What's new in lupus nephritis?

Andreas Schwarting
Mainz, Germany

13th National Congress of EPEMY, 4th September 2021

Disclosures

- I have received speaker fee from GSK for this lecture
- Speaker fees: Janssen, GSK
- Grant support: GSK, Pfizer, Actelion, AbbVie, Roche

Discuss a case study with lupus nephritis

Data from BLISS LN and clinical implementation

SLE patients that may benefit from biological treatment

Patient history

31 years old, female, SLE with:

- cutaneous manifestation, Raynaud
- Arthralgia, arthritis
- Fatigue
- Lupus nephritis

Personal communication of Professor Schwarting.

Lupus nephritis diagnosis

- Nephrotic syndrome, active sediment
- biopsy: LN IV (A/C)

Personal communication of Professor Schwarting.

Therapy for LN

- Induction therapy with:
  - 3 x 500 mg cyclophosphamide i.v.
    - *6 weeks later ➔ leukopenia*
  - switch to MMF
    - *2 weeks later ➔ gastrointestinal side effects*

Personal communication of Professor Schwarting.

MMF = Mycophenolate Mofetil.

Follow up

persistent proteinuria > 1g, active sediment ➔

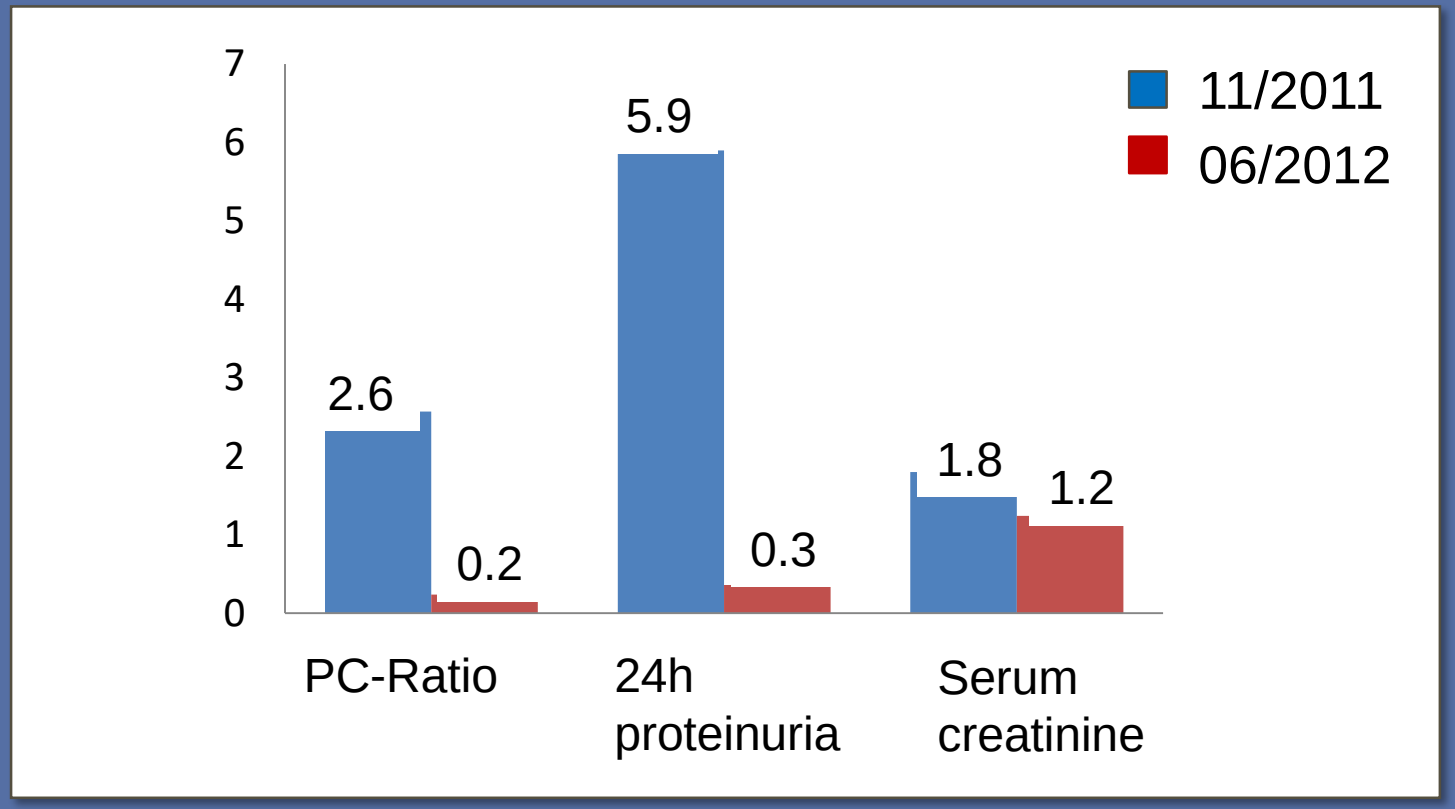
- switch to ciclosporin (2 x 50 mg)
- start Belimumab (01/2012)

Personal communication of Professor Schwarting.

Patient case with LN

Personal communication of Professor Schwarting.

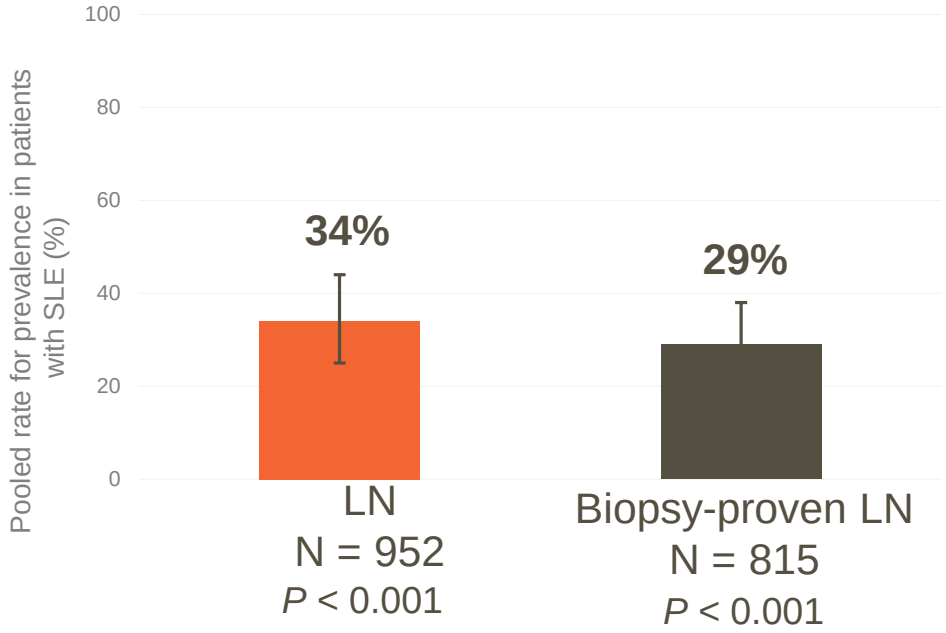
Follow-up



- **Why is the lupus nephritis so important ?**

Lupus Nephritis is a Frequent Complication and Severe Manifestation of SLE

Pooled Rate for Prevalence of LN and biopsy-proven LN in SLE (N = 2,781)[1a]



This graph has been independently created by GSK from the original data in the source.

Approximately **40%** of patients with SLE have lupus nephritis (with or without biopsy-confirmed)[4]

LN is the most common manifestation presenting at diagnosis[2] and most commonly occurs within a year of diagnosis[3]

[a] Meta-analysis: 5 studies reported both LN and biopsy-proven LN.

LN = lupus nephritis; SLE = systemic lupus erythematosus.

1. Wang H, et al. Arch Rheumatol. 2017;33(1):17–25 DOI: 10.5606/ArchRheumatol.2017.6127; 2. Anders HJ, et al. Nat Rev Dis Primers. 2020;6(7):1–25 DOI: 10.1038/s41572-019-0141-9; 3. Nakano M, et al. Lupus. 2019;28:1062–1073 DOI: 10.1177/0961203319860200; 4. Hanly JG et al. Rheumatol. 2016;55:252-262. DOI: 10.1093/rheumatology/kev311)

The average lifespan of the kidneys is **~120 years**

- **irreversible !**

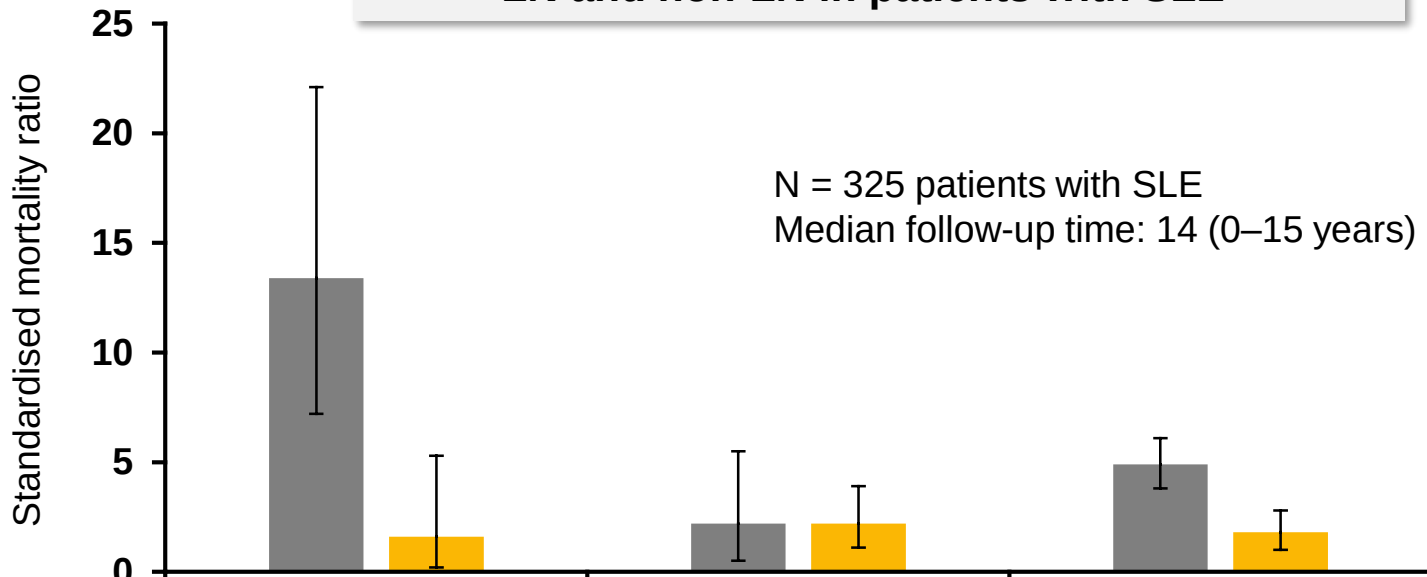
As more nephrons are lost, GFR decreases, and patients may progress to CKD and eventually ESKD

CKD = chronic kidney disease; eGFR = estimated glomerular filtration rate; ESKD = end stage kidney disease; LN = lupus nephritis

Anders HJ, et al. Nat Rev Dis Primers. 2020;6(7). DOI: 10.1038/s41572-019-0141-9

The presence of lupus nephritis in patients with SLE increases mortality

Standardised mortality ratio for LN and non-LN in patients with SLE[1a]



	16–39 yo	40–59 yo	60–79 yo	≥ 80 yo
LN SMR	13,4	2,2	4,9	5,2
Non-LN SMR	1,6	2,2	1,8	1,6

Oslo, Norway

Population-based study on LN and its impact on outcomes in SLE patients

1999–2008

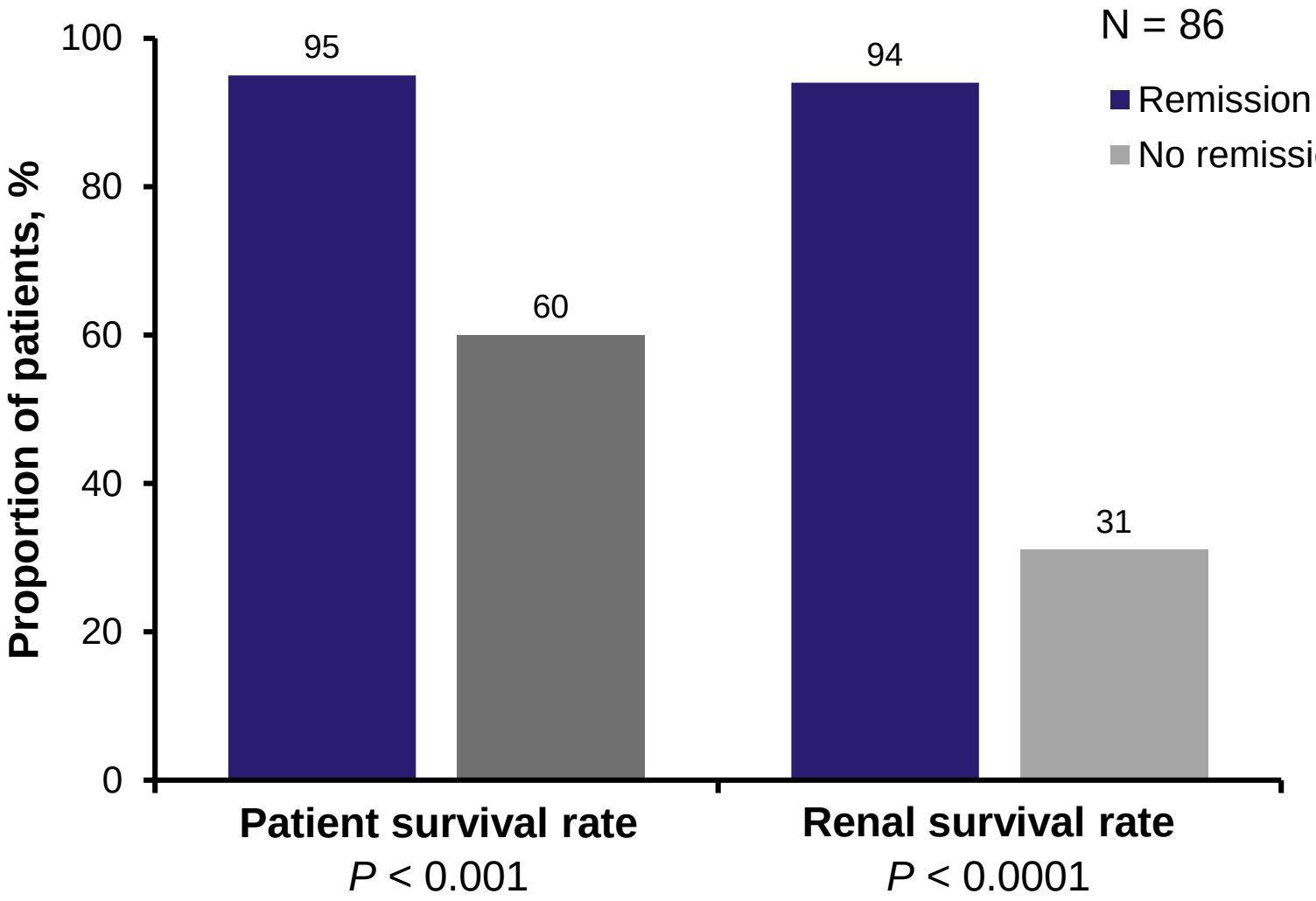
N = 325

[a] SMRs were estimated by comparing deaths in the SLE cohort with age- and gender-matched population controls.

ACR = American College of Rheumatology; SMR = standardised mortality ratio; yo = years old.

Moe SE, et al. Lupus 2019;28:818–825.

Remission of lupus nephritis is associated with an improvement in long-term patient and renal survival



Following an average of 10 years of follow-up, patient and renal survival rates **improved** with remission of lupus nephritis

Korbet SM, et al. Am J Kidney Dis 2000;35:904–914.

Treatment goals for lupus nephritis

Nature Reviews article[1] and EULAR guidelines[2a]

Recommendations for lupus nephritis[1,2]

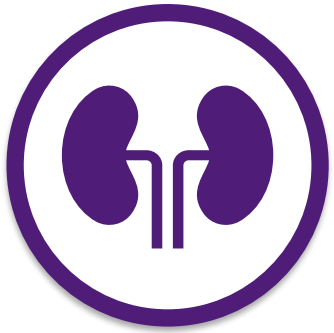
- Reduce morbidity and mortality
- Minimise treatment-associated toxicity
- Preserve long-term kidney function
- Improve disease-related quality of life
- Prevent **renal flares**
- Achieve rapid remission of active disease
- Prevent **organ damage** progression
- Control of **comorbidities**

[a] Applying a Delphi-based methodology, 15 research questions were selected for systematic literature review.

1. Anders HJ, et al. Nat Rev Dis Primers 2020;6:1–25;
2. Fanouriakis A, et al. Ann Rheum Dis 2020;79:713–723.

Data from BLISS LN and clinical implementation

Strategies to manage lupus nephritis are evolving, but there is still a large unmet need in these patients



Lupus nephritis is a **frequent and severe complication** of SLE[1]

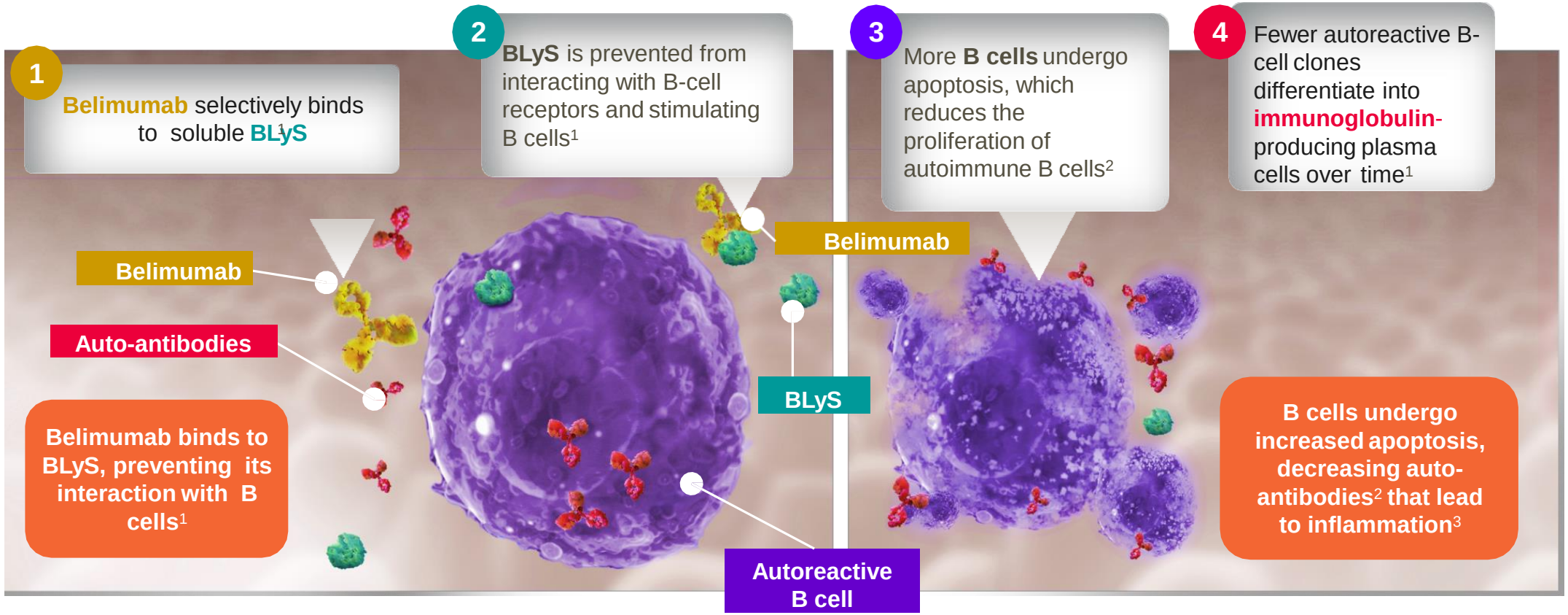
AE = adverse event; GC = glucocorticoid; IV = intravenous; uPCR = urine protein:creatinine ratio.

1. Hanly JG, et al. Rheumatology (Oxford) 2016;55:252–262;

Anti-BLyS = pathophysiology-based *targeted* approach[1-3]

1. Petri M et al. Arthritis Rheum 2013;65:2143–2153;
2. Friebus-Kardash J, et al. Nephrol Dial Transplant 2018;33:54–64;
3. Petri M, et al. Arthritis Rheum 2008;58:2453–2459.

Mechanism of action: belimumab specifically inhibits soluble BLyS



Belimumab does not directly bind to B cells or directly deplete memory B cell populations

BLyS = B lymphocyte stimulator

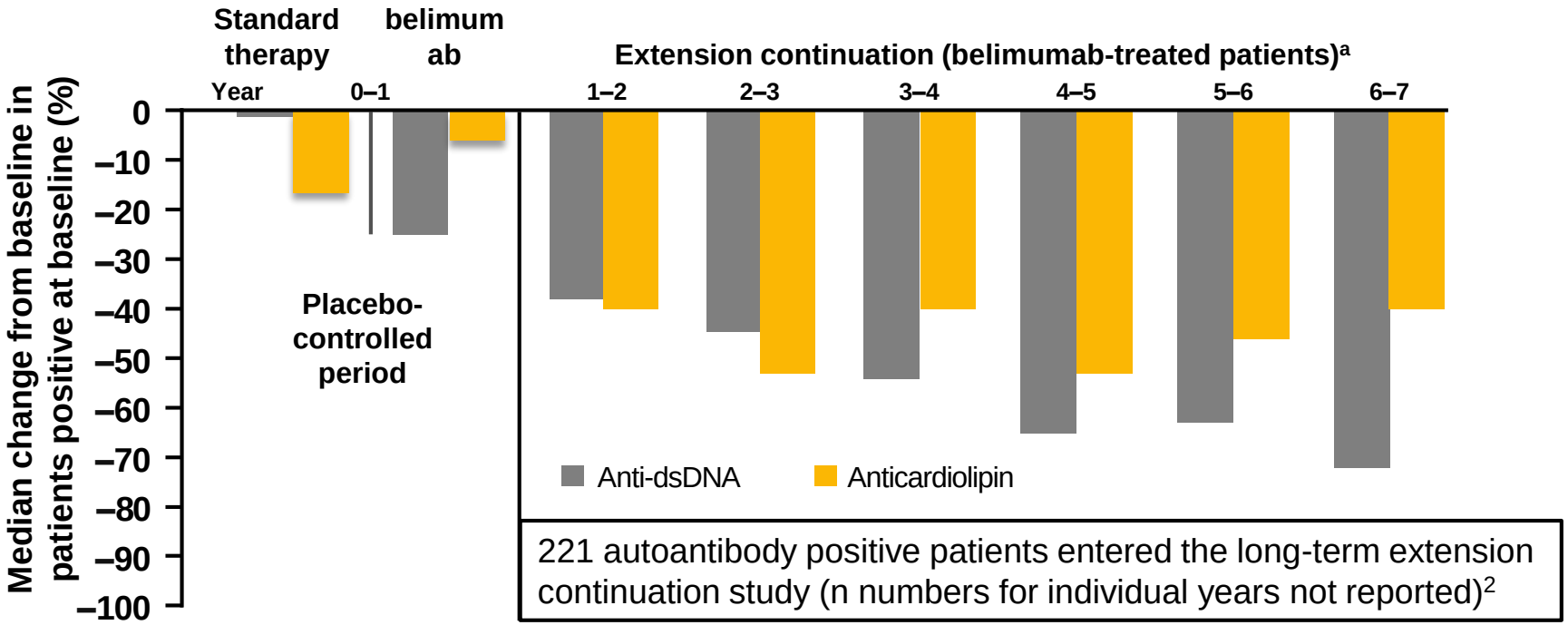
1. Belimumab SPC April 2021. 2. Cancro MP *et al.* J Clin Invest. 2009;119:1066–73. 3. Mok CC & Lau CS. J Clin Pathol. 2003;56:481–90.

Belimumab Phase II study[1]

This study failed the primary endpoint

Patients with active lupus nephritis were excluded

Patients were not required to have positive autoantibodies



Changes in anti-dsDNA and anticardiolipin were observed over time among patients receiving belimumab[2]

- The data show changes in IgG autoantibody levels in patients positive for the respective autoantibodies at baseline[2]
- **Limitations of this extension study:[2]**
  - The population that entered the extension study may be enriched with patients who responded to or tolerated belimumab
  - There was no matched-control group to directly compare long-term data

[a] Patients who switched from placebo to belimumab were included from first belimumab exposure.
IgG = Immunoglobulin G.

1. Wallace D, et al. Arthritis Rheum. 2009;61(9):1168–1178;
2. Ginzler EM, et al. J Rheumatol 2014;41:300–309.

Belimumab Phase II study[1]

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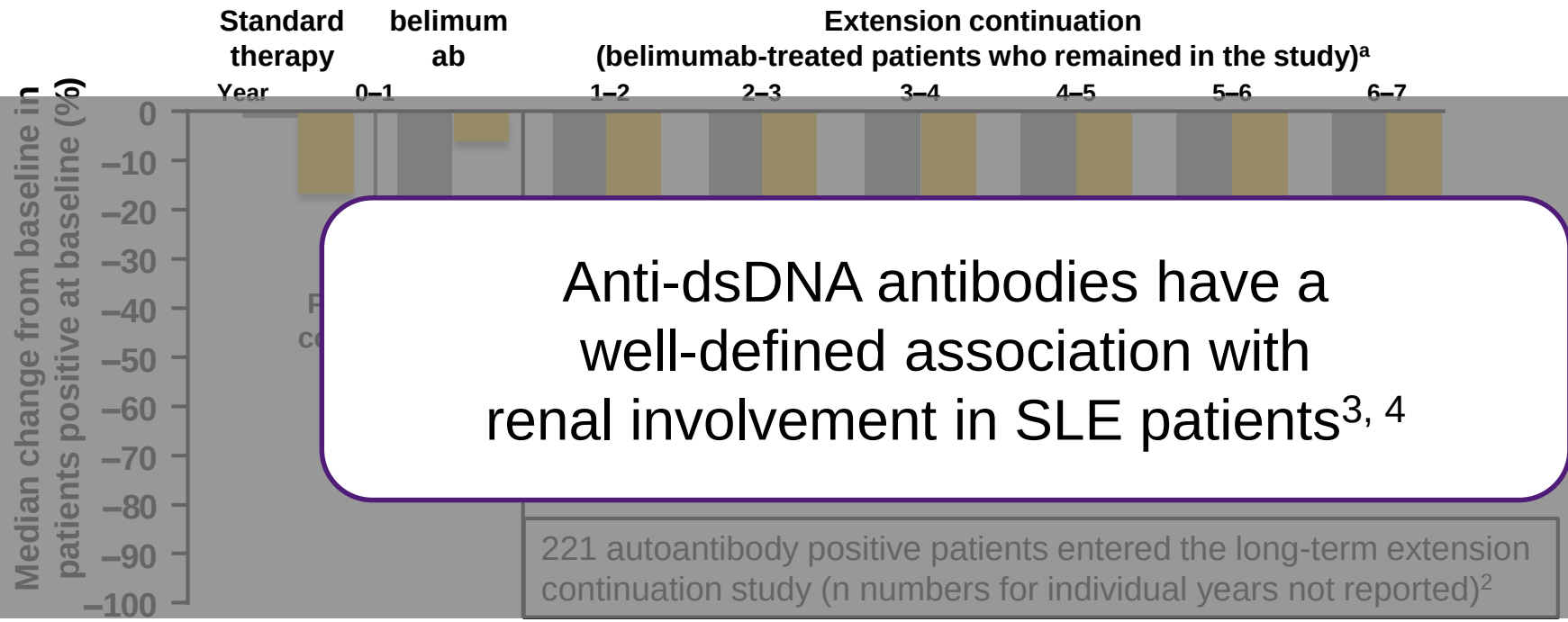

Anti-dsDNA antibodies have a well-defined association with renal involvement in SLE patients[3, 4]

Changes in anti-dsDNA and anticardiolipin were observed over time among patients receiving belimumab[2]

221 autoantibody positive patients entered the long-term extension continuation study (n numbers for individual years not reported)[2]

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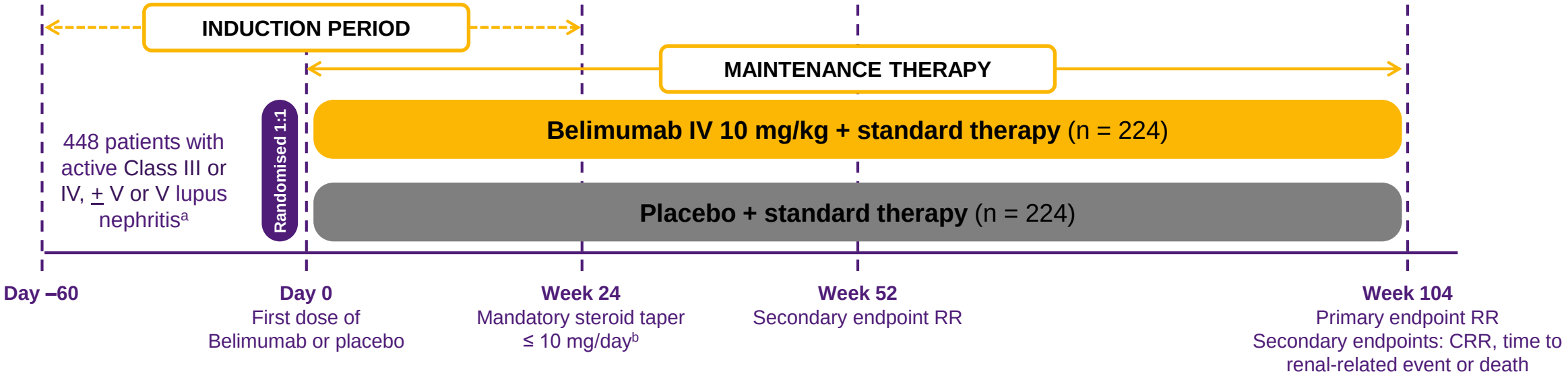
1. Wallace D, et al. Arthritis Rheum. 2009;61:1168–1178;
2. Ginzler EM, et al. J Rheumatol 2014;41:300–309.
3. Giles BM & Boackle SA. Immunol Res 2013;55:10–21;
4. Rahman A & Isenberg DA. N Engl J Med 2008;358:929–939.

Strategies to manage lupus nephritis are evolving, but there is still a large unmet need in these patients

Belimumab added to standard therapy could improve renal outcomes in patients with active LN[1]

1. Furie R, et al. N Engl J Med 2020;383:1117–1128.

BLISS-LN study design:[1] belimumab added to induction and maintenance therapy



[a] Confirmed biopsy proven in the past 6 months: III or IV +/- V, or pure V (A or A/C) and uPCR ≥ 1.0 g/g;
[b] Belimumab could be initiated up-to 60 days after the beginning of induction background therapy;
[c] Increases above 10 mg/day after Week 24 were deemed a treatment failure.

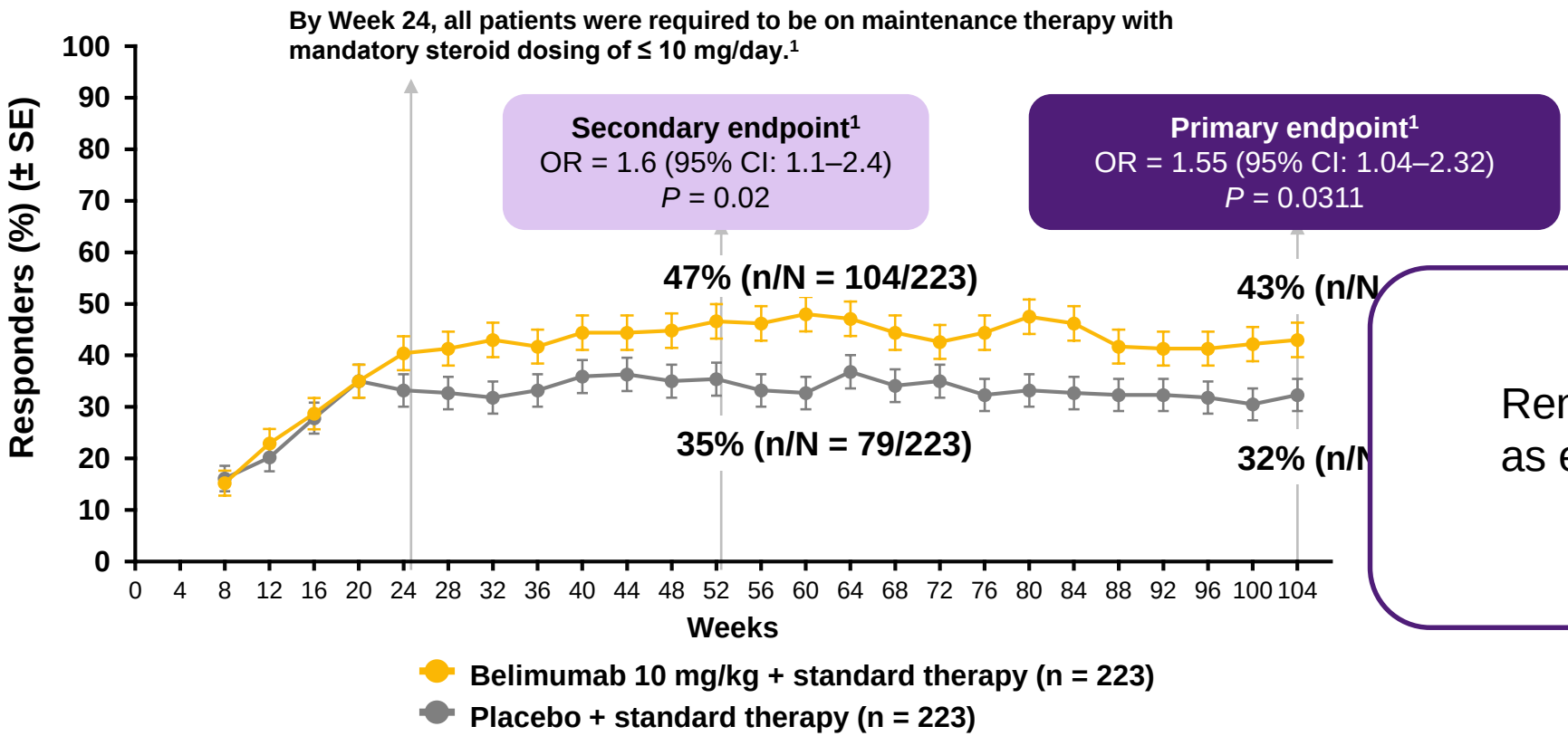
A/C = active/chronic; AZA = azathioprine; CRR = complete renal response; CYC = cyclophosphamide; IV = intravenous; MMF = mycophenolate mofetil; RR = renal response; uPCR = urine protein:creatinine ratio.

1. Furie R, et al. N Engl J Med 2020;383:1117–1128;

Significantly more patients receiving belimumab achieved renal response vs. standard therapy alone at Week 104

Renal response by visit[a,1]

Primary endpoint: Week 104
Key secondary endpoint: Week 52



Patients on Belimumab had

55%

greater odds of achieving renal response at Week 104

Renal response was observed as early as **Week 24[b]**

Not a treatment failure[b]

[a] The same patient may not have responded at each time point.
[b] Pre-specified, supportive analysis. Results are descriptive.

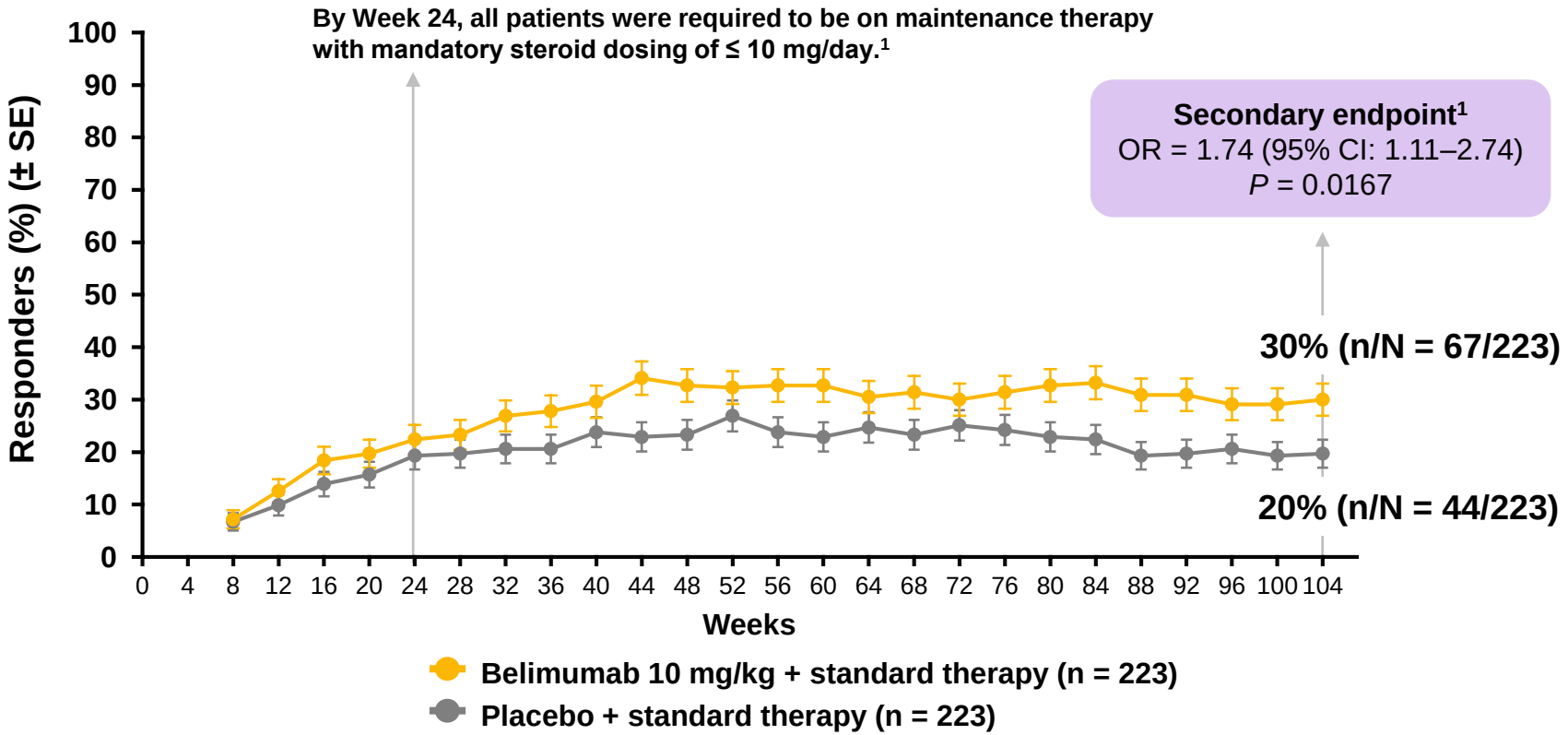
CI = confidence interval; OR = odds ratio; SE = standard error.

1. Furie R, et al. N Engl J Med 2020;383:1117–1128;

Significantly more patients receiving Belimumab achieved CRR vs. standard therapy alone at Week 104

Complete renal response (CRR) by visit[a,1]

Key secondary endpoint: Week 104



Patients on belimumab had

74%

greater odds of achieving complete renal response

Definition of CRR

eGFR ≥ 90 mL/min/1.73 m² or no more than 10% below pre-flare value, and;

Urine protein:creatinine ratio < 0.5, and;

Not a treatment failure[b]

[a] The same patient may not have responded at each time point.

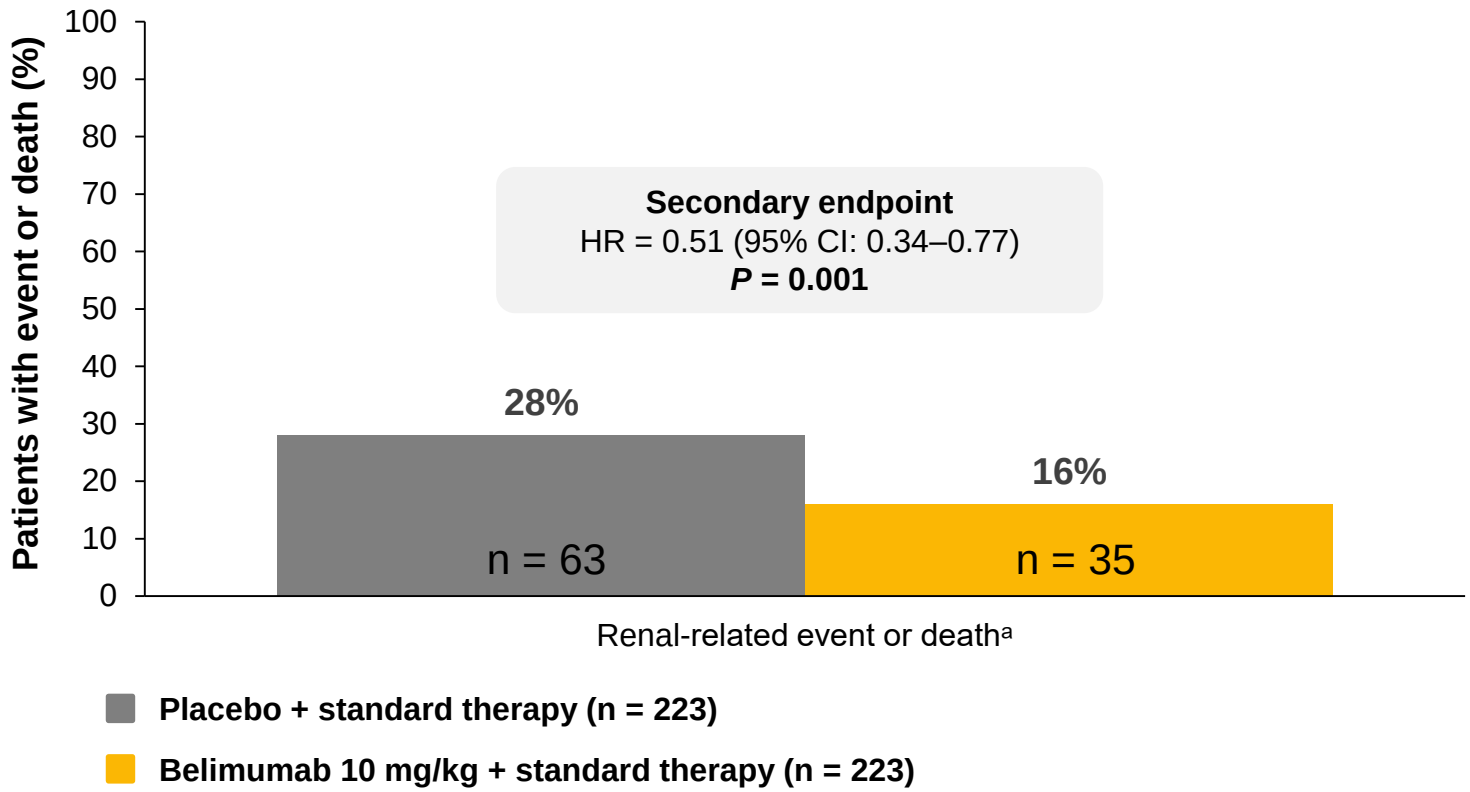
CRR = complete renal response; OR = odds ratio; SE = standard error.

1. Furie R, et al. N Engl J Med 2020;383:1117–1128;

Belimumab reduced the risk of renal-related events or death when added to standard therapy vs. standard therapy alone

Probability of renal-related event or death

Key secondary endpoint



Patients on belimumab had a

49%

reduced risk of a renal-related event or death

Definition of renal-related event

1) **ESKD, or**
2) **doubling of serum creatinine, or**
3) **renal worsening (increased proteinuria and/or impaired renal function), or**
4) **renal disease-related treatment failure[b]**

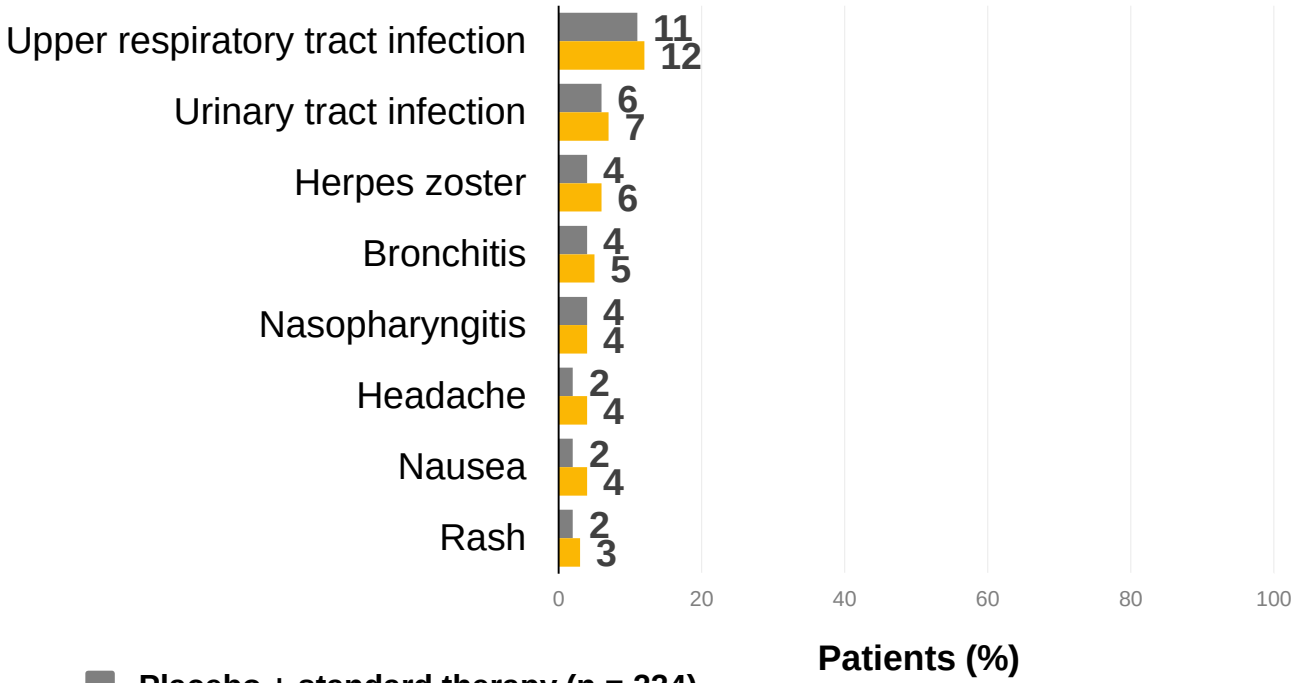
[a] Deaths in each group: Belimumab, n = 1; standard therapy, n = 2.

CI = confidence interval; HR = hazard ratio.

Furie R, et al. N Engl J Med 2020;383:1117–1128.

BLISS-LN: summary of adverse events[a]

Treatment-related adverse events[1b]



Adverse events in the BLISS-LN trial were consistent with those observed in adult IV trials conducted in patients with SLE[2]

[a] Only adverse events that occurred during the intervention period are listed;
[b] This category includes all patients who had at least one event. Relatedness of the intervention to the event was determined by the site investigators.

IV= intravenous

1. Furie R, et al. N Engl J Med 2020;383:1117–1128;
2. Belimumab SmPC April 2021.

BLISS-LN data and clinical implementation

Disease modification (“lupus modifier”)

Belimumab use in SLE

Indication

- **Belimumab is indicated as add-on therapy in adult patients with active, autoantibody-positive systemic lupus erythematosus (SLE) with a high degree of disease activity (e.g., positive anti-dsDNA and low complement) despite standard therapy**

- **Belimumab is indicated in combination with background immunosuppressive therapies for the treatment of adult patients with active lupus nephritis**

Belimumab SPC, last update April 2021

Belimumab use in SLE

Patients that are anticipated to respond

- Clinically and serologically active SLE patients

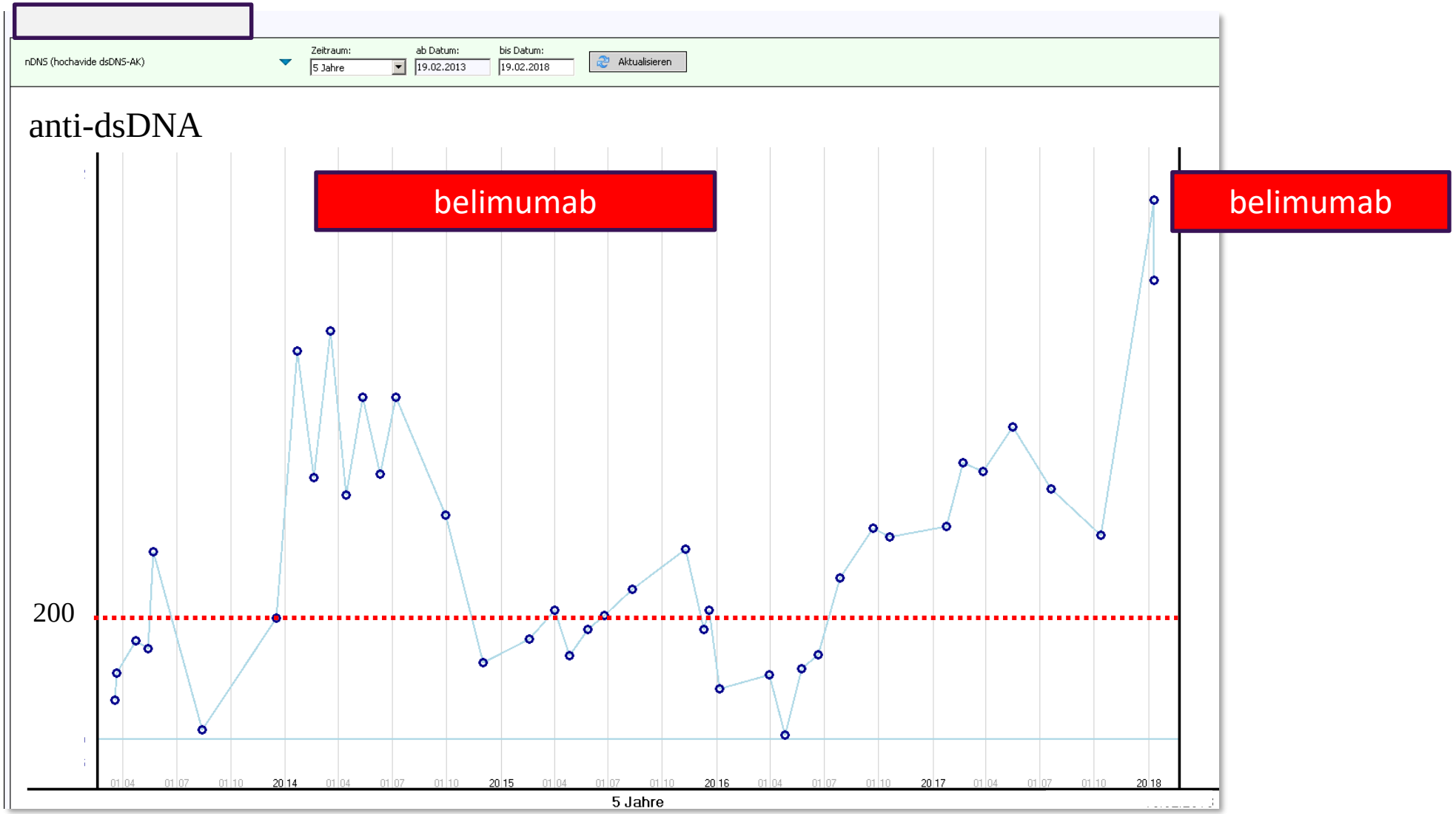
- Patients with LN in combination with induction therapy

- All SLE patients with upregulated Blys !

Belimumab = ***Pathophysiology – based targeted therapy for Lupus and LN***

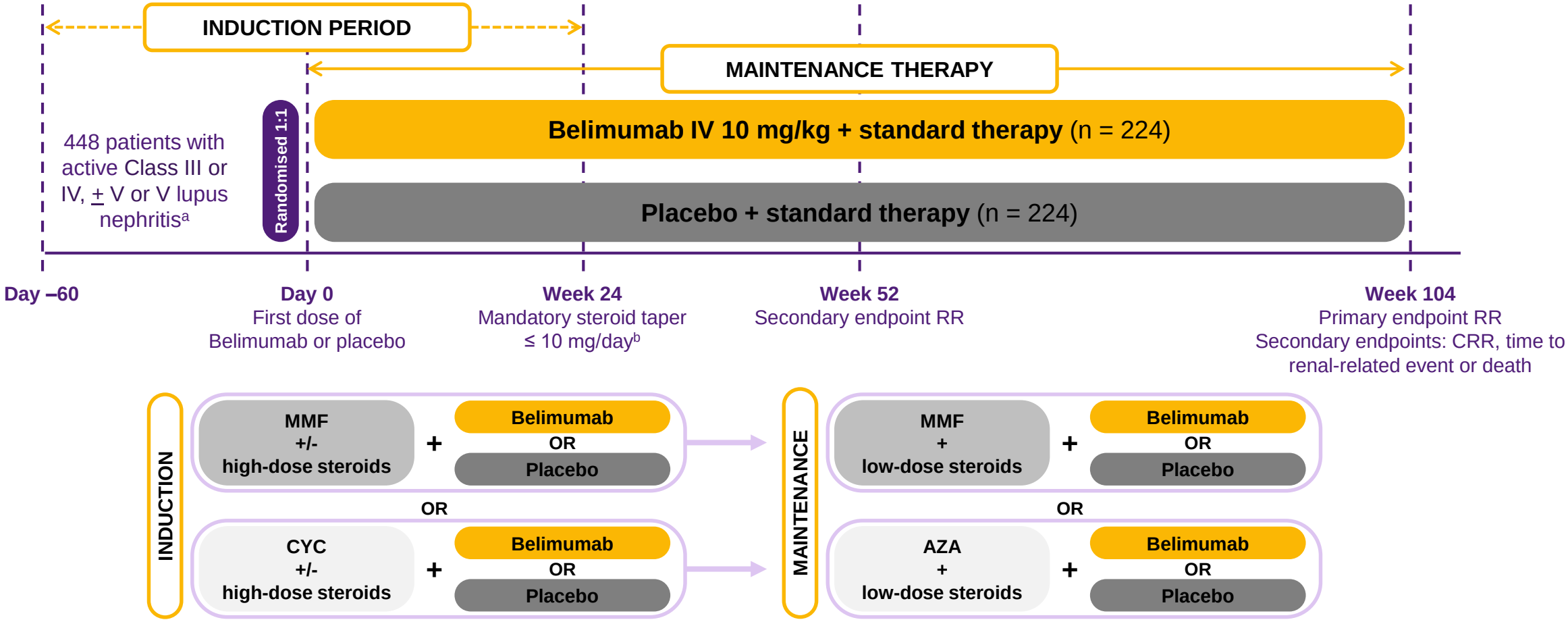
Σας ευχαριστώ για την προσοχή σας !

Case study II – A.M.



Back up slides BLISS LN

BLISS-LN study design:[1] belimumab added to induction and maintenance therapy



[a] Confirmed biopsy proven in the past 6 months: III or IV +/- V, or pure V (A or A/C) and uPCR ≥ 1.0 g/g;
[b] Belimumab could be initiated up-to 60 days after the beginning of induction background therapy;
[c] Increases above 10 mg/day after Week 24 were deemed a treatment failure.

A/C = active/chronic; AZA = azathioprine; CRR = complete renal response; CYC = cyclophosphamide; IV = intravenous; MMF = mycophenolate mofetil; RR = renal response; uPCR = urine protein:creatinine ratio.

1. Furie R, et al. N Engl J Med 2020;383:1117–1128;

Primary and key secondary endpoints of the BLISS-LN study[1,2]

Renal response (RR) at Week 104

Primary endpoint[1]

Definition of RR[a]

eGFR ≥ 60 mL/min/1.73 m² or no more than 20% below pre-flare value, and

Urine protein:creatinine ratio ≤ 0.7, and

Not a treatment failure[b]

Complete renal response (CRR) at Week 104

Secondary endpoint[1]

Definition of CRR

eGFR ≥ 90 mL/min/1.73 m² or no more than 10% below pre-flare value, and

Urine protein:creatinine ratio < 0.5, and

Not a treatment failure[b]

Time to renal-related event or death

Secondary endpoint[2]

Definition of renal-related event

1) **ESKD, or**
2) **Doubling of serum creatinine, or**
3) **Renal worsening (increased proteinuria and/or impaired renal function), or**
4) **Renal disease-related treatment failure[b]**

Patients had to meet all three components of RR or CRR at two consecutive visits to be considered a responder[2]

[a] RR is equivalent to PERR;
[b] Treatment failures were defined as patients who dropped out of the trial early or received prohibited medications. For these endpoints, in order to be considered a responder, steroid dose had to be reduced to ≤ 10 mg/day from Week 24.

CRR = complete renal response; eGFR = estimated glomerular filtration rate; ESKD = end-stage kidney disease; PERR = primary efficacy renal response; RR = renal response.

1. Furie R, et al. N Engl J Med 2020;383:1117–1128;
2. Furie R, et al. N Engl J Med 2020;383:1–15 (supplementary).

Key inclusion and exclusion criteria

Inclusion criteria:[1]

- Adult: ≥ 18 years old
- SLE clinically diagnosed by 1997 ACR criteria
- Autoantibody-positive: positive ANA and/or anti-dsDNA
- Active lupus nephritis: biopsy confirmed in past 6 months (Class III or IV, ± V or V)
- Clinically active renal disease at screening requiring induction therapy with CYC ± high-dose steroids or MMF ± high-dose steroids

Exclusion criteria:[1,2]

- Previously failed **both** CYC and MMF induction therapies
- On dialysis within the past year or eGFR < 30 mL/min/1.73 m^2 at screening
- Received induction therapy with CYC within 3 months prior to induction therapy for the study
- Received B-cell targeted therapy (e.g., rituximab) within the past year
- Severe active CNS lupus within 60 days of baseline
- Required management of acute or chronic infections within the past 60 days

ACR = American College of Rheumatology; ANA = antinuclear antibody; CNS = central nervous system; CYC = cyclophosphamide; eGFR = estimated glomerular filtration rate; MMF = mycophenolate mofetil.

1. Furie R, et al. N Engl J Med 2020;383:1117–1128;
2. Clinical protocol document HGS1006-C1121. Available at: https://clinicaltrials.gov/ProvidedDocs/39/NCT01639339/Prot_000.pdf (accessed May 2021).

Baseline demography and disease characteristics of the BLISS-LN trial

	Placebo (n = 223)	Belimumab 10 mg/kg (n = 223)	Total (N = 446)
Age, mean (SD), years	33.1 (10.6)	33.7 (10.7)	33.4 (10.7)
Gender: Female [vs. Male], n (%)	196 (88%)	197 (88%)	393 (88%)
SLE disease duration, median (IQR), years	3.3 (0.2–8.0)	3.3 (0.3–8.1)	3.3 (0.2, 8.1)
LN disease duration, median (IQR), years	0.2 (0.1–3.4)	0.2 (0.1–3.3)	0.2 (0.1, 3.3)
Race or ethnic group, n (%)			
Asian	109 (49%)	114 (51%)	223 (50%)
White	75 (34%)	73 (33%)	148 (33%)
Black	31 (14%)	30 (13%)	61 (14%)
American Indian or Alaska Native	6 (3%)	4 (2%)	10 (2%)
Multiple races or ethnic groups	2 (1%)	2 (1%)	4 (1%)
Geographic region, n (%)			
Asia	105 (47%)	106 (48%)	211 (47%)
Europe	45 (20%)	41 (18%)	86 (19%)
United States or Canada	38 (17%)	38 (17%)	76 (17%)
Americas, excl. United States or Canada	35 (16%)	38 (17%)	73 (16%)
Renal biopsy class, n (%):[a]			
Class III or IV	132 (59%)	126 (56%)	258 (58%)
Class III + V or Class IV + V	55 (25%)	61 (27%)	116 (26%)
Class V	36 (16%)	36 (16%)	72 (16%)

[a] Renal biopsy performed within 6 months prior to or during screening.

IQR = interquartile range; SD = standard deviation.

Furie R, et al. N Engl J Med 2020;383:1117–1128.

Baseline disease characteristics of mITT population

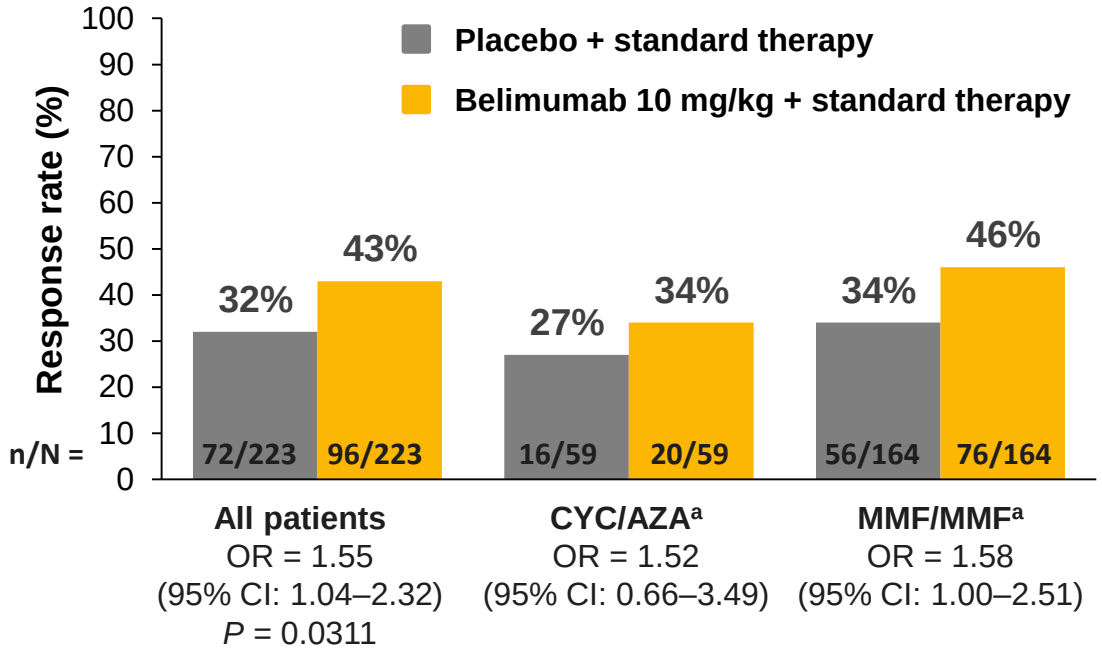
	Placebo (n = 223)	Belimumab 10 mg/kg (n = 223)	Total (N = 446)
Urine protein:creatinine ratio (g/g), n (%)			
< 3	131 (59%)	132 (59%)	263 (59%)
≥ 3	92 (41%)	91 (41%)	183 (41%)
Estimated GFR (mL/min/1.73m^2), n (%)			
≥ 60	182 (82%)	190 (85%)	372 (83%)
≥ 90	133 (60%)	131 (59%)	264 (59%)
Biomarkers, n (%)			
Anti-dsDNA positive (≥ 30 IU/mL)	169 (76%)	173 (78%)	342 (77%)
Anti-C1q positive (≥ 22.2 U/mL)	172/221 (78%)	181/223 (81%)	353 (79%)
Anti-Sm positive (≥ 15 KU/L)	72/219 (33%)	73/223 (33%)	145 (33%)
Low C3 (< 90 mg/dL)	133 (60%)	134 (60%)	267 (60%)
SLEDAI-S2K, mean (SD)			
SLEDAI-S2K	12.2 (4.8)	12.5 (5.3)	12.3 (5.0)

C = complement; GFR = glomerular filtration rate; mITT = modified intent to treat; SD = standard deviation; SLEDAI-S2K = Systemic Lupus Erythematosus Disease Activity Index 2000.

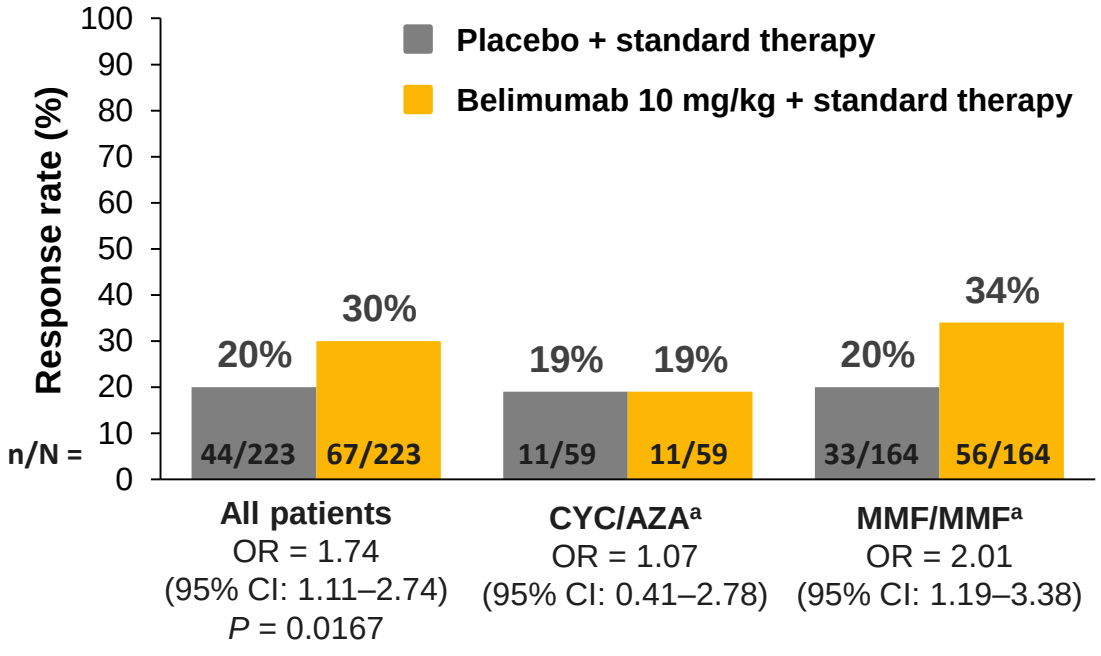
Furie R, et al. N Engl J Med 2020;383:1117–1128.

Renal response and complete renal response at Week 104 by induction regimen

Renal response at Week 104 by induction regimen



Complete renal response at Week 104 by induction regimen



[a] Pre-specified, supportive analysis. Results are descriptive.

AZA = azathioprine; CI = confidence interval; CYC = cyclophosphamide; MMF = mycophenolate mofetil; OR = odds ratio.

Furie R, et al. N Engl J Med 2020;383:1–15 (supplementary appendix).

BLISS-LN: summary of adverse events

n (%)	Placebo + standard therapy (n = 224)	Belimumab 10 mg/kg + standard therapy (n = 224)
All adverse events	211 (94)	214 (96)
Treatment-related adverse events	119 (53)	123 (55)
All serious adverse events[b]	67 (30)	58 (26)
All treatment-related serious adverse events[b]	25 (11)	23 (10)
Adverse events resulting in discontinuation	29 (13)	29 (13)
Adverse events of special interest		
Malignancies		
Excluding NMSC[c]	0%	2 (1)
Including NMSC[c]	0%	3 (1)
Post-infusion systemic reactions	29 (13)	26 (12)
All infections of special interest, including opportunistic infections, herpes zoster, tuberculosis, and sepsis	34 (15)	30 (13)
Serious infections	7 (3)	9 (4)
Depression, suicide or self-injury	16 (7)	11 (5)
C-SSRS suicidal ideation or behaviour during trial intervention	12 (5)	7 (3)
Death	5 (2)	6 (3)

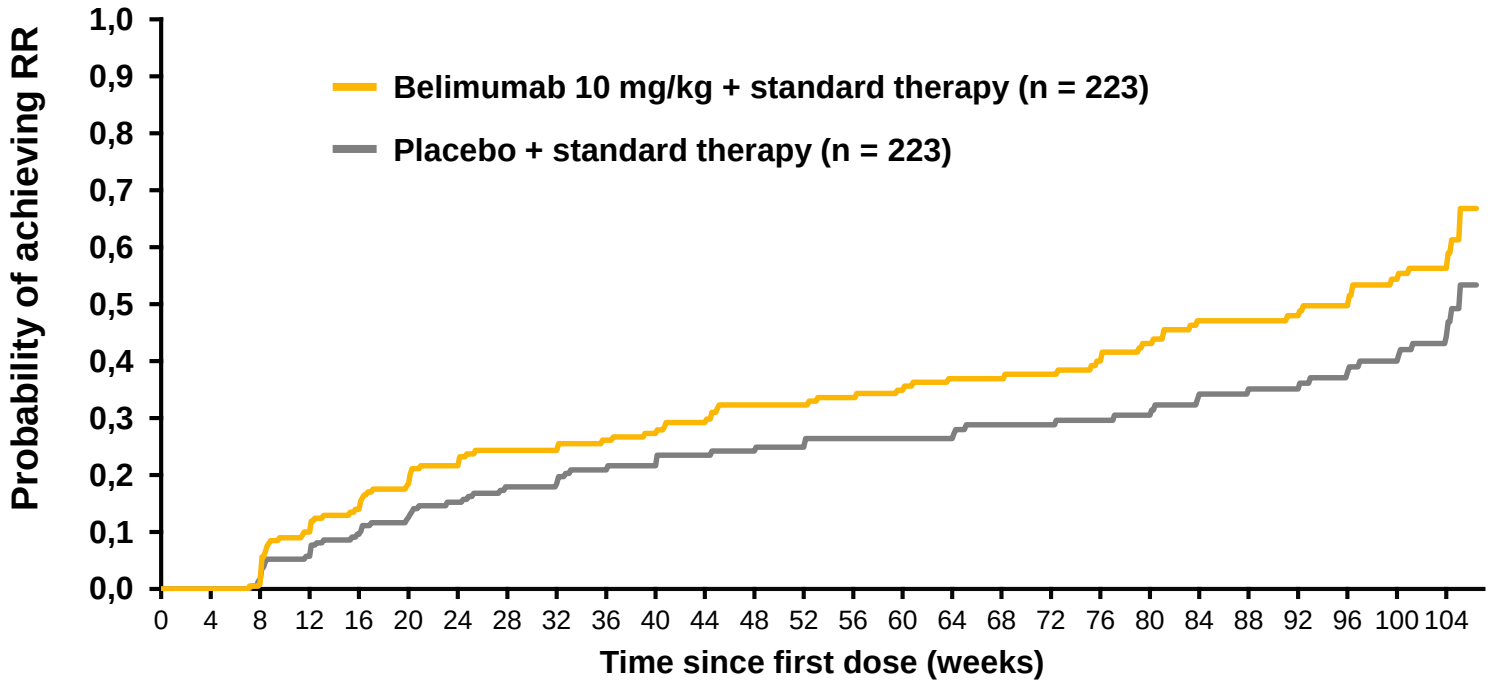
[a] Only adverse events that occurred during the intervention period are listed; [b] This category includes all patients who had at least one event. Relatedness of the intervention to the event was determined by the site investigators; [c] This category includes tumours of unspecified cancer that were adjudicated as cancer.

C-SSRS = Columbia-Suicide Severity Rating Scale; NMSC = non-melanoma skin cancer.

Furie R, et al. N Engl J Med 2020;383:1117–1128.

More patients receiving belimumab achieved RR and sustained this response through Week 104 vs. standard therapy alone

Time to first RR that is maintained through Week 104[a]



Belimumab, n	211	170	150	128	117	106	102	91	81	72	61	55	33
Placebo, n	207	182	165	135	120	107	97	93	84	78	68	64	43

Patients on belimumab had a

46%

increased likelihood of achieving RR that was maintained to Week 104[b]

Hazard ratio = 1.46 (95% CI: 1.07–1.98)

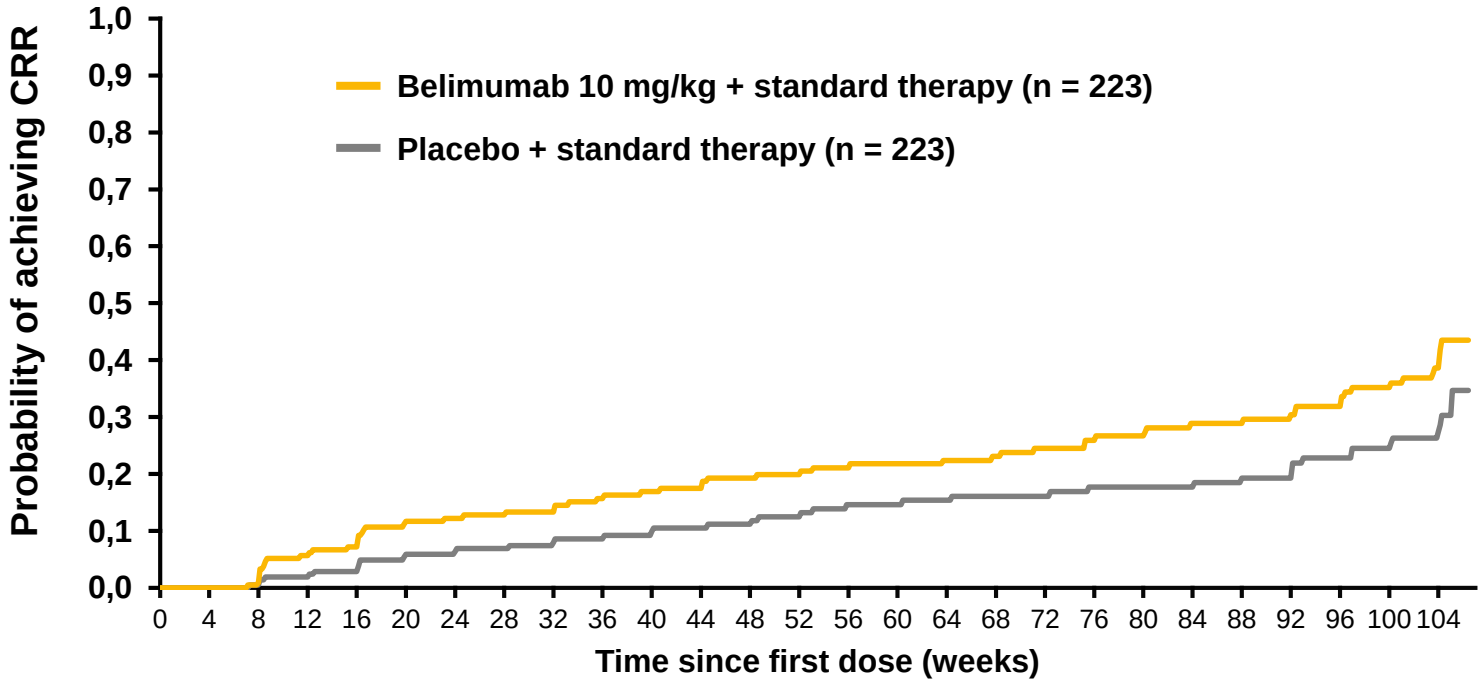
[a] Subjects with investigational product discontinuation, treatment failure, study withdrawal, or who were lost to follow-up, or death are censored;
[b] Pre-specified, supportive analysis. Results are descriptive.

CI = confidence interval; RR = renal response.

Furie R, et al. N Engl J Med 2020;383:1117–1128.

More patients receiving belimumab achieved CRR and sustained this response through Week 104 vs. standard therapy alone

Time to first CRR that is maintained through Week 104[a]



Belimumab, n	211	184	169	150	138	131	126	118	106	101	92	85	58
Placebo, n	209	196	183	156	143	132	120	115	108	102	95	90	62

Patients on Belimumab had a

58%

increased likelihood of achieving CRR that was maintained to Week 104[b]

Hazard ratio = 1.58 (95% CI: 1.08–2.31)

[a] Subjects with investigational product discontinuation, treatment failure, study withdrawal, or who were lost to follow-up, or death are censored;
[b] Pre-specified, supportive analysis. Results are descriptive.

CI = confidence interval; CRR = complete renal response.

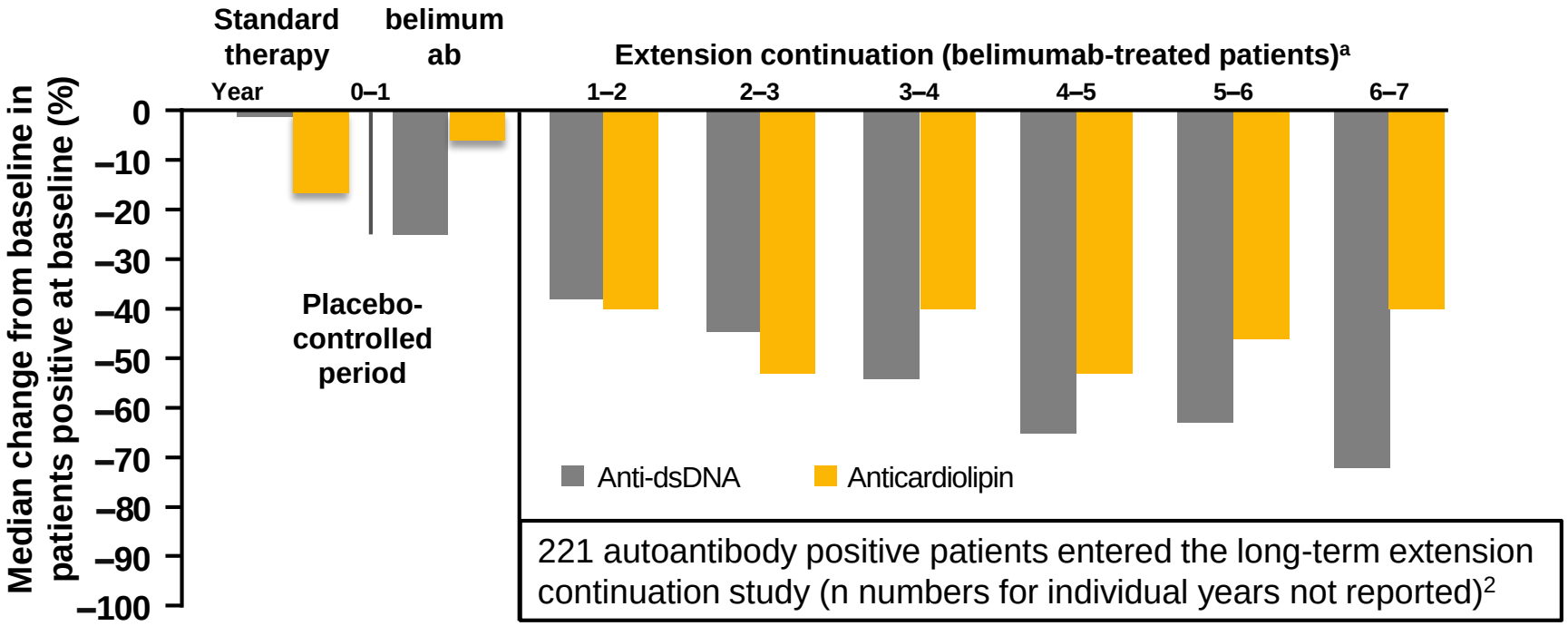
Furie R, et al. N Engl J Med 2020;383:1117–1128.

Belimumab Phase II study[1]

This study failed the primary endpoint

Patients with active lupus nephritis were excluded

Patients were not required to have positive autoantibodies



Changes in anti-dsDNA and anticardiolipin were observed over time among patients receiving belimumab[2]

- The data show changes in IgG autoantibody levels in patients positive for the respective autoantibodies at baseline[2]
- **Limitations of this extension study:[2]**
  - The population that entered the extension study may be enriched with patients who responded to or tolerated belimumab
  - There was no matched-control group to directly compare long-term data

[a] Patients who switched from placebo to belimumab were included from first belimumab exposure.
IgG = Immunoglobulin G.

1. Wallace D, et al. Arthritis Rheum. 2009;61(9):1168–1178;
2. Ginzler EM, et al. J Rheumatol 2014;41:300–309.

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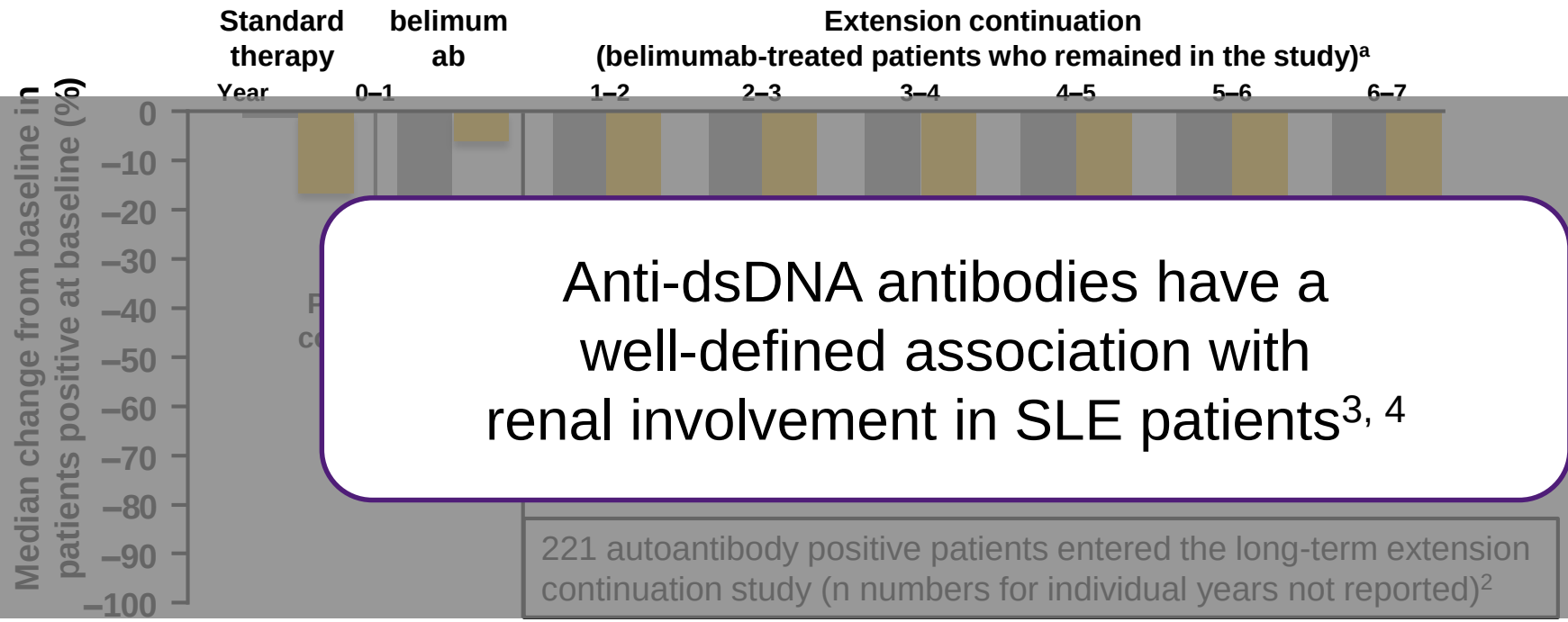

Anti-dsDNA antibodies have a well-defined association with renal involvement in SLE patients[3, 4]

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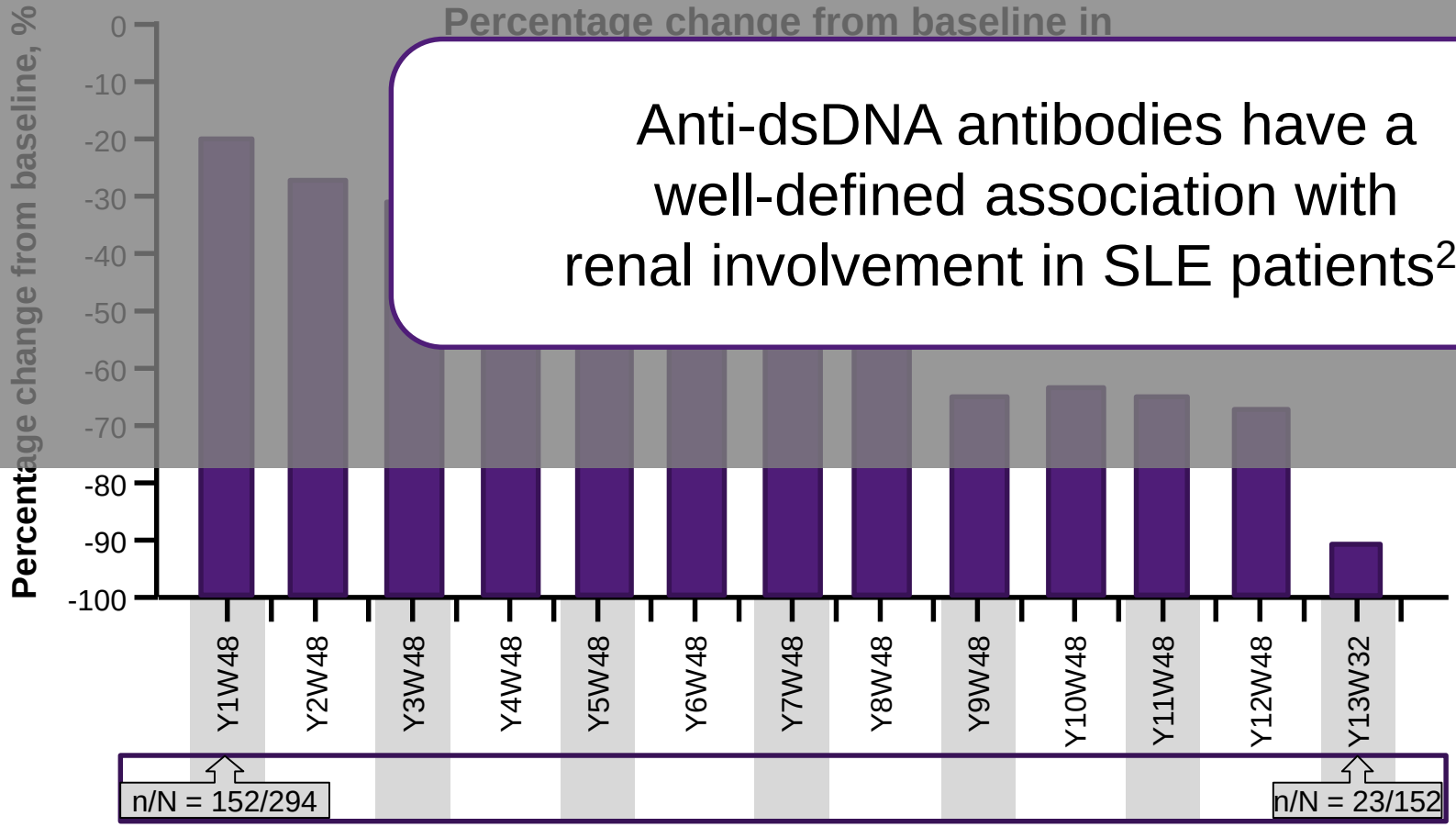
4. Rahman A & Isenberg DA. N Engl J Med 2008;358:929–939.

Percentage change from baseline in



Anti-dsDNA antibodies have a well-defined association with renal involvement in SLE patients[2,3]

13-year open-label long-term continuation trial

Limitation: Patients who remained in the study were likely to be those who responded to or tolerated belimumab better than patients who withdrew

Limitation: Not all absolute data are available. Available data indicates a large decrease in patient numbers over time.

1. Wallace S, et al. Arthritis Rheumatol 2019;71:1125–1134;
2. Giles BM & Boackle SA. Immunol Res 2013;55:10–21;
3. Rahman A & Isenberg DA. N Engl J Med 2008;358:929–939.

Βοηθήστε να γίνουν τα φάρμακα πιο ασφαλή και Αναφέρετε
ΟΛΕΣ τις ανεπιθύμητες ενέργειες για
ΟΛΑ τα φάρμακα
Συμπληρώνοντας την «ΚΙΤΡΙΝΗ ΚΑΡΤΑ»

Παρακαλούμε επικοινωνήστε με την εταιρεία για επιβεβαίωση πλήρως ενημερωμένων δεδομένων, για οποιαδήποτε πληροφορία ή/και αναφορά Ανεπιθύμητων Ενεργειών στο τηλέφωνο 210 6882100.

Πριν τη συνταγογράφηση συμβουλευτείτε την Περίληψη Χαρακτηριστικών του Προϊόντος, η οποία είναι διαθέσιμη κατόπιν αιτήσεως στην εταιρεία.

Λ.Τ:

BENLYSTA INJ.SOL 200MG/1ML BTx4 PF.PENS x1ML	904,04€
BENLYSTA PD.C.SO.IN 120MG/VIAL BTx1VIAL	164,8€
BENLYSTA PD.C.SO.IN 400MG/VIAL BTx1VIAL	498,36€

% επιχορήγησης από τους οργανισμούς κοινωνικών ασφαλίσεων:100%
Φαρμακευτικό προϊόν για το οποίο απαιτείται περιορισμένη ιατρική συνταγή.

Φαρμακευτικό προϊόν για το οποίο απαιτείται περιορισμένη ιατρική συνταγή (Βλ. Παράρτημα Ι: Περίληψη των Χαρακτηριστικών του Προϊόντος, παράγραφος 4.2).

Η θεραπεία με Benlysta θα πρέπει να ξεκινά και να επιβλέπεται από εξειδικευμένο ιατρό, με εμπειρία στη διάγνωση και τη θεραπεία του ΣΕΛ. Συνιστάται η πρώτη υποδόρια ένεση του Benlysta να γίνεται υπό την επίβλεψη ενός επαγγελματία υγείας σε χώρο επαρκώς εξοπλισμένο για τη διαχείριση αντιδράσεων υπερευαισθησίας, αν παραστεί ανάγκη. Ο επαγγελματίας υγείας πρέπει να παρέχει κατάλληλη εκπαίδευση στην τεχνική της υποδόριας χορήγησης και εκπαίδευση σχετικά με σημεία και συμπτώματα αντιδράσεων υπερευαισθησίας (βλέπε παράγραφο 4.4). Ο ασθενής μπορεί να κάνει την ένεση μόνος του ή μπορεί ο φροντιστής του ασθενούς να χορηγεί το Benlysta εφόσον ο επαγγελματίας υγείας το κρίνει σκόπιμο.

ΠΧΠ: Benlysta, INN-belimumab (gskpro.com) τελευταία ανανέωση 04/21

Λεπτομερείς πληροφορίες για το παρόν φαρμακευτικό προϊόν είναι διαθέσιμες στον δικτυακό τόπο του Ευρωπαϊκού Οργανισμού Φαρμάκων http://www.ema.europa.eu

Λ. Κηφισίας 266, 152 32 Χαλάνδρι, Τηλ. 2106882100
www.glaxosmithkline.gr