psarras, Wittmann and Vital Nat Rev Rheum 2022

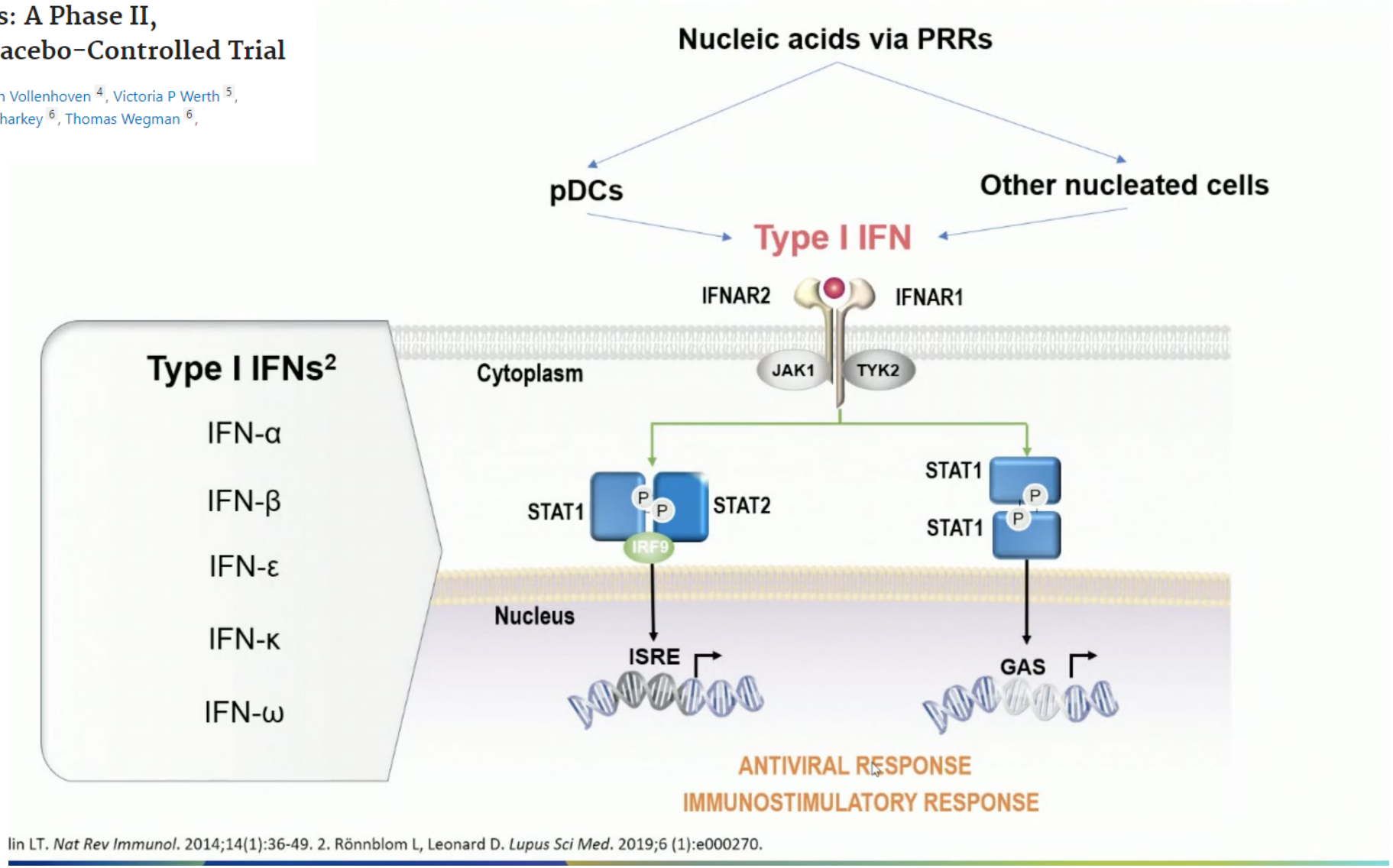
Efficacy and Safety of ABBV-599 High Dose (Elsubrutinib 60 mg and Upadacitinib 30 mg) and Upadacitinib Monotherapy for the Treatment of Systemic Lupus Erythematosus: A Phase 2, Double-blind, Placebo-Controlled Trial

Joan T. Merrill,[1] Yoshiya Tanaka,[2] David D'Cruz,[3] Karina Vila-Rivera,[4] Daniel Siri,[5] Xiaofeng Zeng,[6] Kristin M. D'Silva,[7] Ling Cheng,[7] Thierry Sornasse,[7] Thao T. Doan,[7] Denise Kruzikas,[7] Alan Friedman[7]

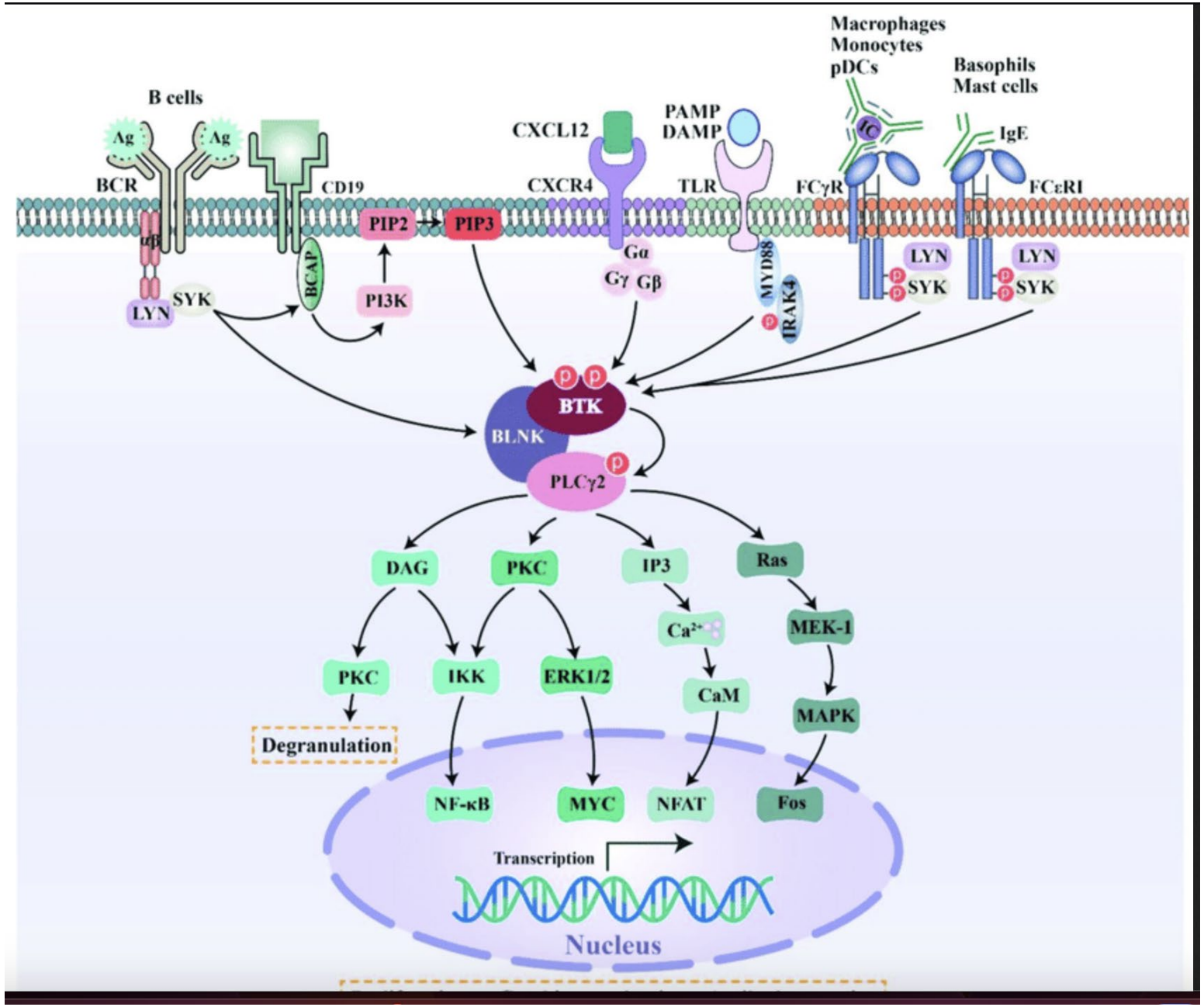
Clinical Trial > Arthritis Rheumatol. 2023 Feb;75(2):242-252. doi: 10.1002/art.42391.
Epub 2022 Nov 11.

Deucravacitinib, a Tyrosine Kinase 2 Inhibitor, in Systemic Lupus Erythematosus: A Phase II, Randomized, Double-Blind, Placebo-Controlled Trial

Eric Morand [1], Marilyn Pike [2], Joan T Merrill [3], Ronald van Vollenhoven [4], Victoria P Werth [5], Coburn Hobar [6], Nikolay Delev [6], Vaishali Shah [6], Brian Sharkey [6], Thomas Wegman [6], Ian Catlett [6], Subhashis Banerjee [6], Shalabh Singhal [6]

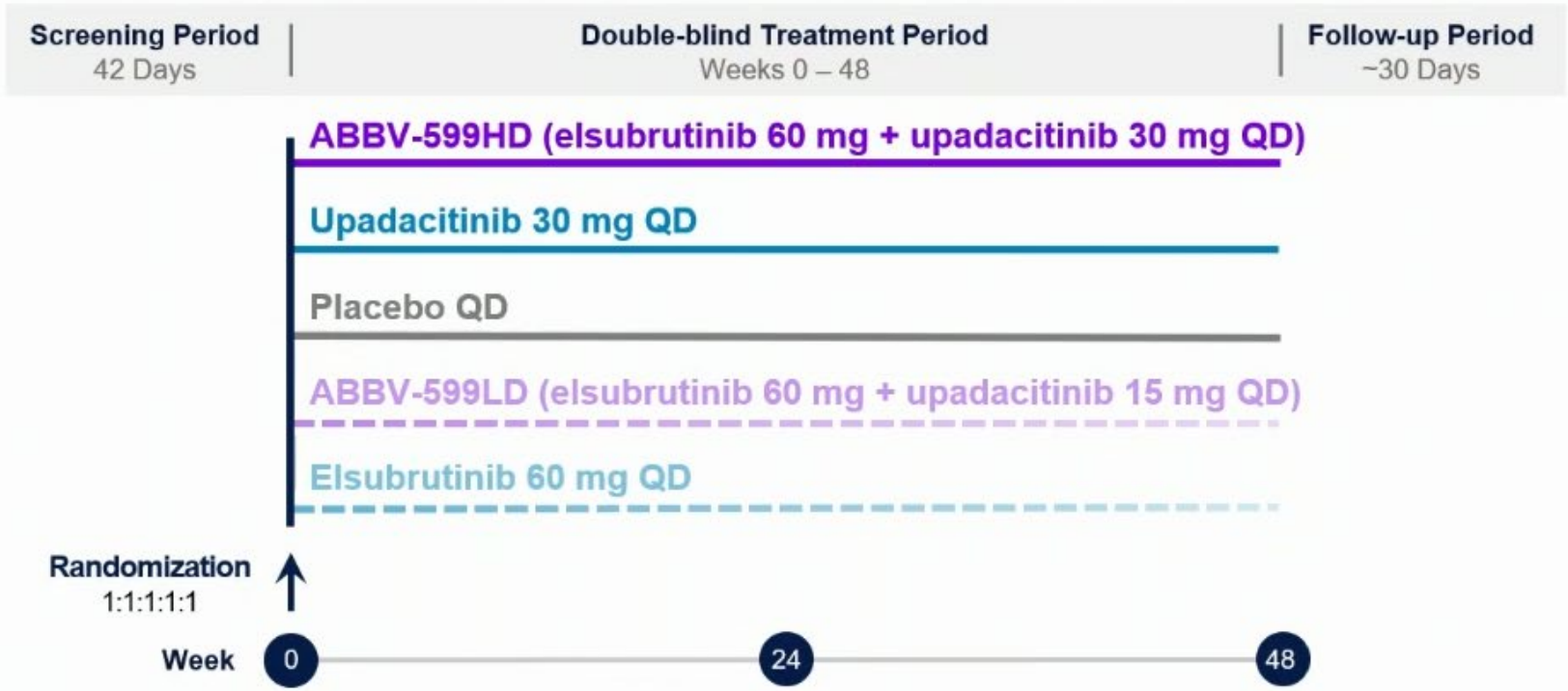


lin LT. *Nat Rev Immunol*. 2014;14(1):36-49. 2. Rönnblom L, Leonard D. *Lupus Sci Med*. 2019;6 (1):e000270.


Macrophages
Monocytes
pDCs
Basophils
Mast cells
B cells
Ag
Ag
BCR
CD19
CXCL12
CXCR4
PAMP
DAMP
TLR
IC
IgE
FCγR
FCεRI
PIP2
PIP3
αβ
BCAP
PI3K
LYN
SYK
Gα
Gγ Gβ
MYD88
IRAK4
LYN
SYK
LYN
SYK
BTK
BLNK
PLCγ2
DAG
PKC
IP3
Ras
Ca2+
MEK-1
PKC
IKK
ERK1/2
CaM
MAPK
Degranulation
NF-κB
MYC
NFAT
Fos
Transcription
Nucleus

Study Design and Treatment

- In the phase 2 SLEek study (NCT03978520), patients were initially randomized 1:1:1:1:1 to receive once-daily ABBV-599 high dose, ABBV-599 low dose, elsubrutinib 60-mg monotherapy, upadacitinib 30-mg monotherapy, or placebo
- After a planned interim analysis when 50% of the patients reached week 24 or withdrew from the study, the ABBV-599 low dose and elsubrutinib 60-mg treatment groups were discontinued due to lack of efficacy (no safety concerns)



HD, high dose; LD, low dose; QD, once daily.

Primary endpoint at week 24:

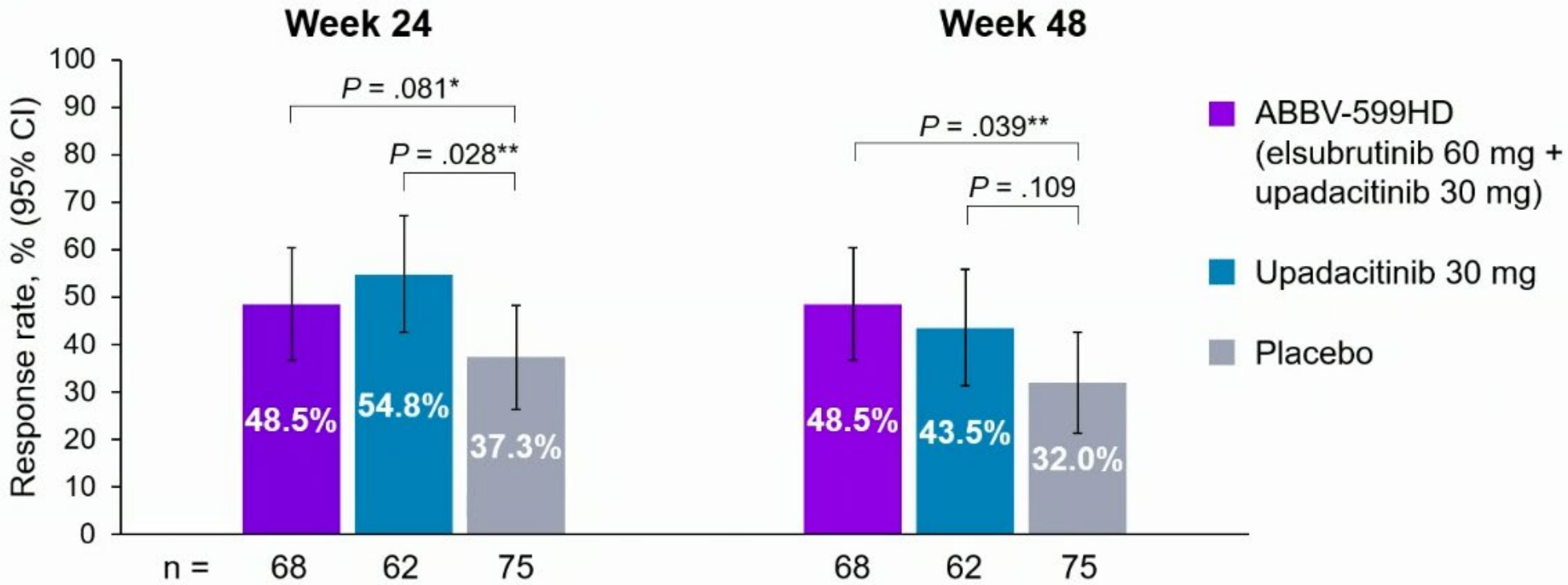
- SLE Responder Index-4 (SRI-4) **and** steroid dose ≤ 10 mg QD

At week 48:

- SRI-4 **and** steroid dose ≤ 10 mg QD
- SRI-4
- British Isles Lupus Assessment Group-based Combined Lupus Assessment (BICLA)
- Lupus Low Disease Activity State (LLDAS)

Achievement of SRI-4 and Steroid Dose ≤ 10 mg QD at Weeks 24 and 48

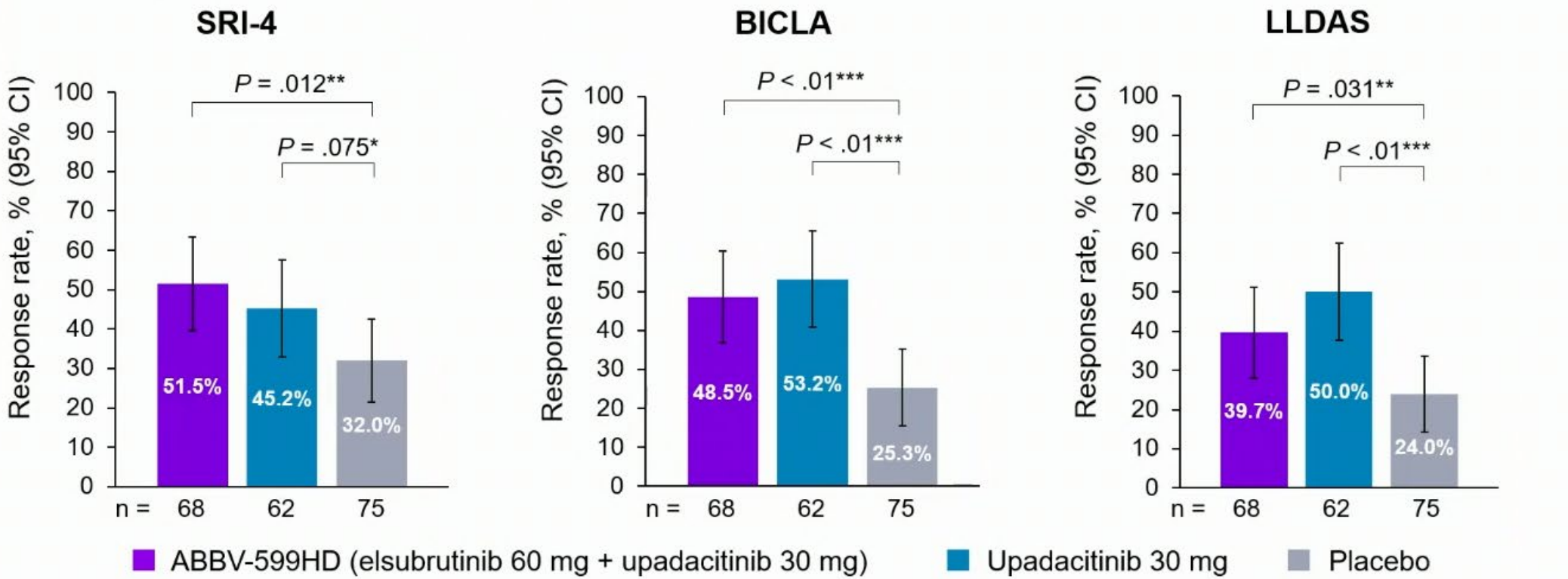
- The primary endpoint (proportion of patients achieving both SRI-4 and steroid dose ≤ 10 mg QD at week 24) was met for the ABBV-599 high dose (elsubrutinib 60 mg + upadacitinib 30 mg) and upadacitinib 30-mg groups vs placebo



ABBV-599HD, elsubrutinib 60 mg QD + upadacitinib 30 mg QD; QD, once daily; SRI-4, Systemic Lupus Erythematosus Responder Index-4.
*$P < .1$; **$P < .05$ vs PBO.

Achievement of Key Efficacy Endpoints at Week 48

- Key efficacy endpoints were achieved at greater rates at week 48 in both the ABBV-599 high dose (elsubrutinib 60 mg + upadacitinib 30 mg) and the upadacitinib 30-mg treatment groups vs the placebo treatment group



ABBV-599HD, elsubrutinib 60 mg QD + upadacitinib 30 mg QD; BICLA, British Isles Lupus Assessment Group-Based Combined Lupus Assessment; LLDAS, Lupus Low Disease Activity State; QD, once daily; SRI-4, Systemic Lupus Erythematosus Responder Index-4.
*$P < .1$; **$P < .05$; ***$P < .01$ vs PBO.

Parameter, n (%)	ABBV-599HD (elsubrutinib 60 mg + upadacitinib 30 mg) (n = 68)	Upadacitinib 30 mg (n = 62)	Placebo (n = 75)
Any TEAE	59 (86.8)	51 (82.3)	59 (78.7)
COVID-19–related TEAE	6 (8.8)	8 (12.9)	9 (12.0)
Serious TEAE	7 (10.3)	13 (21.0)	13 (17.3)
TEAE leading to discontinuation of study drug	9 (13.2)	6 (9.7)	5 (6.7)
TEAE resulting in death	1 (1.5)[a]	0	0

3V-599HD, elsubrutinib 60 mg QD + upadacitinib 30 mg QD; ELS, elsubrutinib; PBO, placebo; QD, once daily; TEAE, treatment-emergent adverse event; UPA, upadacitinib.
ath from acute respiratory failure due to COVID-19.

Safety: Adverse Events of Special Interest

- There were no cases of malignancy or venous thromboembolism
- There were 3 non-fatal cardiovascular events (1 myocardial infarction [placebo]; 2 non-fatal strokes due to ruptured cerebral aneurysms [1 with ABBV-599 high dose, 1 with upadacitinib 30 mg])

AESI, n (%)	ABBV-599HD (elsubrutinib 60 mg + upadacitinib 30 mg) (n = 68)	Upadacitinib 30 mg (n = 62)	Placebo (n = 75)
Serious infection	5 (7.4)	7 (11.3)	3 (4.0)
Opportunistic infection excluding TB and herpes zoster[a]	0	1 (1.6)	1 (1.3)
Herpes zoster	8 (11.8)	4 (6.5)	3 (4.0)
Active TB	0	0	1 (1.3)
Possible malignancy	0	0	0
Malignancy	0	0	0
Anemia	3 (4.4)	2 (3.2)	3 (4.0)
Neutropenia	1 (1.5)	2 (3.2)	1 (1.3)
Lymphopenia	0	2 (3.2)	0
Renal dysfunction	1 (1.5)	1 (1.6)	0
Hepatic disorder	3 (4.4)	1 (1.6)	1 (1.3)
Adjudicated VTE	0	0	0
Any adjudicated MACE	1 (1.5)	1 (1.6)	1 (1.3)
Non-fatal myocardial infarction[b]	0	0	1 (1.3)
Non-fatal stroke[c]	1 (1.5)	1 (1.6)	0

ABBV-599HD, elsubrutinib 60 mg QD + upadacitinib 30 mg QD; AESI, adverse event of special interest; MACE, major adverse cardiovascular event; QD, once daily; TB, tuberculosis; VTE, venous thromboembolism.

[a]Opportunistic infections were oesophageal candidiasis (placebo) and *Pneumocystis jirovecii* pneumonia (upadacitinib 30 mg).

[b]Occurred in a 61-year-old woman with a family history of cardiovascular disease.

[c]Non-fatal strokes were both due to ruptured cerebral aneurysms:

- 47-year-old woman receiving ABBV-599HD had a ruptured cerebral aneurysm on day 231 of study drug. She underwent craniotomy and surgical trapping of the cerebral aneurysm.
- 53-year-old woman receiving UPA 30 mg had a ruptured cerebral aneurysm and subarachnoid hemorrhage on day 199 of study drug. She underwent a craniotomy for clipping of a right middle cerebral artery bifurcation aneurysm.

10:30 - 12:00 The future perspectives in the treatment of SLE & Sjögren's

CHAIRS : NATHALIE COSTEDOAT-CHALUMEAU, RONALD VAN VOLLENHOVEN

June 1, 2023
EULAR 2023 Meeting
Abstract # OP0142

Efficacy And Safety Of Telitacicept, A Novel BLyS/APRIL Dual Inhibitor, In Patients With Primary Sjögren'S Syndrome: A Phase 2, Randomized, Placebo-Controlled 24-Week Study

Ronald van Vollenhoven[1], Dong Xu[2], Shangzhu Zhang[2], Cibo Huang[3], Chenghui Huang[4], Li Qing[5], Xiaomei Li[6], Meiqing Chen[7], Xiumei Liu[8], Yi Liu[9], Zhijun Li[10], Jiankang Hu[11], Chunde Bao[12], Wei Wei[13], Jing Tian[14], Xinwang Duan[15], Xiaofeng Zeng[2]*

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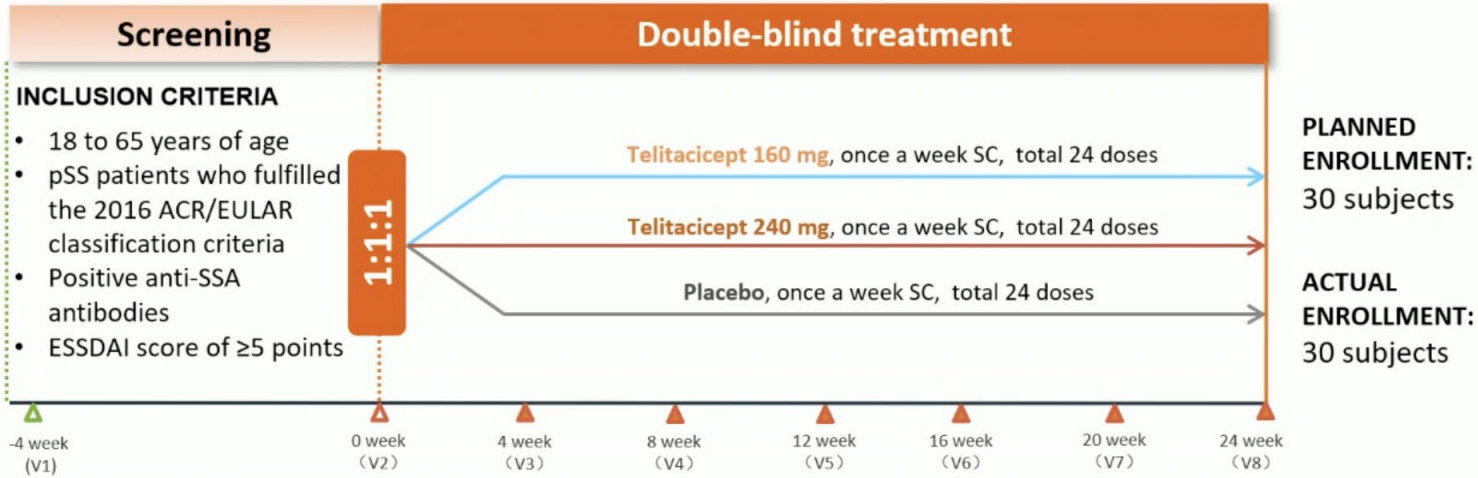
Ronald van Vollenhoven

Efficacy and Safety of telitacicept, a novel BLyS/APRIL dual inhibitor, in patients with primary Sjögren's syndrome: a phase 2, randomized, placebo-controlled 24-week study

Study Design

Primary Endpoint:

- Change from baseline in the ESSDAI score at Week 24



PLANNED ENROLLMENT:
30 subjects

ACTUAL ENROLLMENT:
30 subjects

ESSDAI, EULAR Sjögren's syndrome disease activity index; ESSPRI, EULAR Sjögren's Syndrome Patient Reported Index; MFI, multidimensional fatigue inventory; pSS, primary Sjögren's syndrome; ACR/EULAR, American College of Rheumatology/European League Against Rheumatism.

Ronald van Vollenhoven

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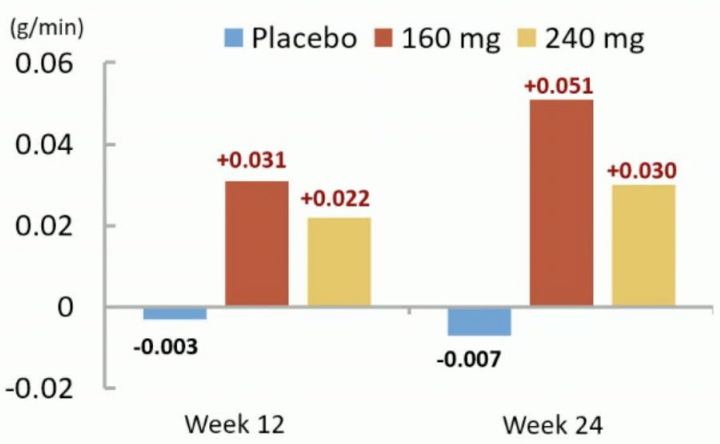
10:30 - 12:00 The future perspectives in the treatment of SLE & Sjögren's

CHAIRS : NATHALIE COSTEDOAT-CHALUMEAU, RONALD VAN VOLLENHOVEN

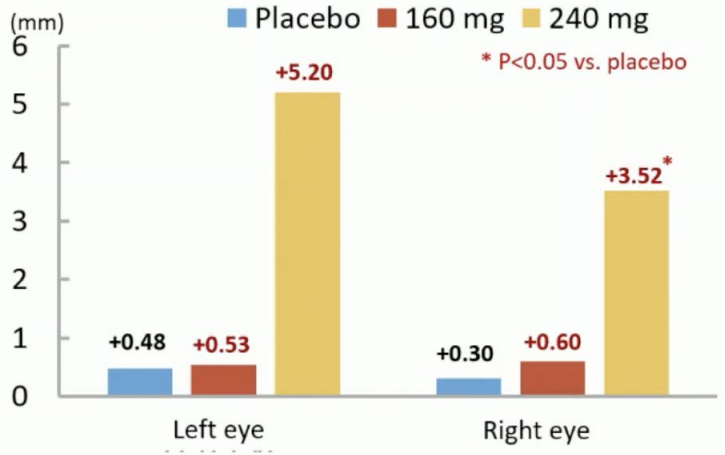
Secondary Endpoints

Efficacy: Unstimulated Whole Saliva Flow and Schirmer's Test

Unstimulated whole saliva flow rate is an assessment of salivary gland function. The subject will be asked to collect the saliva in his/her mouth into a test tube for 15 minutes.
Schirmer's test is an assessment of lacrimal gland function in which a strip of filter paper is applied under the eyelid to measure the quantity of tear production by the length in millimeters that the strip wets during the 5-minute test period.



Change from baseline in the unstimulated whole saliva flow (g/min) at Week 12 and 24 (FAS, mean)



Change from baseline in the length of the wet strip (Schirmer's test, mm) at Week 24 (FAS, mean)

FAS, full analysis set.

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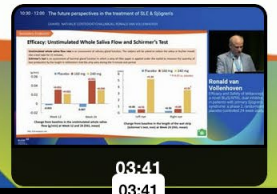

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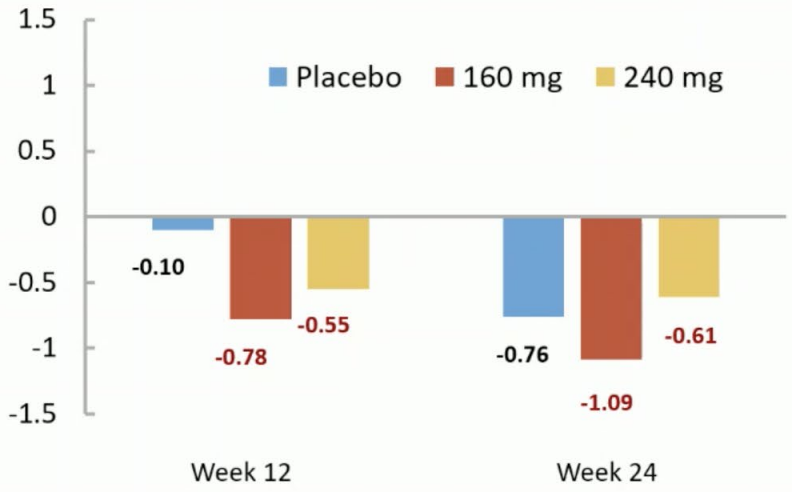
31 MAY – 3 JUNE

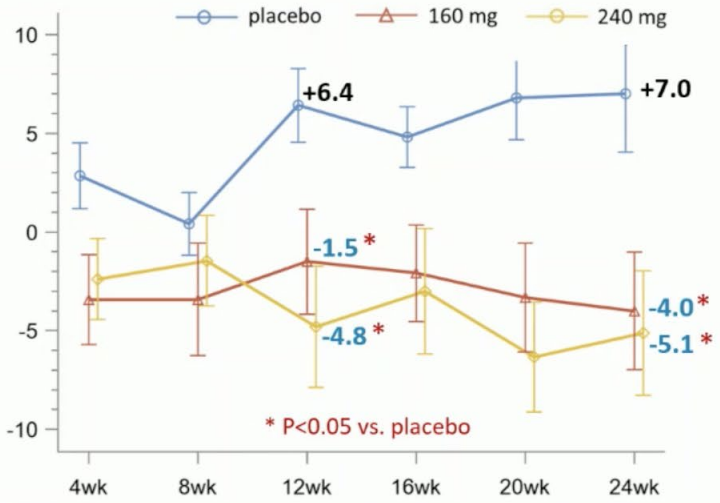
Secondary Endpoints

Efficacy: ESSPRI and MFI-20

ESSPRI change from baseline at Week 12 and 24 (FAS, mean)



MFI-20 change from baseline (FAS, mean±SE)



MFI-20 is a 20-item self-report instrument designed to measure fatigue. Higher total scores correspond with more acute levels of fatigue.

ESSPRI, EULAR Sjögren's Syndrome Patient Reported Index; MFI, multimensional fatigue inventory; FAS, full analysis set; SE, standard error.

Ronald van Vollenhoven

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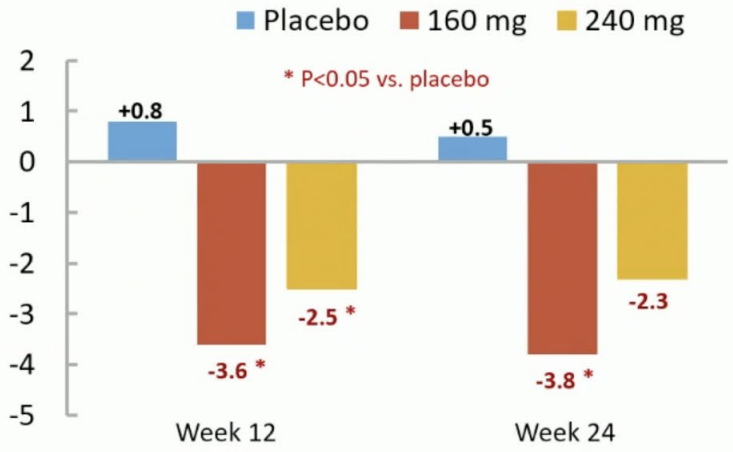
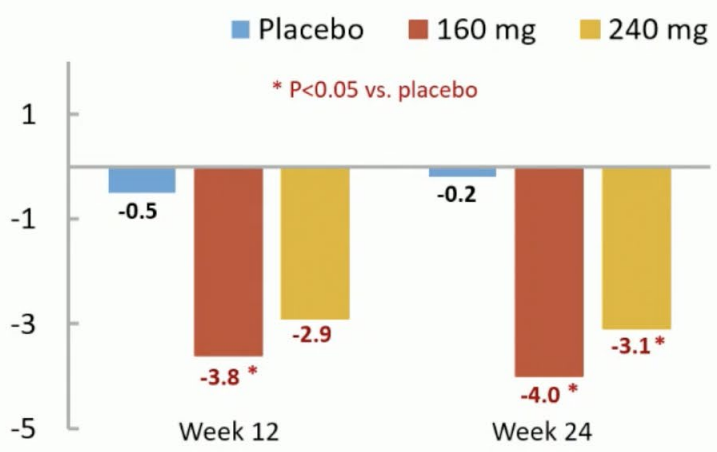
Primary Endpoint

Efficacy: ESSDAI Change from Baseline

Efficacy analyses of the ESSDAI change from baseline were based on the FAS and PPS



ESSDAI change from baseline at Week 12 and 24 (FAS, LS mean)



ESSDAI change from baseline at Week 12 and 24 (PPS, LS mean)

ESSDAI, EULAR Sjögren's syndrome disease activity index; FAS, full analysis set; PPS, per-protocol set; LS mean, least square mean.

Ronald van Vollenhoven

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Study Design

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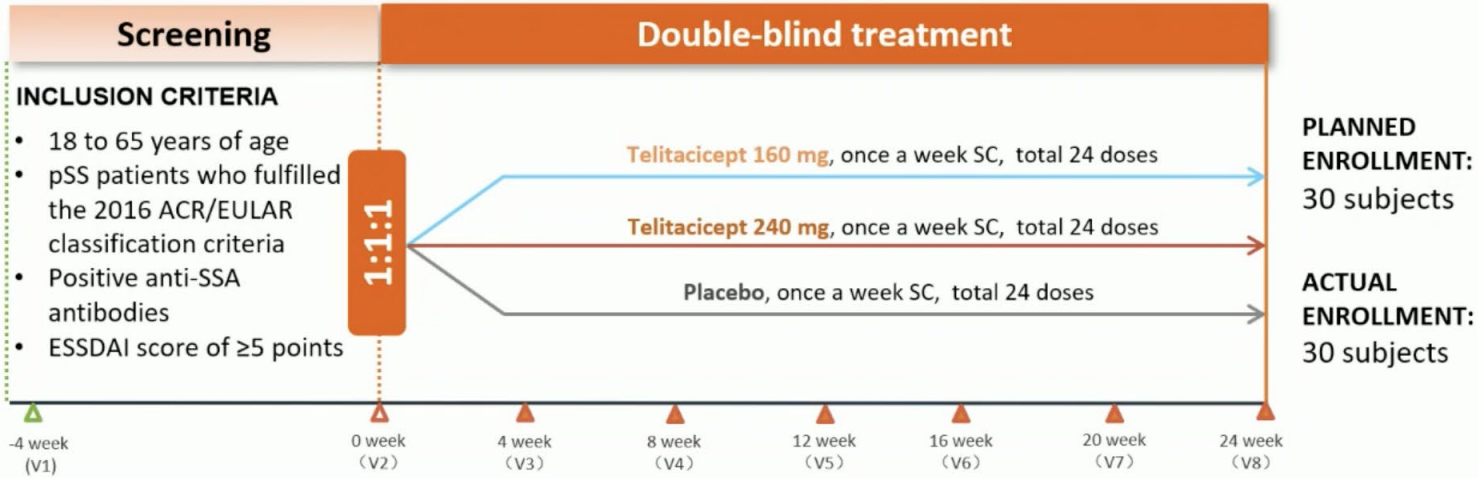

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- **Efficacy and Safety of Dazodalibep (VIB4920/HZN4920) in Subjects with Sjögren's Syndrome: A Phase 2, Randomized, Double-Blind, Placebo-Controlled, Proof of Concept Study**

- **Dazodalibep (VIB4920/HZN4920) in Sjögren's Subjects with an Unacceptable Symptom Burden: Safety and Efficacy from a Phase 2, Randomized, Double-Blind Study (late braking abstracg**

- **LONG TERM SAFETY AND EFFICACY OF CAR-T CELL TREATMENT IN REFRACTORY SYSTEMIC LUPUS ERYTHEMATOSUS - DATA FROM THE FIRST SEVEN PATIENTS**
- **Georg Schett**