Nouvelles thérapeutiques anti-lymphocytaires B

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Service de médecine interne, hôpital Henri Mondor, Créteil

20 mai 2026 - Actualités néphrologiques

Liens d’intérêt

- Board : UCB, Sanofi, Incyte, Novartis
- Sessions formation : Amgen, Novartis, LFB, Sanofi

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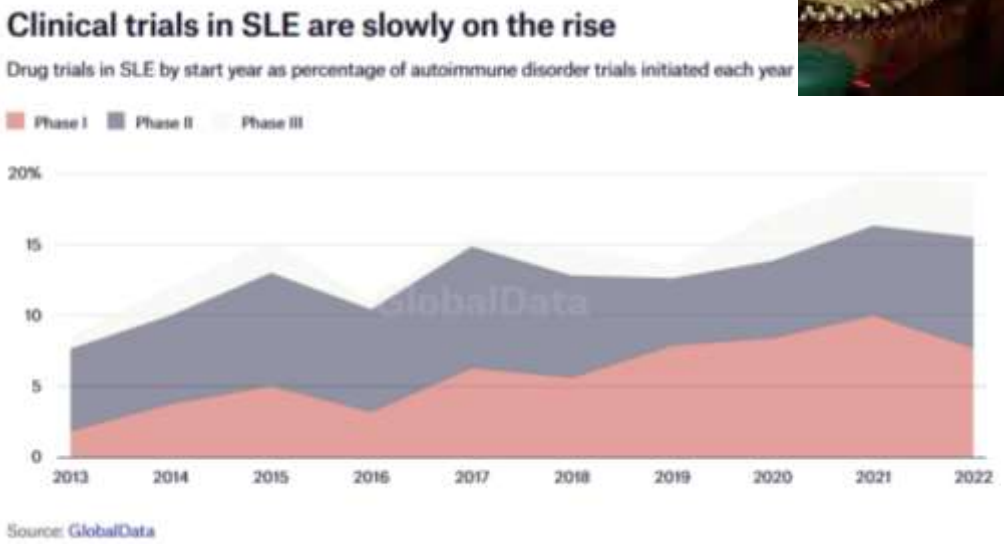


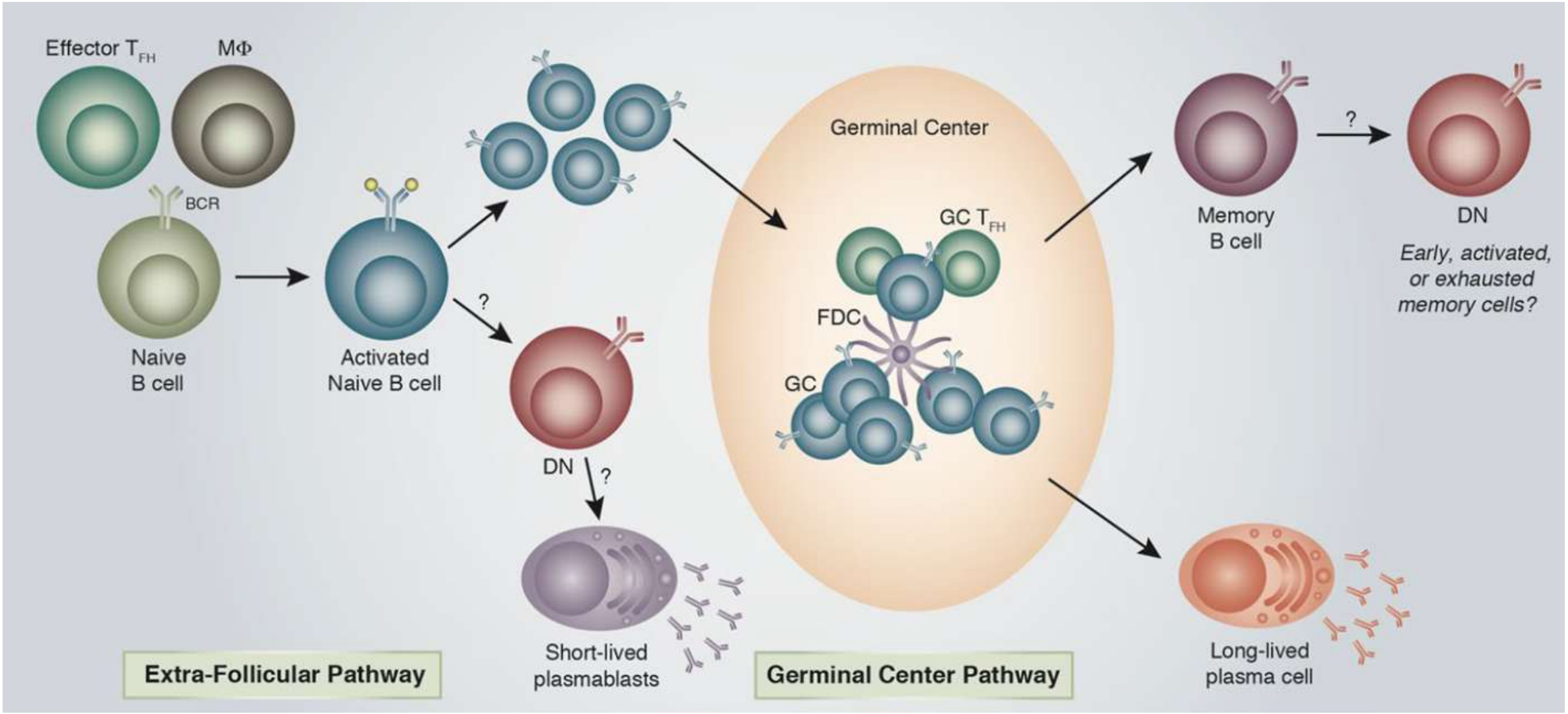
Drug name	Mechanism	Phase	Endpoint	Results	References
Adaptive immunity					
BIIB059	anti-BDCA2	II SLE/CLE	DAS28 w24 CLASI w16	Successful	NCT02847598
		III SLE	SRI-4 w52	Ongoing	NCT04895241
					NCT04961567
		II LN	CRR w52	Successful	Furie et al. (46)
		III LN	CRR w76	Ongoing	NCT04221477
		III LN	PERR w104	Successful	Furie et al. (107)
		II SLE	IgG anti-dsDNA w52	Successful	Shipa et al. (102)
		II LN	Safety (met); Secondary: CR or PR w48 (not met)	Failed	Atisha-Fregoso et al. (105)
		III SLE	Remission w52	Failed	Aranow et al. (104)
		II SLE	BICLA w24	Successful	NCT02804763
		III SLE	BICLA w48	Ongoing	NCT04294667
		II SLE	Resolution of arthritis or rash w24	Successful	Wallace et al. (108)
BRAVE I, II					
Tofacitinib	anti-JAK1/3				
BMS-986165	anti-TYK2				
Deucravacitinib	anti-TYK2				
Upadacitinib	anti-JAK1				
Indirect impact on B cells					
Anifrolumab	anti-IFNAR				
Secukinumab	anti-IL17A				
Ustekinumab	anti-IL12/23				

Nouvelles thérapeutiques anti-lymphocytaires B

- Déplétion lymphocytes B
- Déplétion plasmocytes
- Inhibiteurs activation B
- Anti-BAFF / APRIL
- Inhibiteurs du complément

- Petites molécules
- Anticorps monoclonaux
- BiTE
- CAR T cells

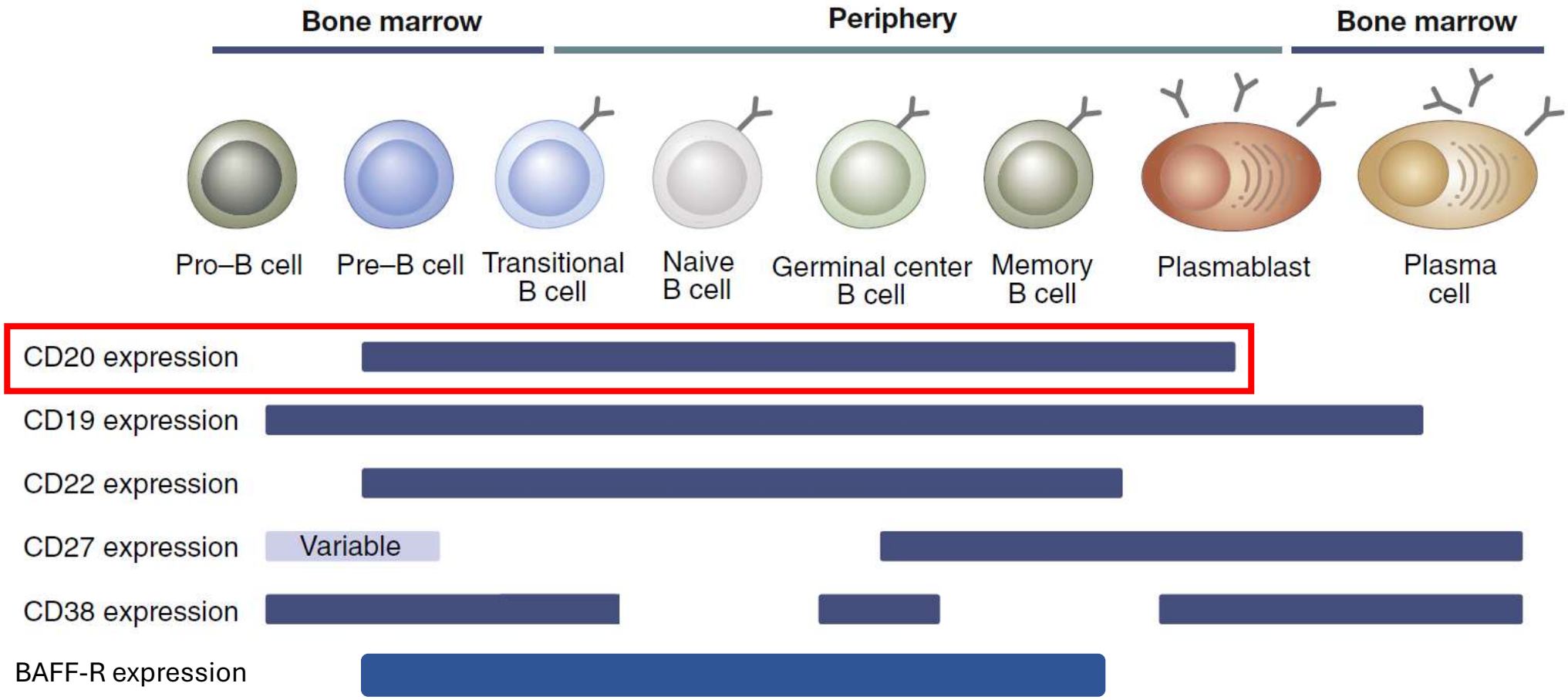
Activation et différenciation B



Sanz, Frontiers Imm 2019

Déplétion lymphocytaire B

Cibler le lymphocyte B



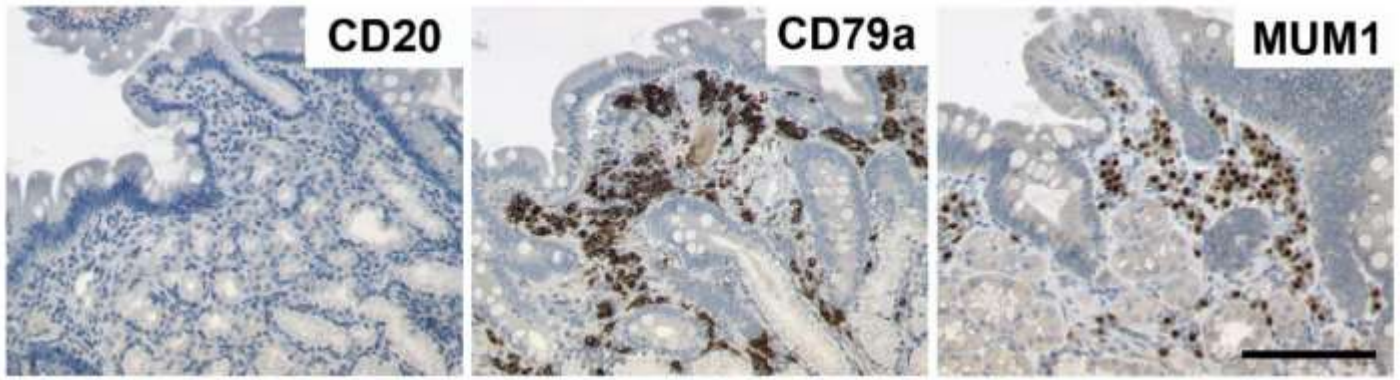
Crickx et al, Kidney int 2020

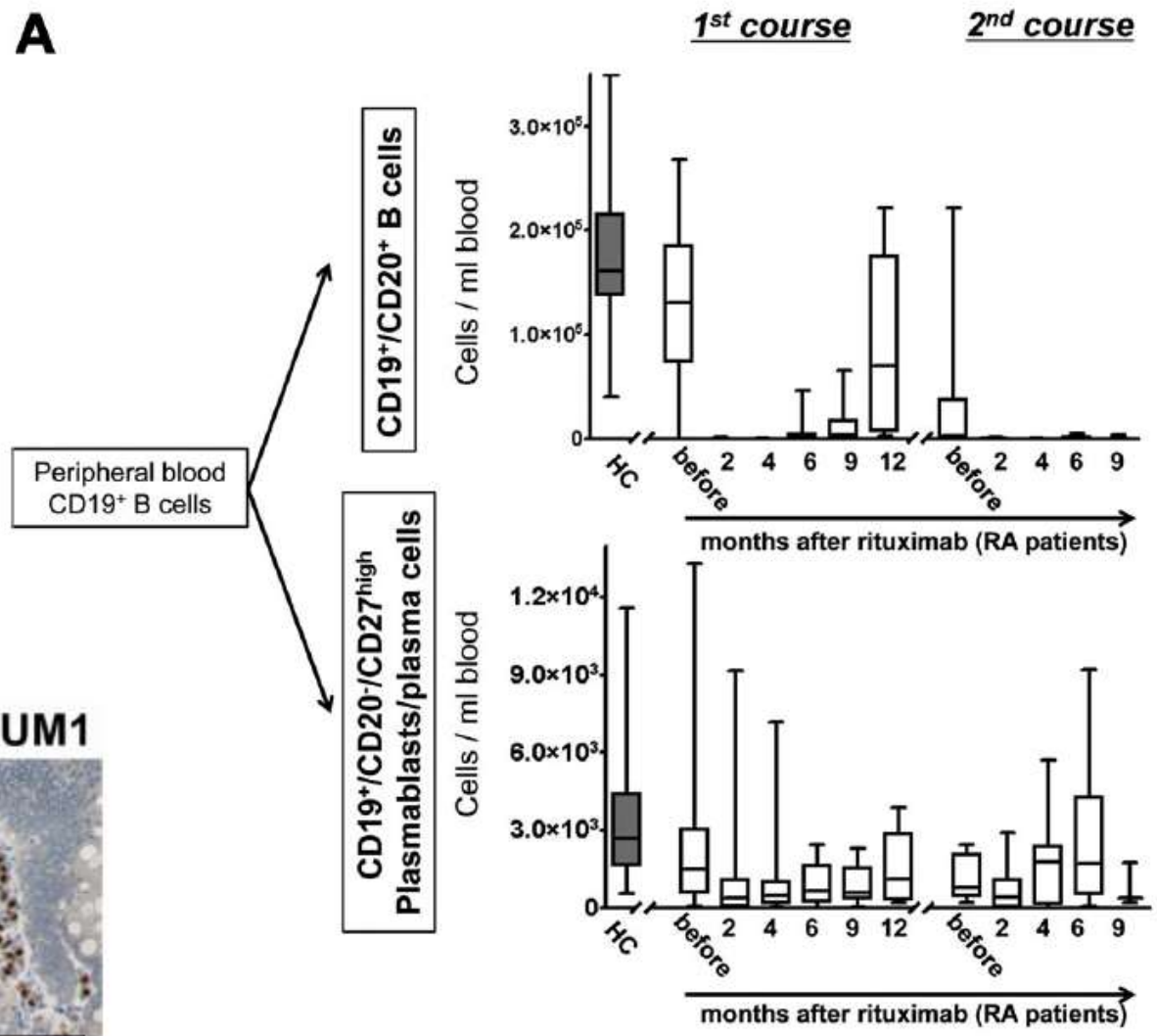
Déplétion B incomplète

- **Rare en périphérie au cours des maladies autoimmunes**

Déplétion B incomplète

- **Rare en périphérie au cours des MAI**

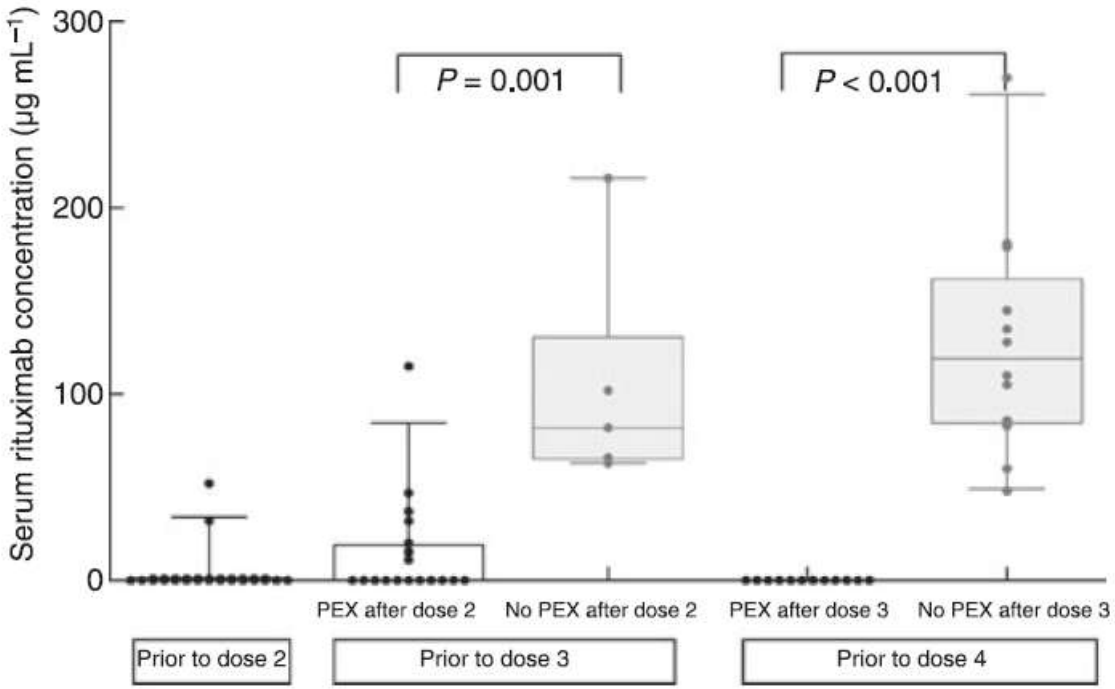




Mei et al, Blood 2010

Déplétion B incomplète

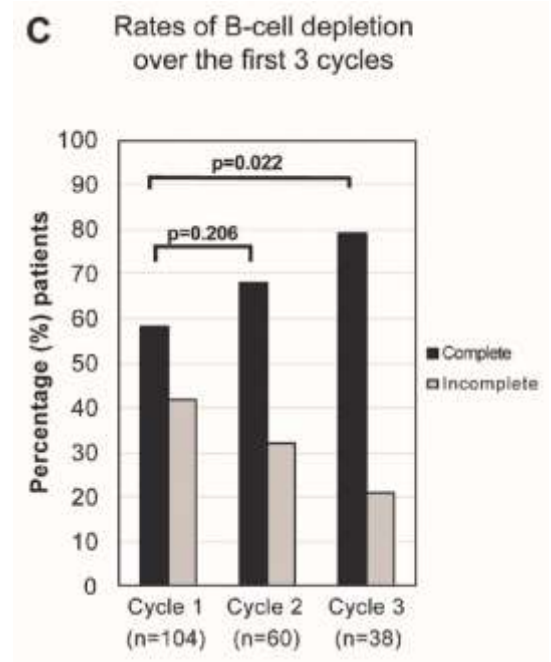
- Rare en périphérie au cours des MAI
- **Influence des lésions glomérulaires / protéinurie et des échanges plasmatiques**

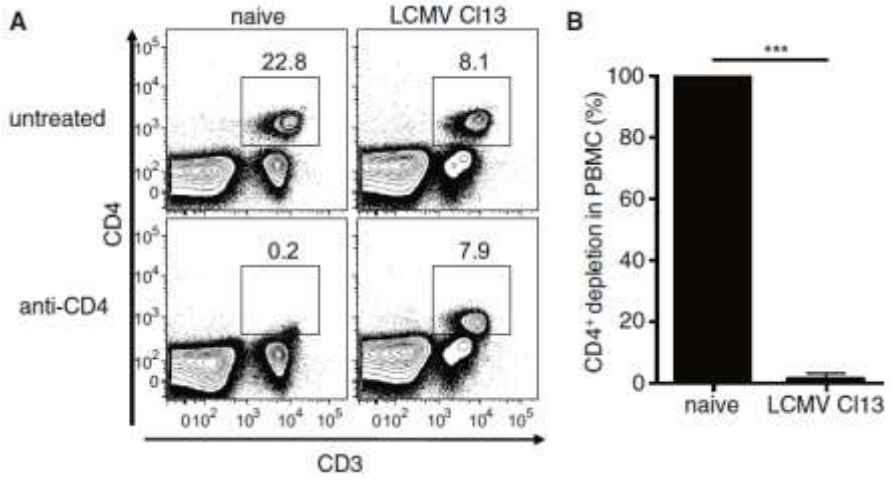


McDonald et al, JTH 2010
Allinovi et al, Nephrology Dialysis Transplantation 2026

Déplétion B incomplète

- Rare en périphérie au cours des MAI
- Influence des lésions glomérulaires / protéinurie et des échanges plasmatiques
- **Influence des complexes immuns circulants**





Yusof et al, ARD 2017

Wieland et al, Immunity 2015

Echecs pharmacologiques – Anticorps anti-rituximab

- Fréquence variable selon la méthode de dosage et la pathologie:
  - Rare en oncohématologie
  - AAV 0%, PR 11%, SEP 30%, lupus 38%

Faustini et al, ART 2021
Wincup et al, ARD 2019

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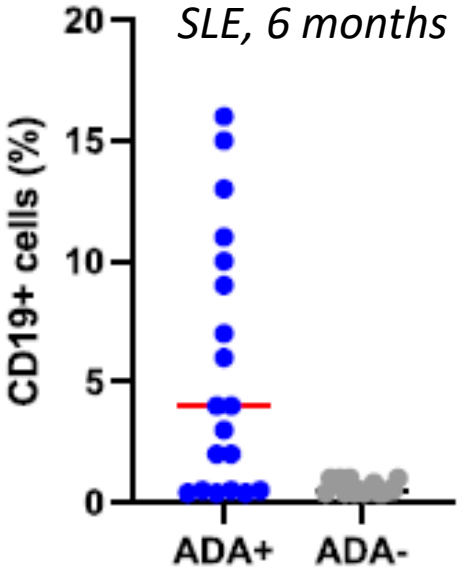
- **Signification clinique controversée** (déplétion plus courte)



Faustini et al, ART 2021
Wincup et al, ARD 2019

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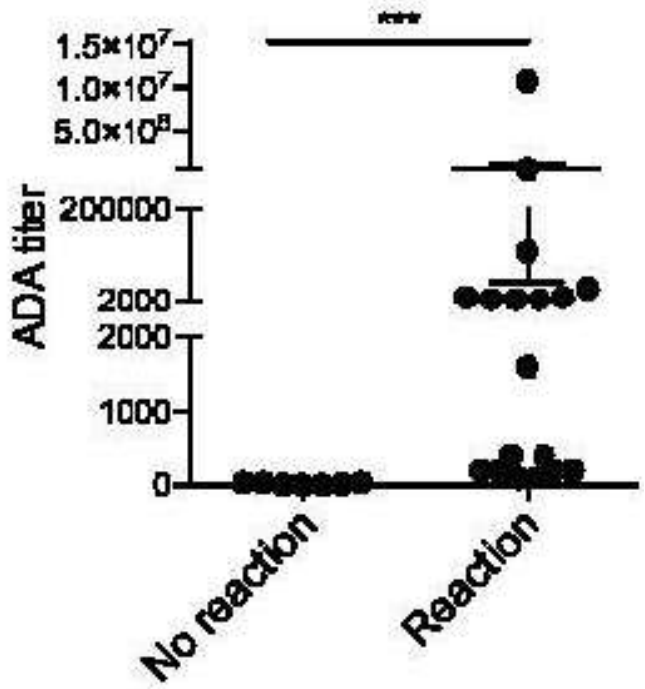
- **Association au risque de réaction**

SLE, retreatment



Faustini et al, ART 2021
Wincup et al, ARD 2019

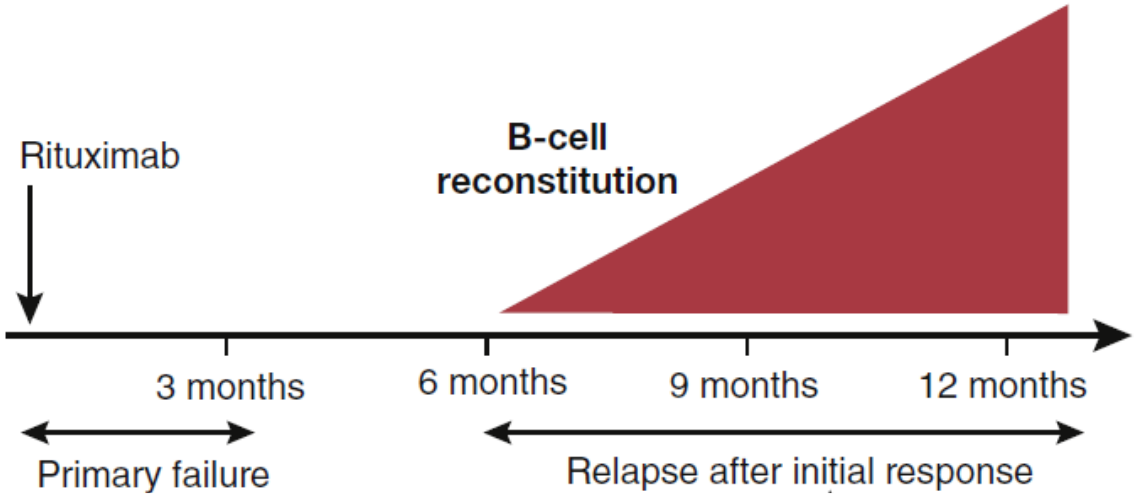
Echecs pharmacologiques – Maladie sérique

- Fréquence variable selon la pathologie
  - Incidence estimée / 10^5 doses:
    - Hémato-onco: 0.5
    - MAI: 6.4
    - SLE: 48.6

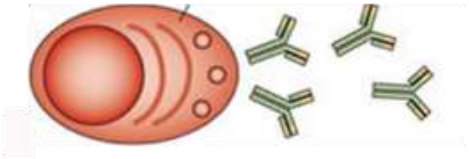
- Efficacité des anti-CD20 humanisés si retraitement nécessaire

Bayer et al, EJIM 2019
Vendramin et al, BJH 2019
Doyle et al, BJH 2022

Déplétion tissulaire incomplète

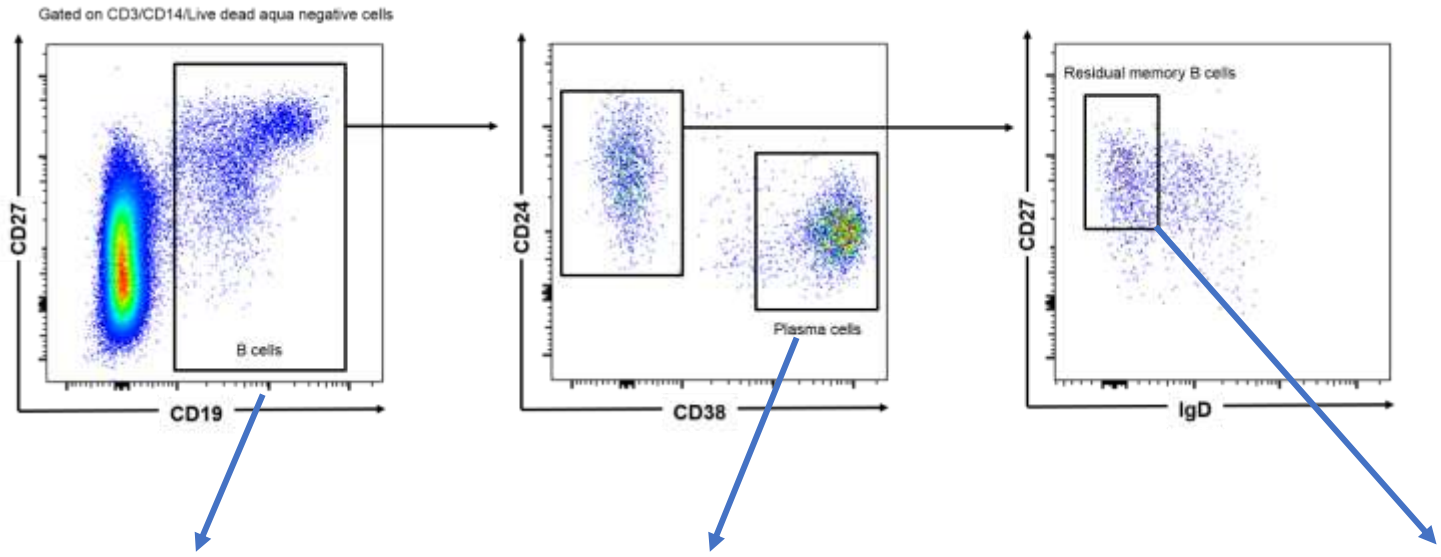


Memory B cells ?



Long-lived plasma cells

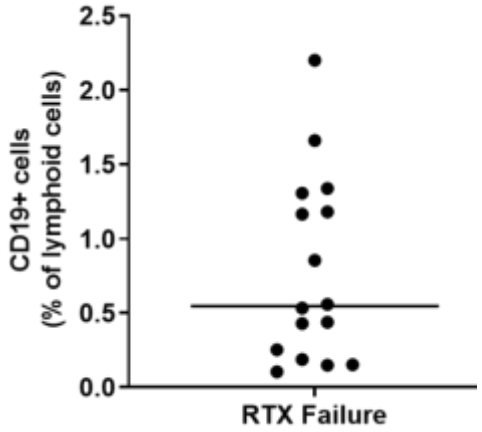
Présence de lymphocytes B mémoires résiduels dans la rate de patients en échec du RTX

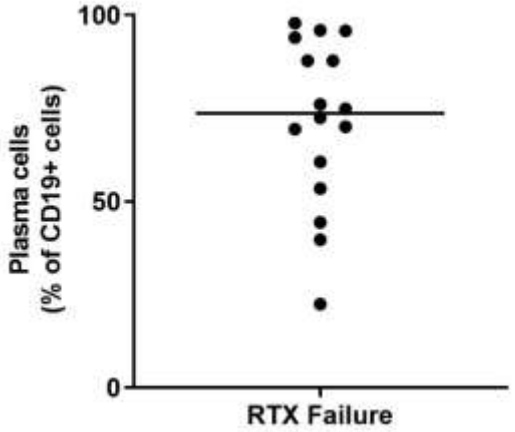


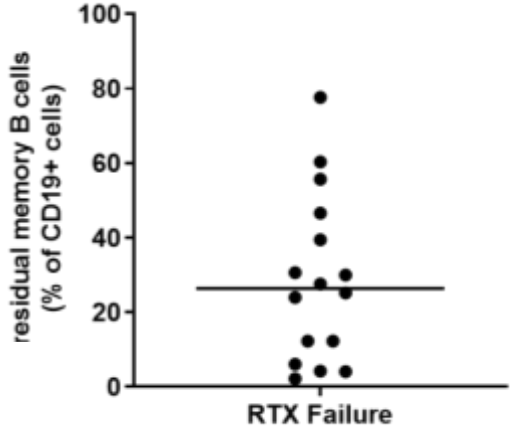
B cells

Plasma cells

Memory B cells



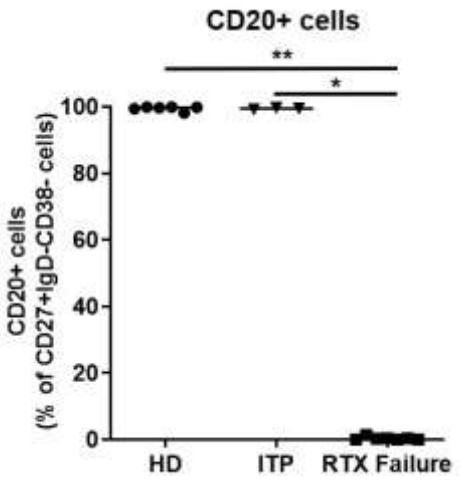


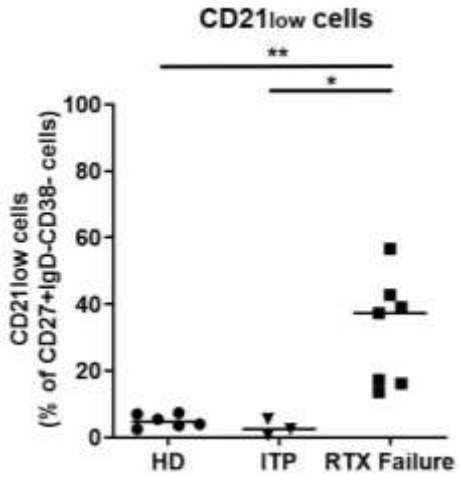


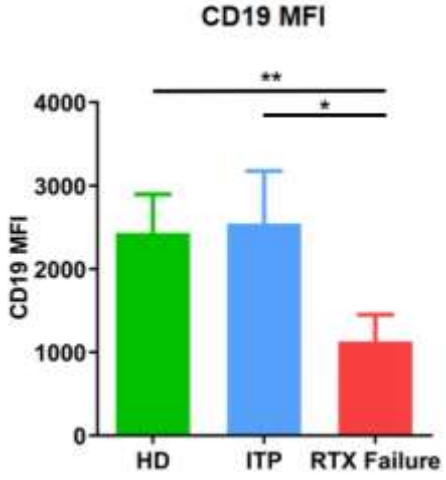
Memory B cells ?

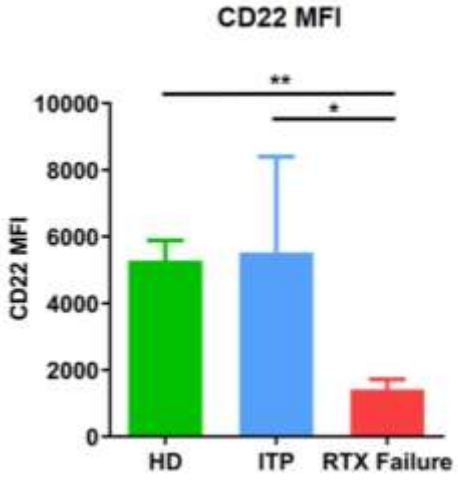
Crickx et al, Sci Transl Med 2021

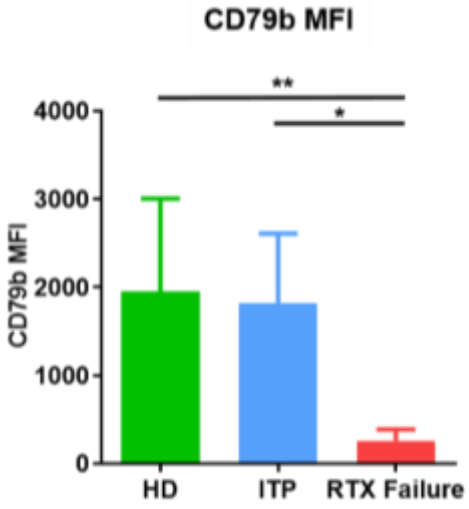
Les lymphocytes B mémoires résiduels ont un phénotype unique

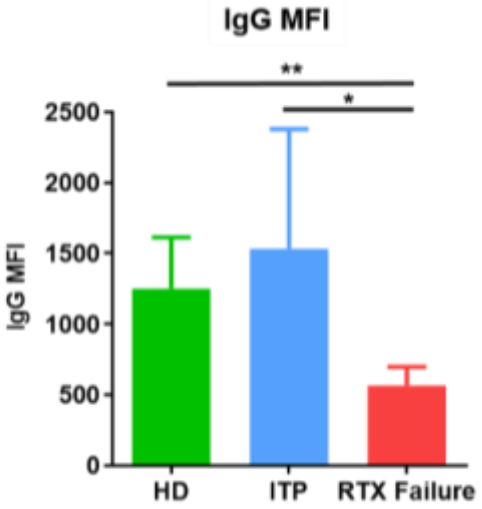


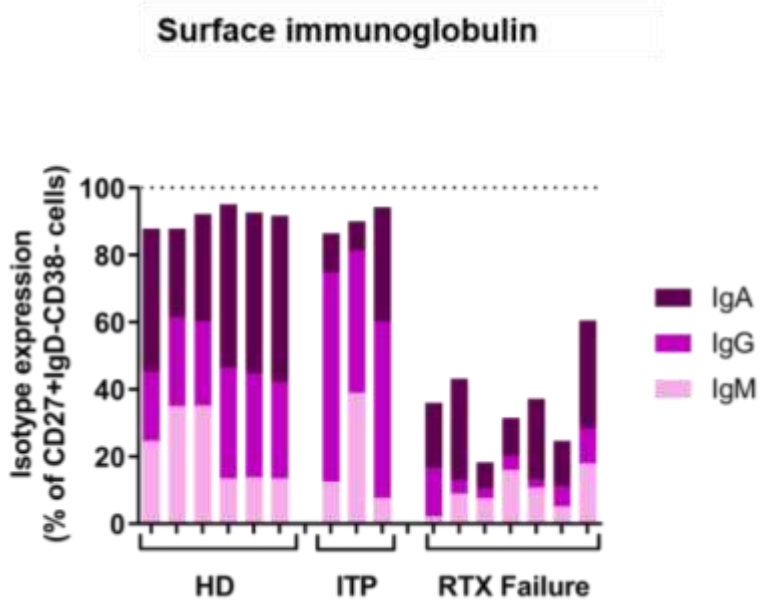


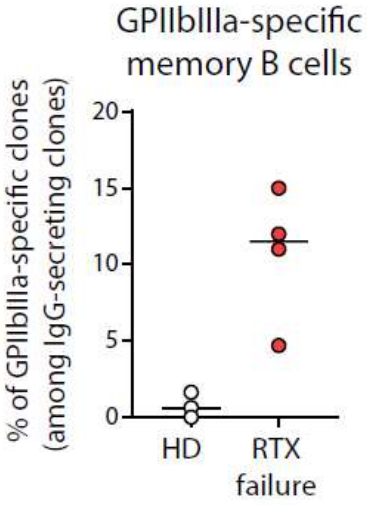






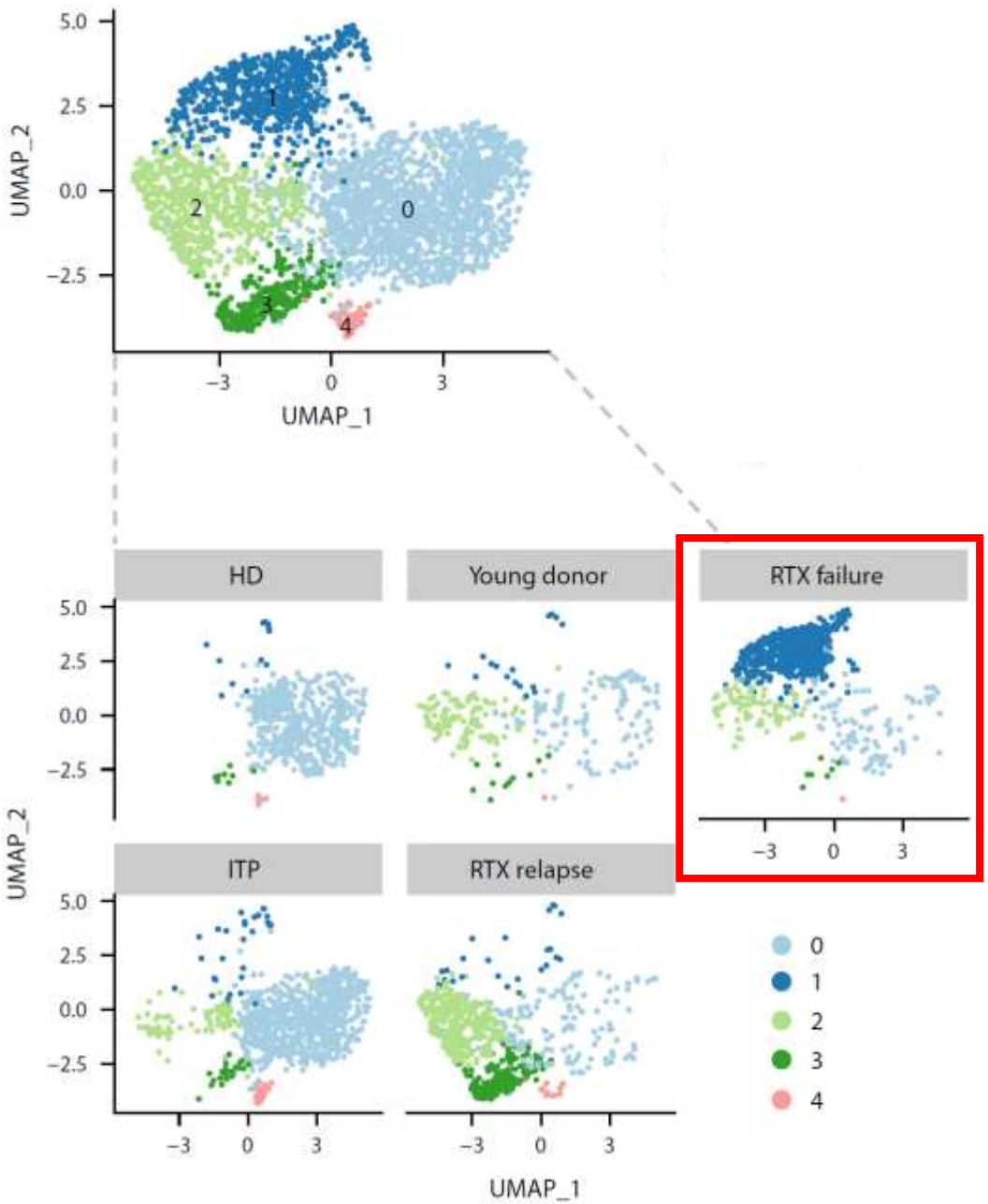


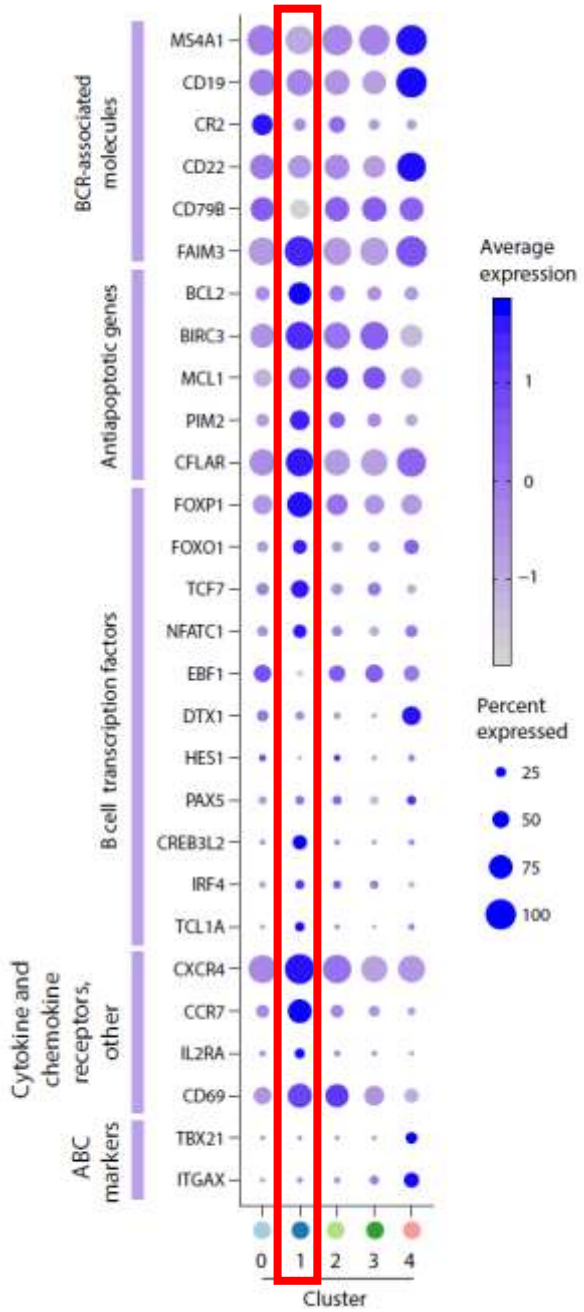




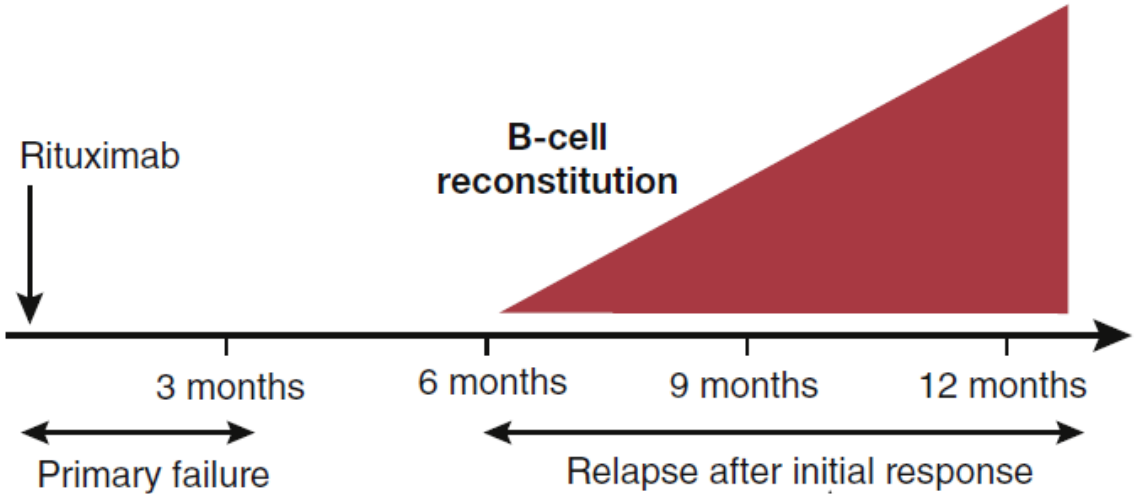
Les lymphocytes B mémoires résiduels ont un transcriptome unique

Memory B cells (scRNA-seq)

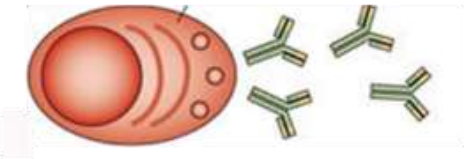




Les lymphocytes B mémoires résistants au RTX contribuent aux rechutes durant la reconstitution lymphocytaire B



Memory B cells



Long-lived plasma cells

Diminution d'expression de l'immunoglobuline de surface et modulation du CD20 après exposition au RTX

Phénotype réversible après disparition du RTX

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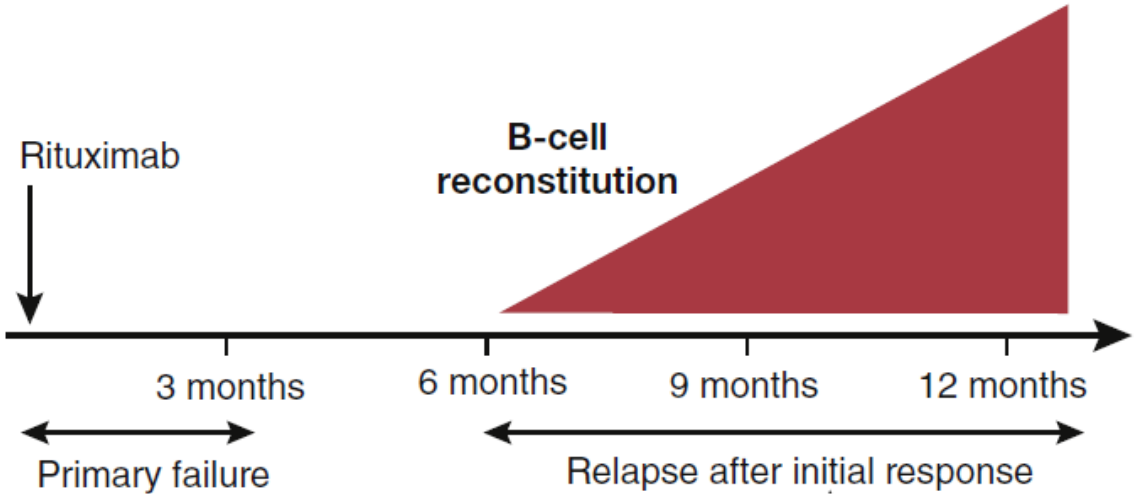
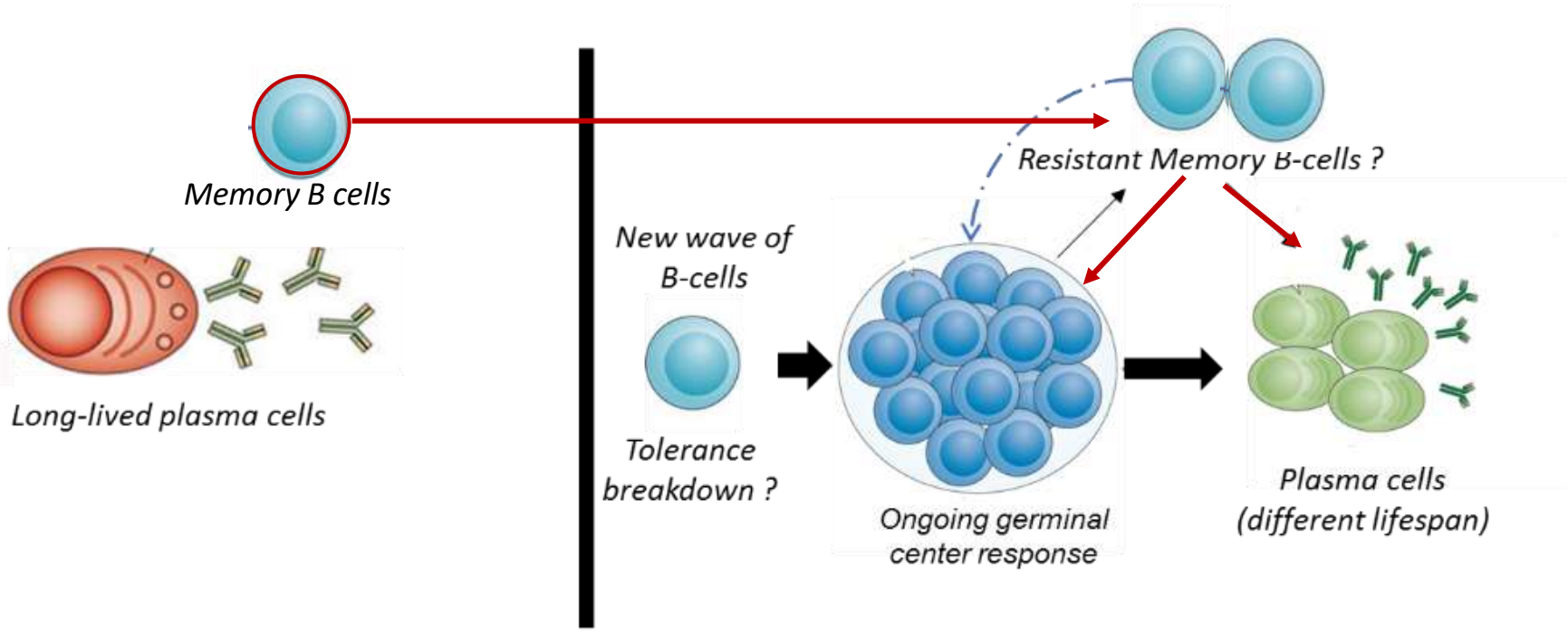




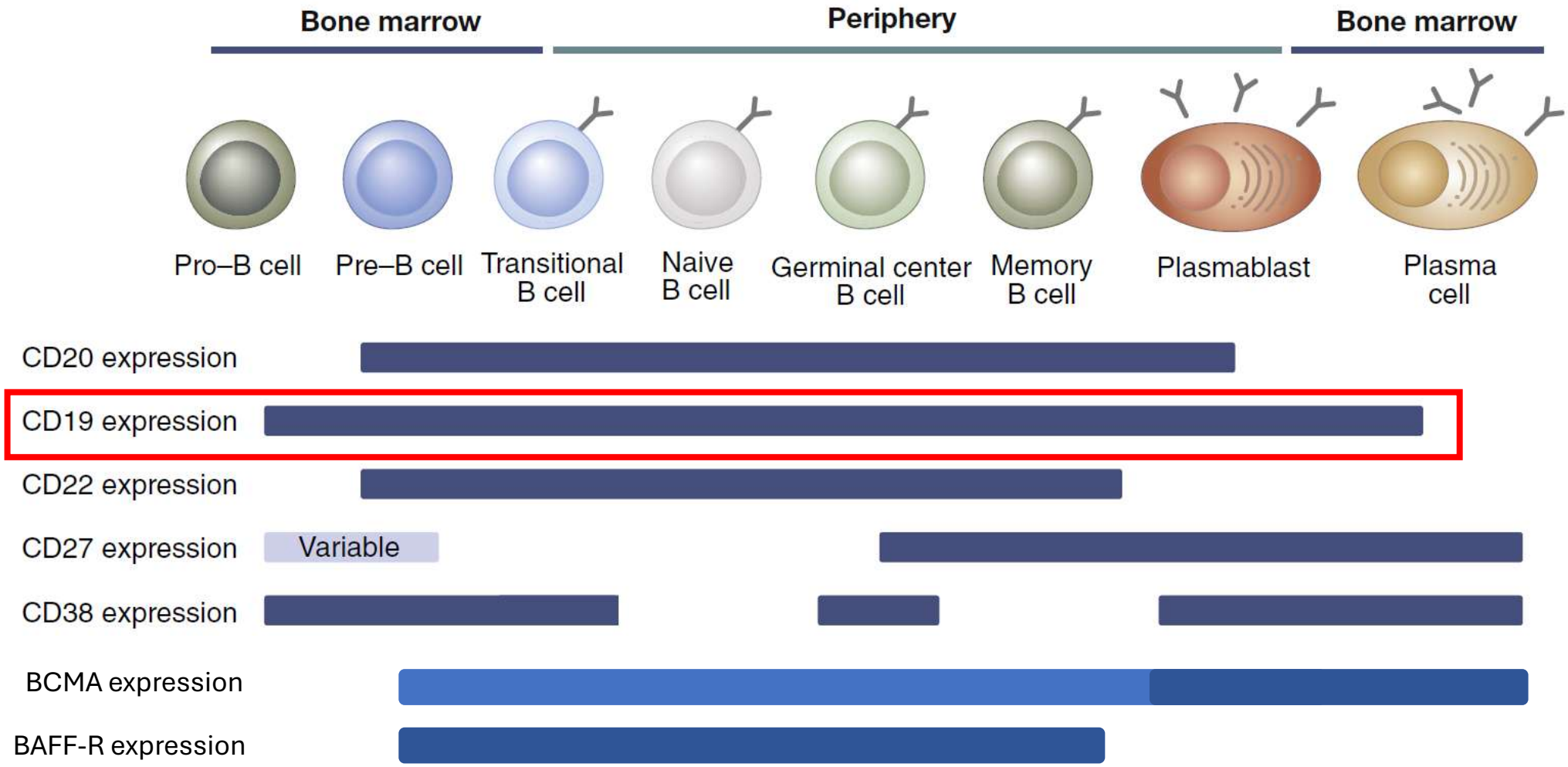
Anti-CD20 de nouvelle génération : une meilleure efficacité ?

- Preuve de concept dans les hémopathies malignes (LLC)
- Efficace en cas de maladie sérique / réaction au RTX
- Données prometteuses chez des patients avec GEM réfractaire au RTX, essais en cours
- Obinutuzumab désormais recommandé par l'EULAR dans la néphrite lupique en première intention
- Beaucoup d'autres indications, souvent mal évaluées et notamment sans comparaison directe avec le RTX

Trial acronym	Description	Number, study participants	Centre	Entry	Intervention	Primary outcome measure	Registration number
pMN							
MAJESTY phase III	randomized, open-label active comparator-controlled	142, completed	Multicentre, 11 countries	pMN	OBI vs. TAC	CR at Week 104	NCT-04629248
ORION phase II	pilot study	20, recruiting	Single centre	pMN	RTX vs. OBI	CR or PR of NS at 12 months	NCT-05050214
LN							
NOBILITY phase II	randomized, double blind, placebo-controlled	125, completed	Multicentre	LN, class III/IV ISN/RPS 2003	OBI vs. placebo	CRR at week 52	NCT-02550652
REGENCY phase III	randomized, double blind, placebo-controlled	271, completed	Multicentre	LN, class III/IV ISN/RPS 2003	OBI vs. placebo	CRR at week 76	NCT-04221477
ALLEGORY phase III	randomized, double blind, placebo-controlled	300, estimated	Multicentre	SLE	OBI vs. placebo	SRI 4 at week 52	NCT-04963296
OBILUP phase III	randomized, open label, controlled non-inferiority	196, estimated	Multicentre	LN, class III or IV (A or A/C) ± V with active lesions in at least 10% of the viable glomeruli	OBI/MMF vs GC/MMF	CRR at week 52	NCT-04702256
ANCA-associated vasculitides							
OBIVAS phase II	randomized, double blind, controlled	26, recruiting	Single centre	PR3-AAV	OBI vs. RTX	CD19$^+$ B-cell depletion in nasal-associated lymphoid tissue	-
Focal segmental glomerulosclerosis/minimal change disease/nephrotic syndrome							
-phase II	single-arm, open label	20, completed	Single centre	IS-resistant pFSGS	OBI	Change in proteinuria at 6 months, 12 months	NCT-04983888

Goede et al., NEJM 2014
Reddy et al., Rheumatology 2017
Faniourakis et al., ARD 2026
Rossi et al., Nephrol Dial Transplant , 2025

Cibler le lymphocyte B et le plasmocyte



Anti-CD19 – anticorps monoclonaux

- Inebilizumab : efficacité démontrée dans la NMO et la MAG4 (sans comparaison directe avec RTX)
- Tafasitamab : protocoles en cours

Cree et al., Lancet 2019
Stone et al., NEJM 2025

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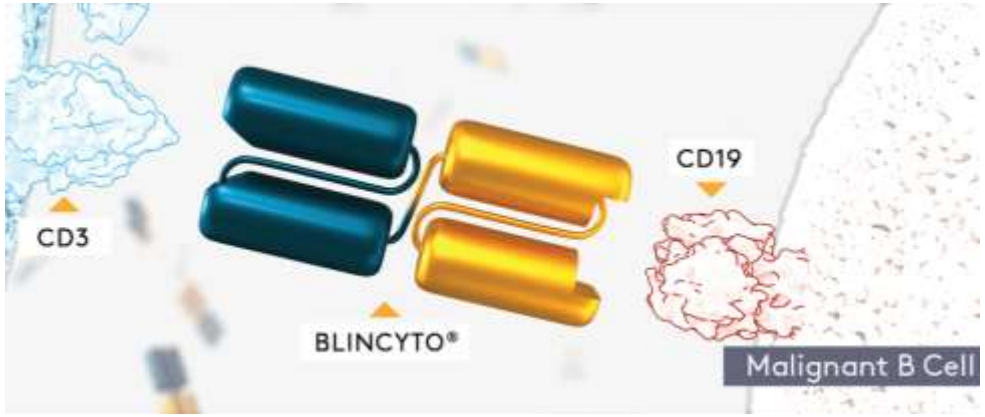
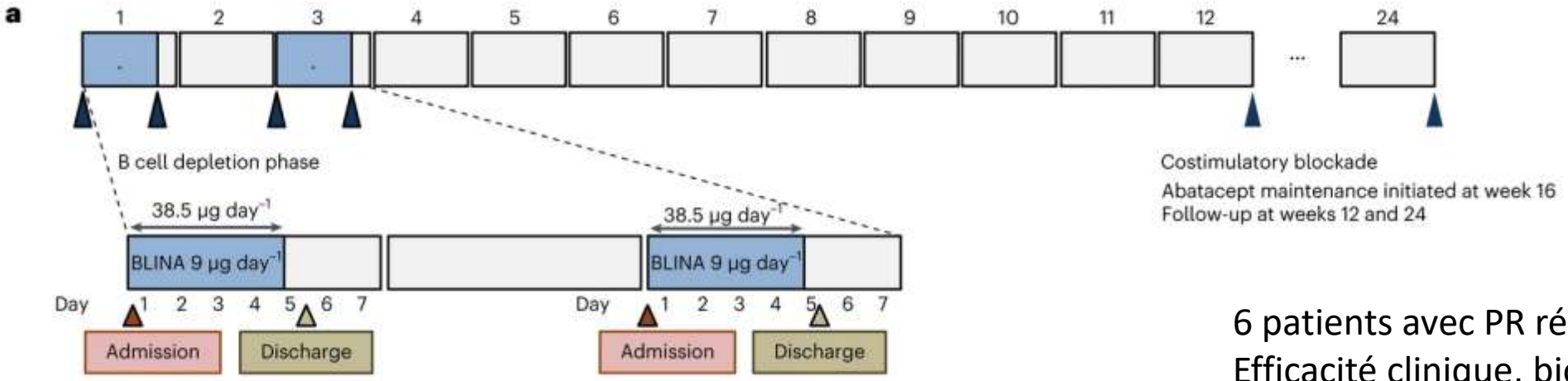
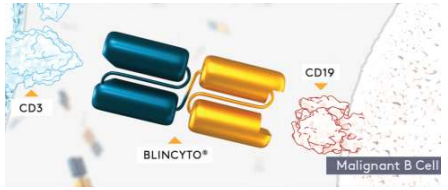
- Blinatumomab (CD3 x CD19 Bi-specific T cell engager)

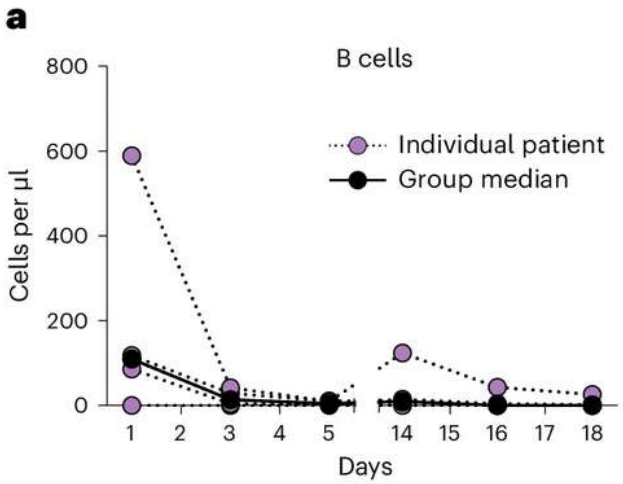


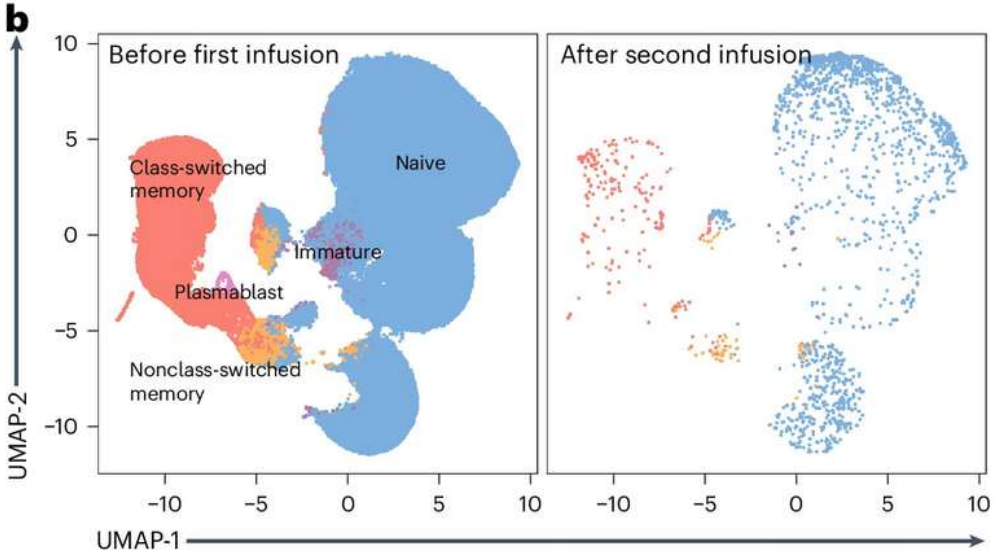
Blinatumomab





6 patients avec PR réfractaire
Efficacité clinique, biologique et échographique

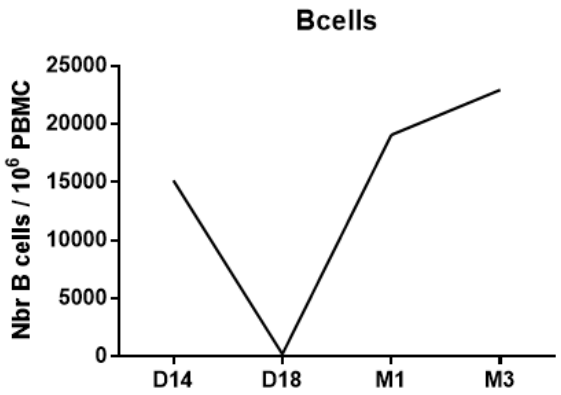


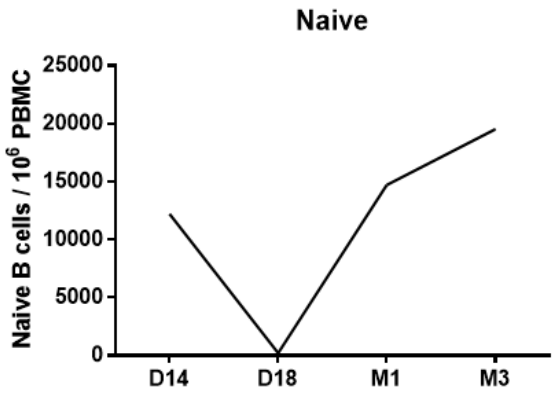


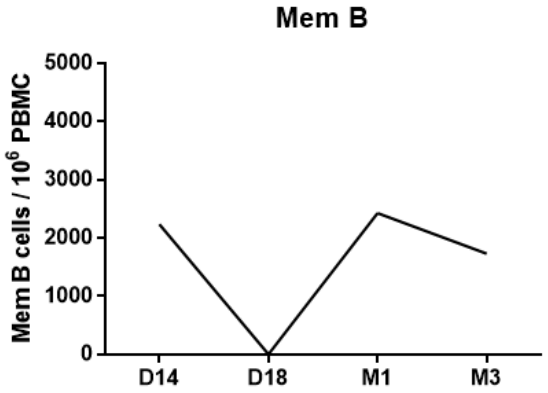
Bucci et al., Nature medicine 2024

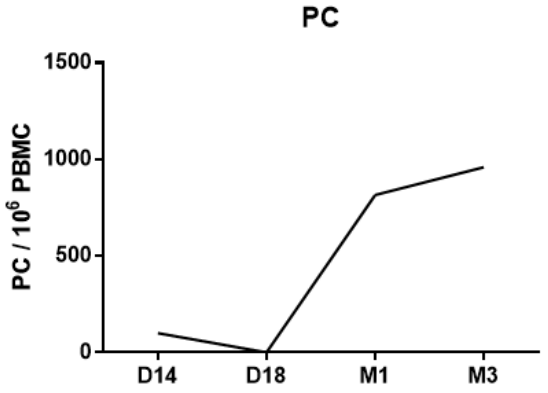
Blinatumomab

1 patient avec PTI réfractaire traité avec le même schéma :
Echec de traitement



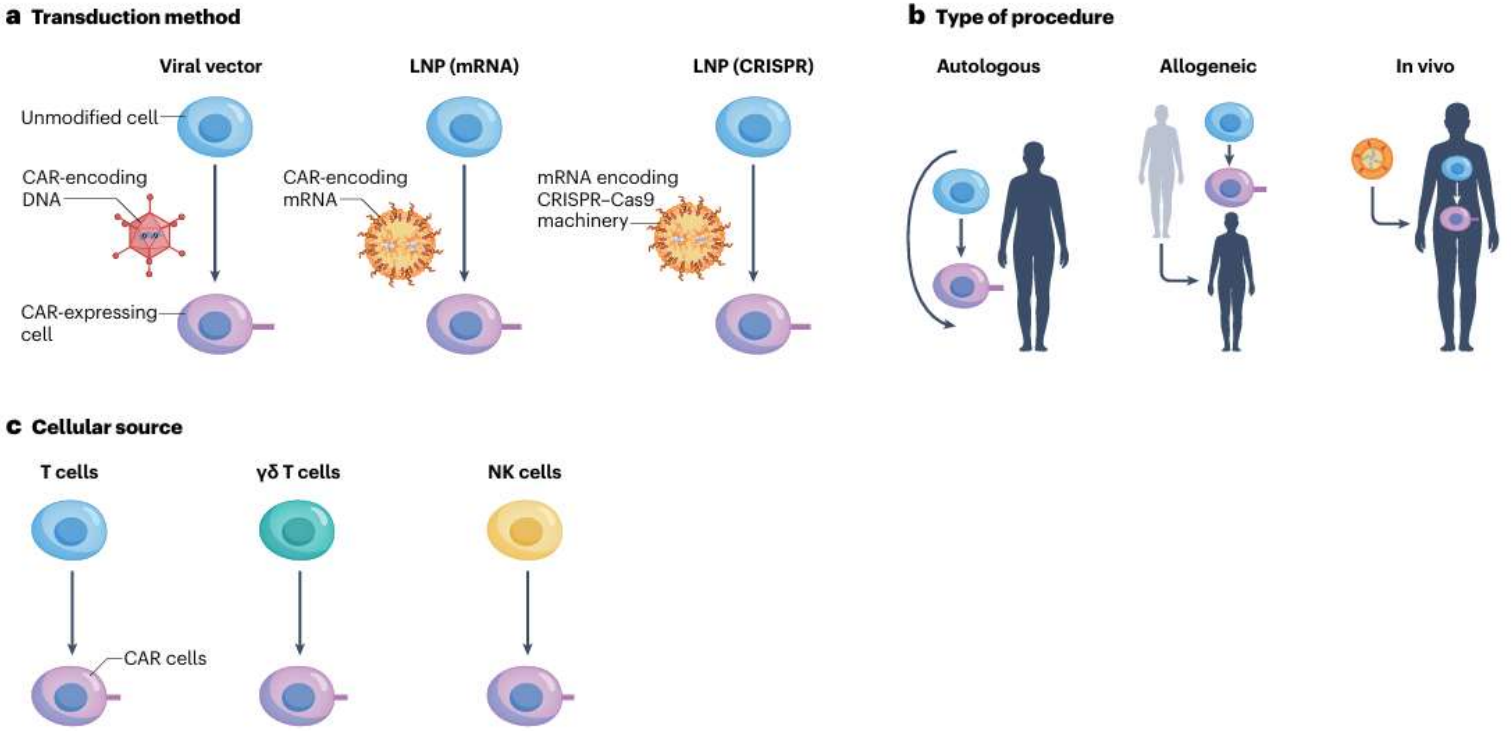






Données non publiées

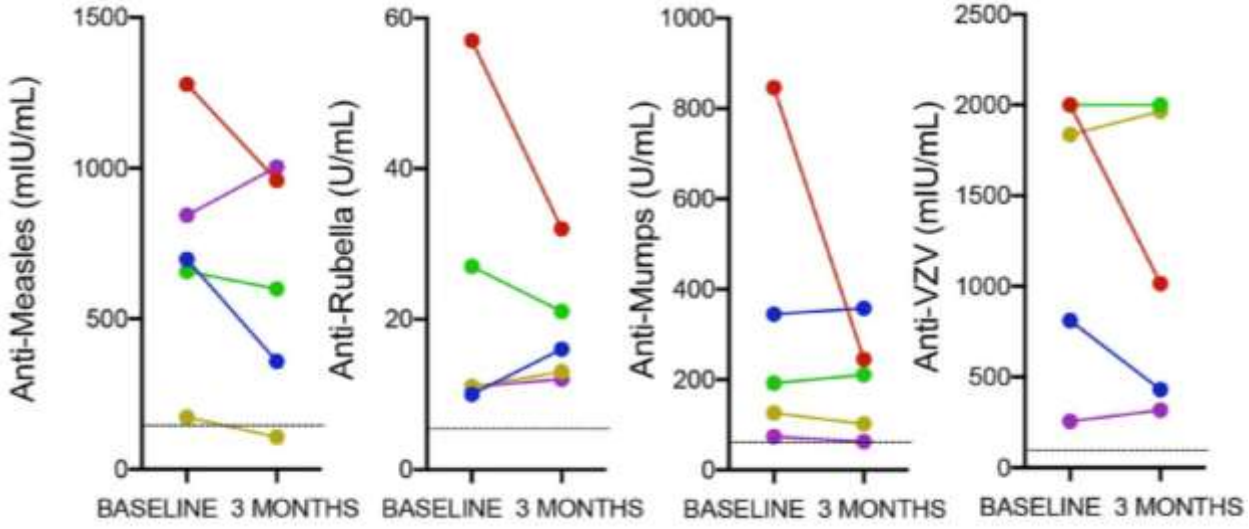
CAR-T cells anti-CD19

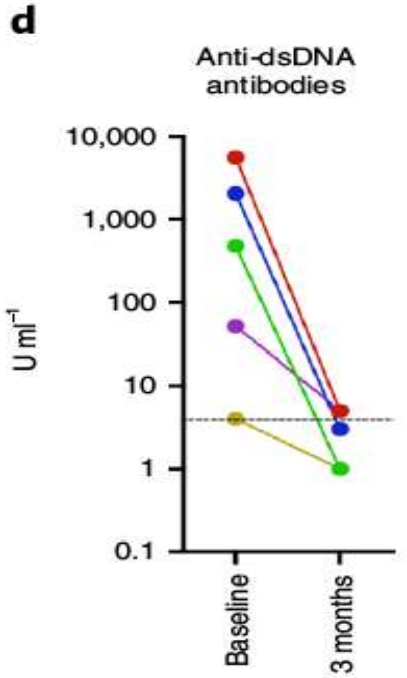


CAR	Dose and conditioning	Safety	Clinical outcome
Systemic lupus erythematosus			
MB-CART19.1: mouse anti-CD19 scFv, CD8 hinge, TNFRSF19 transmembrane domain, 4-1BB co-stimulatory domain, CD3ζ activation domain	1×10^8 cells kg^{-1} CYC 1,000 mg $m^{-2} \times 1$ day FLU 25 mg $m^{-2} \times 3$ days	No CRS or ICANS	Very rapid (~1 month) and profound improvement in autoantibody levels and clinical disease activity
MB-CART19.1: mouse anti-CD19 scFv, CD8 hinge, TNFRSF19 transmembrane domain, 4-1BB co-stimulatory domain, CD3ζ activation domain	1×10^8 cells kg^{-1} CYC 1,000 mg $m^{-2} \times 1$ day FLU 25 mg $m^{-2} \times 3$ days	Grade 1 CRS in 3 of 5 patients; no ICANS	Favourable safety, strong efficacy and durability of drug-free remission confirmed B cells returned in all patients after a median of 110 days
Anti-BCMA-CD19 compound CAR: 2-unit scFv with anti-BCMA fused to anti-CD19 by a self-cleaving P2A peptide	$1.5–3 \times 10^6$ cells kg^{-1} Conditioning was used (agents not specified)	Grade 1 CRS; no ICANS	Reduced autoantibodies and prolonged disease remissions IVIG was administered monthly until B cell recovery
Systemic sclerosis			
MB-CART19.1: mouse anti-CD19 scFv, CD8 hinge, TNFRSF19 transmembrane domain, 4-1BB co-stimulatory domain, CD3ζ activation domain	1×10^8 cells kg^{-1} CYC 500 mg $m^{-2} \times 1$ day FLU 12.5 mg $m^{-2} \times 3$ days	Grade 1 CRS; no ICANS	Reduction in autoantibodies, reduction in fibroblast activation, and clinical stabilization or improvement
Mouse anti-CD19 scFv, human IgG1–CH2CH3 hinge, CD28 transmembrane domain, CD28 and 4-1BB co-stimulatory domains, CD3ζ activation domain	5×10^8 cells kg^{-1} CYC 500 mg $m^{-2} \times 3$ days FLU 30 mg $m^{-2} \times 3$ days	Grade 1 CRS; no ICANS	Reduction in autoantibodies, reduction in fibroblast activation, and clinical improvement in skin fibrosis and lung function Prolonged CAR T cell persistence
Idiopathic inflammatory myopathy			
MB-CART19.1: mouse anti-CD19 scFv, CD8 hinge, TNFRSF19 transmembrane domain, 4-1BB co-stimulatory domain, CD3ζ activation domain	1×10^8 cells kg^{-1} CYC 1,000 mg $m^{-2} \times 1$ day FLU 25 mg $m^{-2} \times 3$ days	Grade 1 CRS; no ICANS	Positive clinical impact with disappearance of autoantibodies and dramatic resolution of myositis and alveolitis
Anti-CD19 scFv, co-stimulatory domain, CD3ζ signalling domain	1.23×10^6 cells kg^{-1} CYC 1,000 mg $m^{-2} \times 1$ day FLU 25 mg $m^{-2} \times 3$ days	Grade 1 CRS; no ICANS	Efficacy and safety comparable with report by Müller et al.[33], but worsening of myalgia and CK elevation post CAR T cell treatment managed with MMF
Systemic lupus erythematosus, systemic sclerosis or idiopathic inflammatory myopathy			
MB-CART19.1: mouse anti-CD19 scFv, CD8 hinge, TNFRSF19 transmembrane domain, 4-1BB co-stimulatory domain, CD3ζ activation domain	1×10^8 cells CYC 1 g m^{-2} FLU 75 mg	Grade 1–2 CRS (9 of 15); Grade 1 ICANS (1 of 15)	Tolerability similar for patients with any of the conditions
Myasthenia gravis			
Descartes-08: RNA CAR T cell, mouse anti-BCMA scFv, CD8 HTM domains, CD28 co-stimulatory domain, CD3ζ activation domain	$3.5–52.5 \times 10^6$ cells kg^{-1} 2× per week–1× per month dosing No lymphodepletion	No CRS or ICANS	Clinical improvement Immunosuppressive therapy was continued and there was no clear decrease in autoantibodies or serum IgG
KYV-101: human anti-CD19 scFv, CD8α HTM domains, CD28 co-stimulatory domain, CD3ζ activation domain	1×10^8 cells CYC 300 mg $m^{-2} \times 3$ days FLU 30 mg $m^{-2} \times 3$ days	No CRS or ICANS	Rapid improvement of clinical disease activity scores and reduction of acetylcholine receptor-specific autoantibodies
Multiple sclerosis			
KYV-101: human anti-CD19 scFv, CD8α HTM domains, CD28 co-stimulatory domain, CD3ζ activation domain	1×10^8 cells CYC 300 mg $m^{-2} \times 3$ days FLU 30 mg $m^{-2} \times 3$ days	Grade 1 CRS (1 of 2); no ICANS	Acceptable safety and CAR T cell enrichment in the CSF without neurotoxicity, with reduced intrathecal antibodies in one patient

Schett et al, Nature Rev Rheum 2024

CAR-T cells anti-CD19 et plasmocytes à longue vie



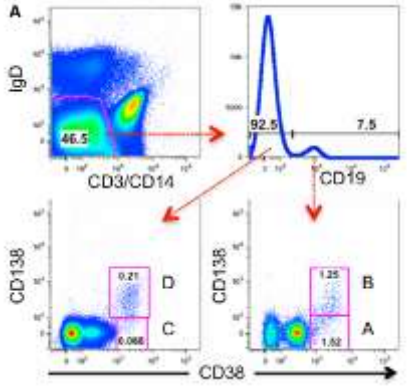


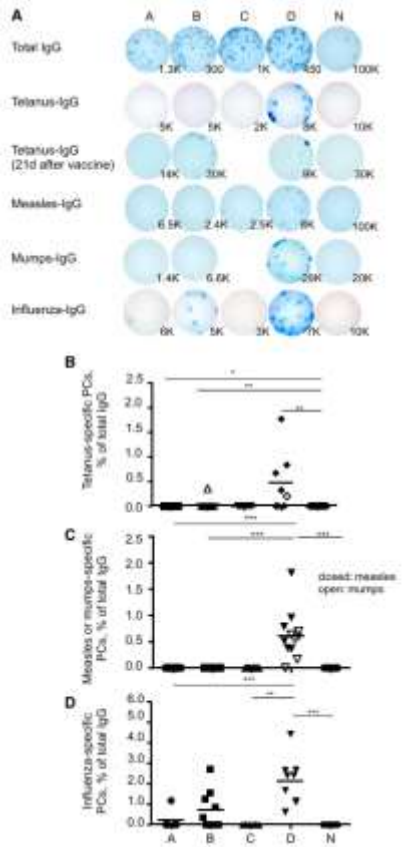
Mackensen et al, Nature medicine 2022

Maturation plasmocytaire

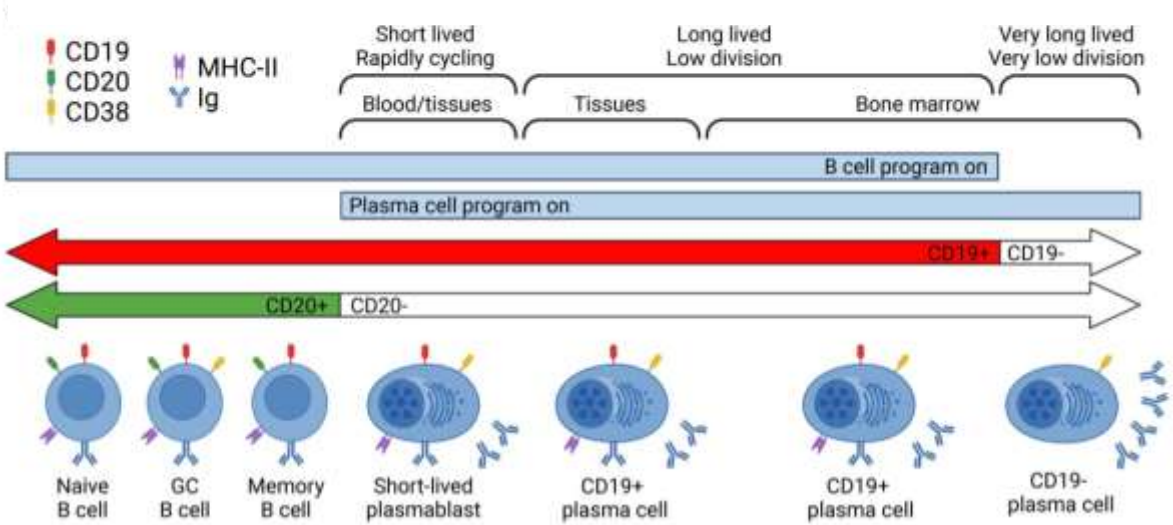
- Compartiment PC CD19- initialement considéré comme à longue durée de vie

- Courte durée de vie et CD19+ ne sont pas synonymes

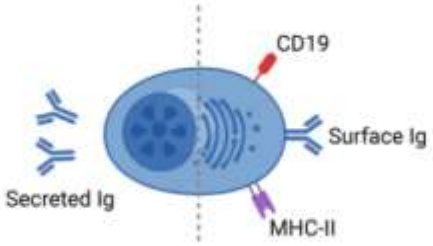




Mei et al, Blood 2015
Halliley et al, Immunity 2015
Suan et al, JI 2025



Plasma cell program
- BLIMP-1
- XBP1
- IRF4
- J chain
- BCMA
- CD38/CD138
- CD28



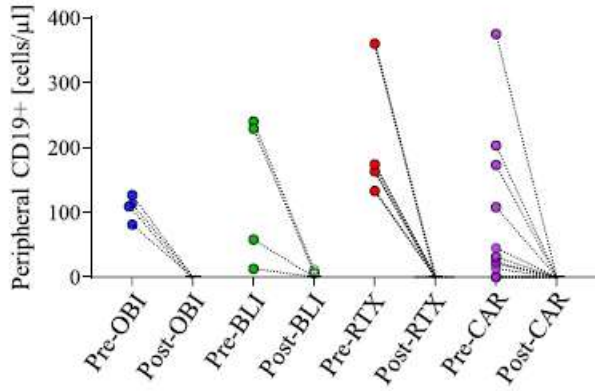
B cell program
- PAX5
- EBF1
- CD19
- Surface Ig
- MHC-II
- CD79A/CD79B
- BTK
- SYK

Déplétion B tissulaire

Treatment	Dose
CD19 CAR-T cells	MB-CART19.1 (Miltenyi), 1×10^6 cells/kg after CYC + Fluda
Obinutuzumab	1000 mg J1 J15
Rituximab	1000 mg J1 J15
Blinatumomab	38.5µg (days 0 to 4), and 112µg (days 11 to 15)

24 patients avec maladie autoimmune (SLE, RA, SSc, IIM)

B *Sang périphérique*

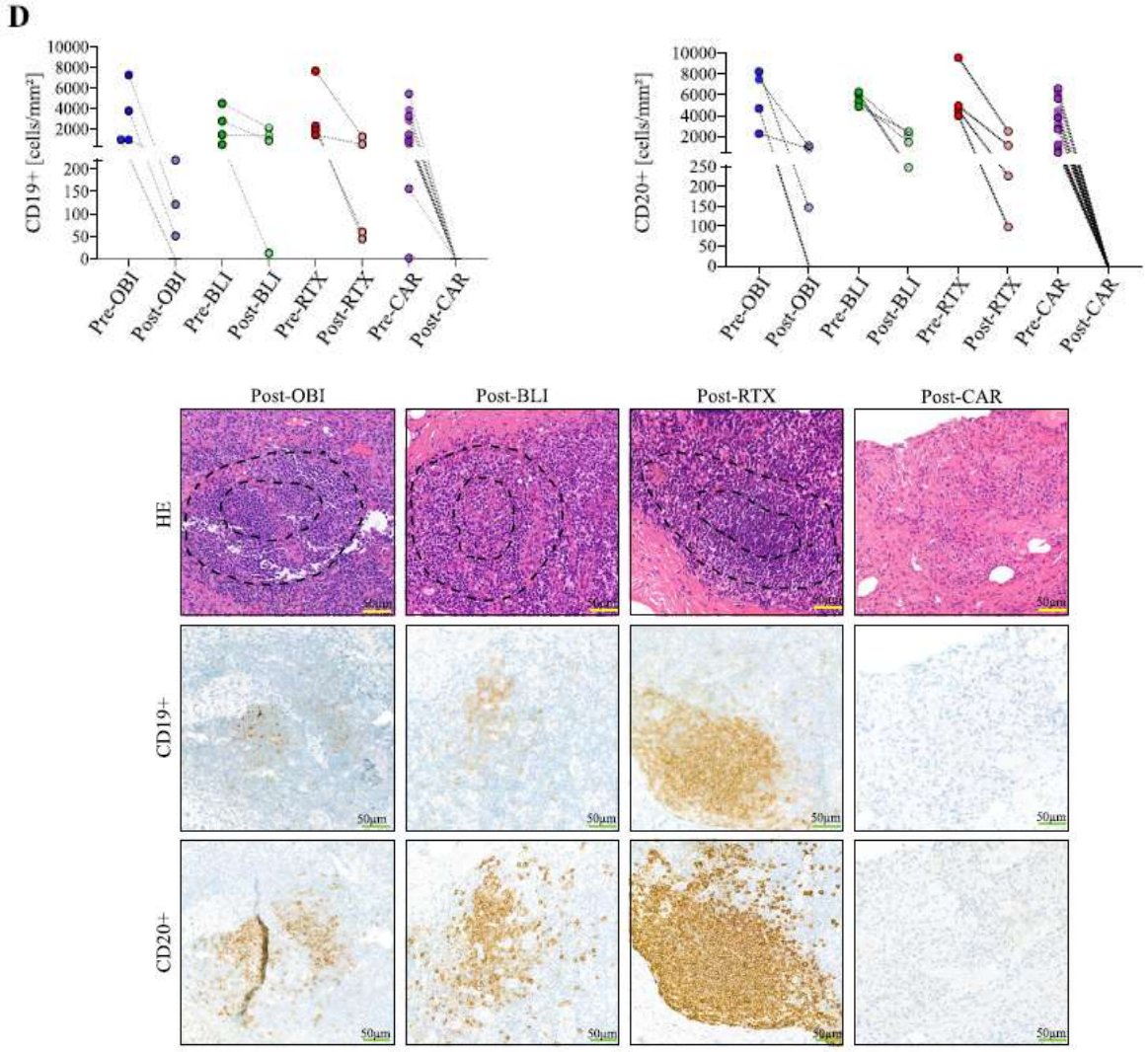


Tur et al, ARD 2025

Déplétion B tissulaire

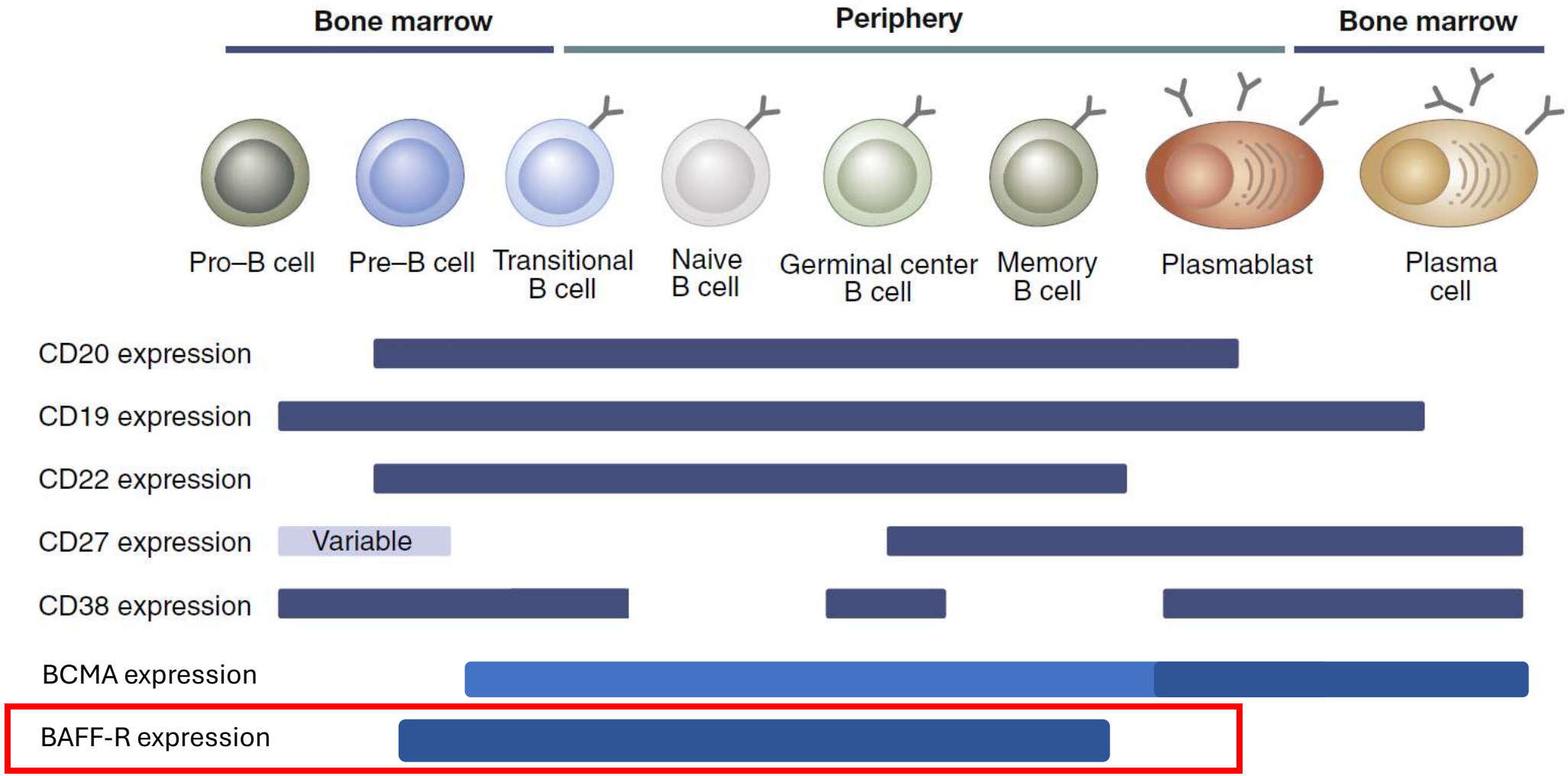
Treatment	Dose	Lymph node B-cell depletion
CD19 CAR-T cells	MB-CART19.1 (Miltenyi), 1×10^6 cells/kg after CYC + Fluda	100%
Obinutuzumab	1000 mg J1 J15	92%
Rituximab	1000 mg J1 J15	86%
Blinatumomab	38.5µg (days 0 to 4), and 112µg (days 11 to 15)	69%

Ganglion inguinal

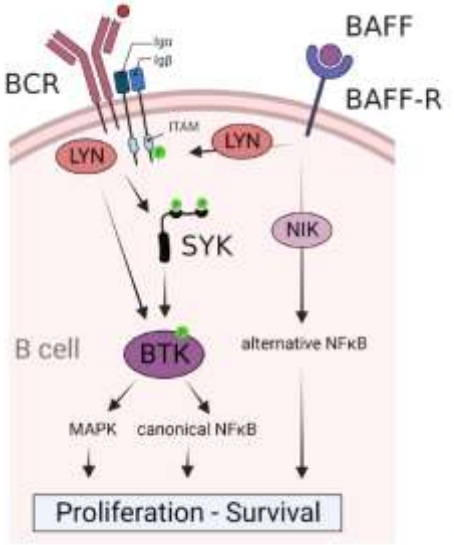


Tur et al, ARD 2025

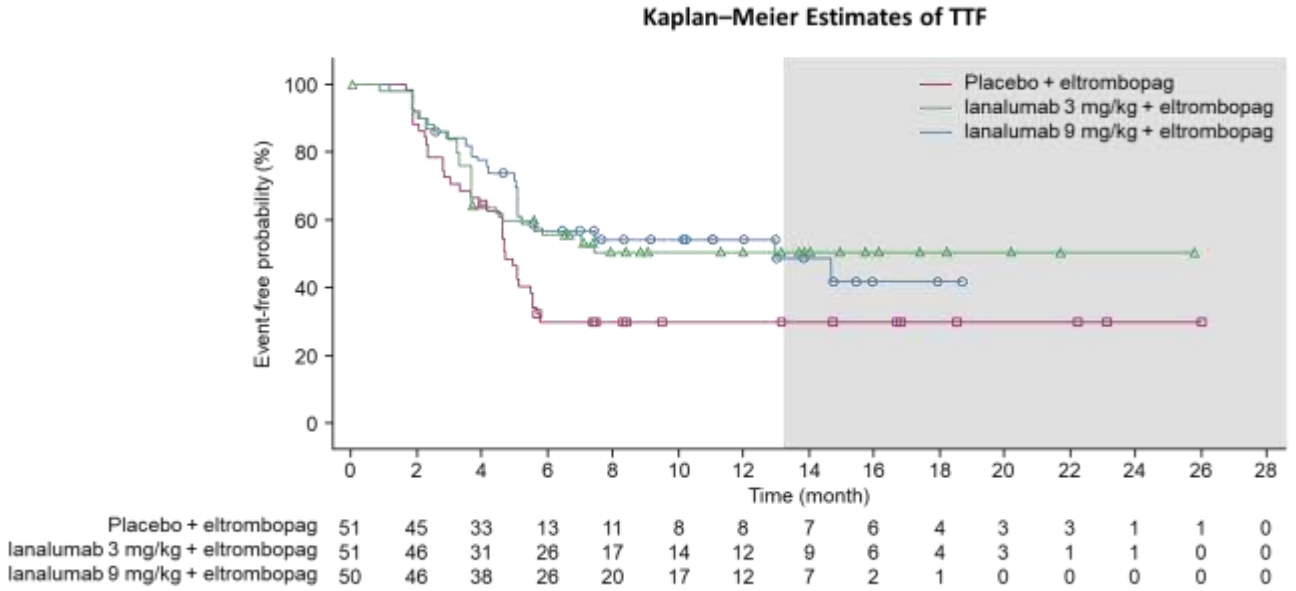
Cibler le lymphocyte B et le plasmocyte



Ianalumab



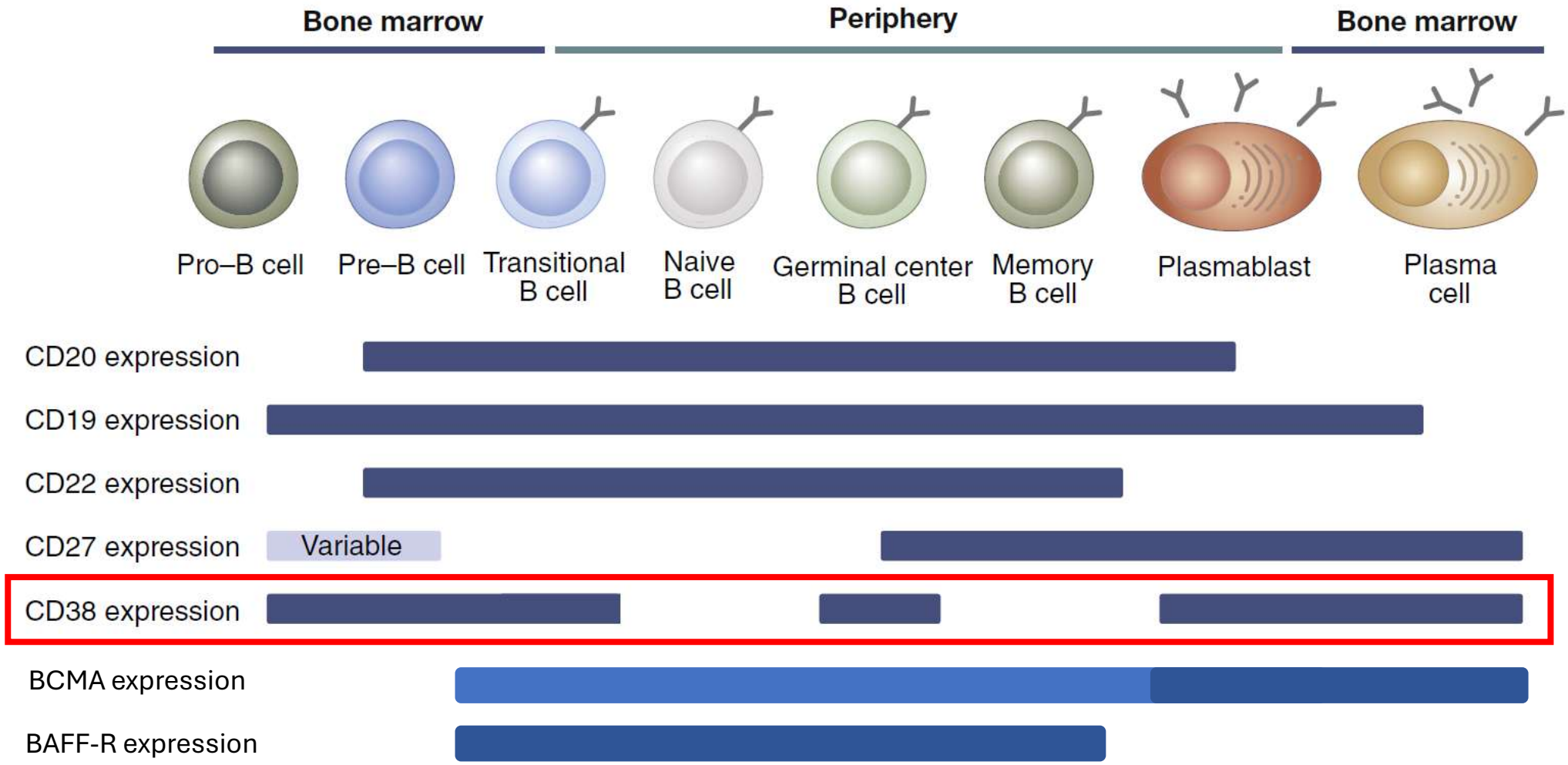
- Anticorps monoclonal anti-BAFF-R
- Efficacité montrée dans plusieurs pathologies (Sjogren et PTI)
- Pas de comparaison directe au RTX



Cuker et al, NEJM 2025

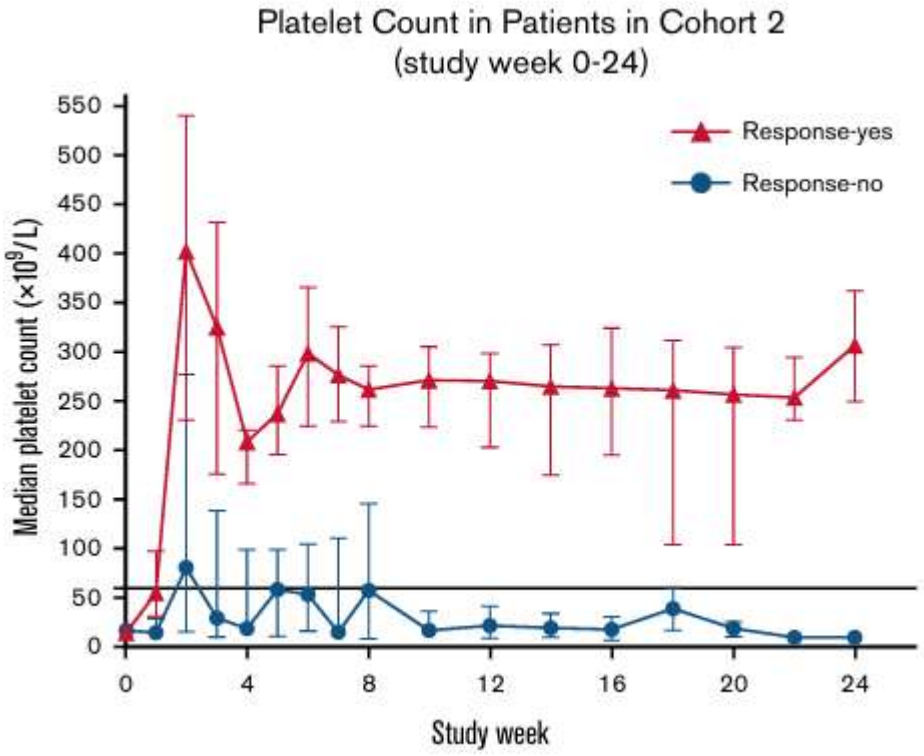
Déplétion plasmocytaire

Cibler le lymphocyte B et le plasmocyte

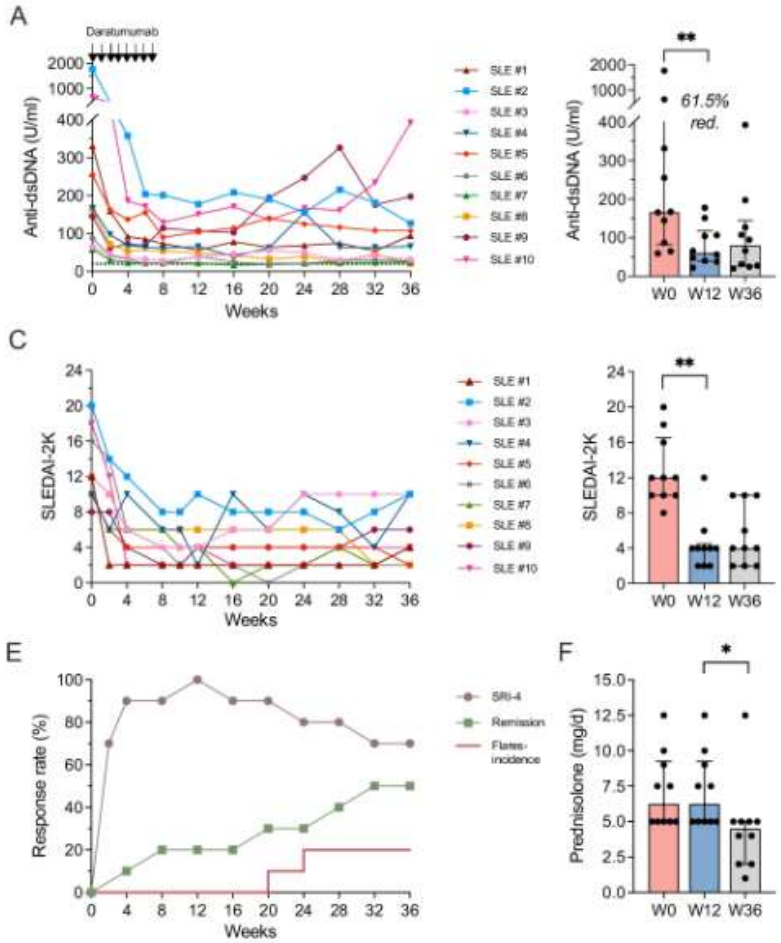


Anti-CD38

- Données avec Daratumumab, Mezagitamab, CM313 (PTI, AHAI, SLE)
- Efficacité (très) rapide chez les patients répondeurs (PTI: 40- 50 %)
- Tolérance correcte mais hypogamma et infections

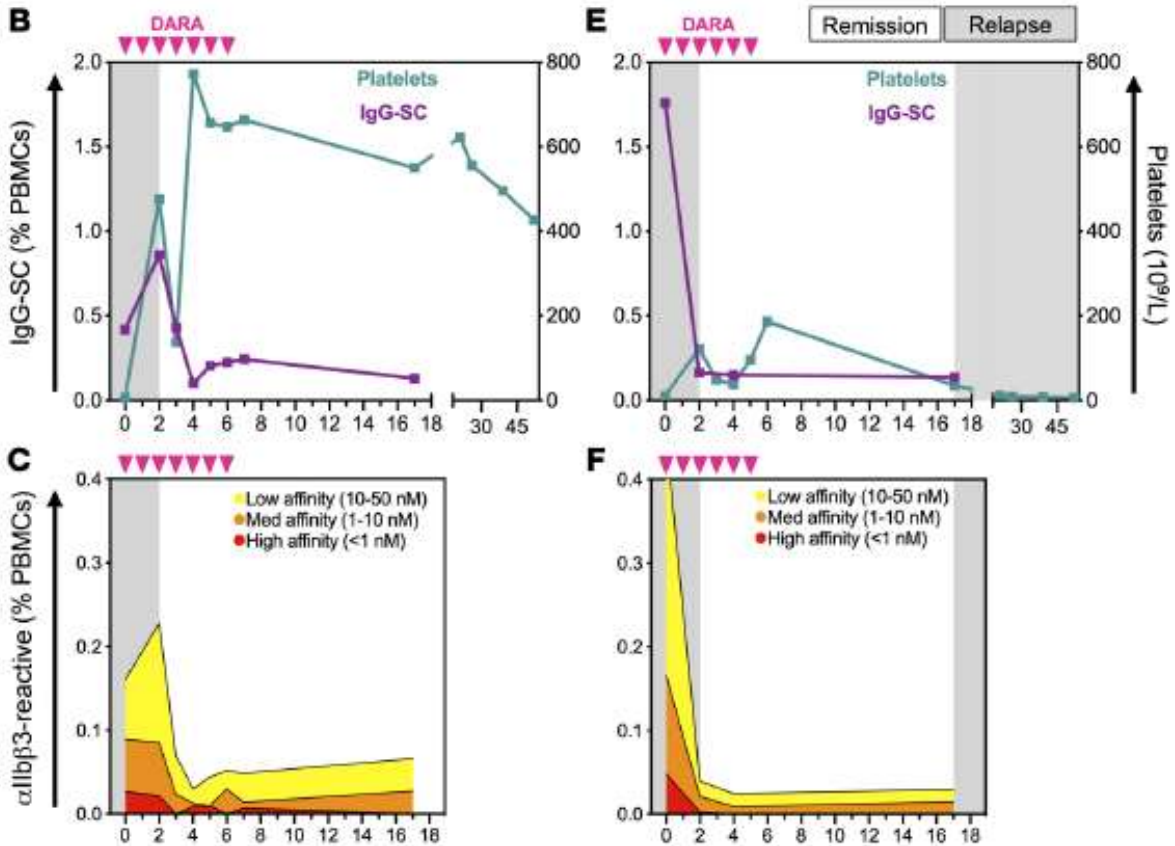


Tsykunova et al. Blood Advances 2025



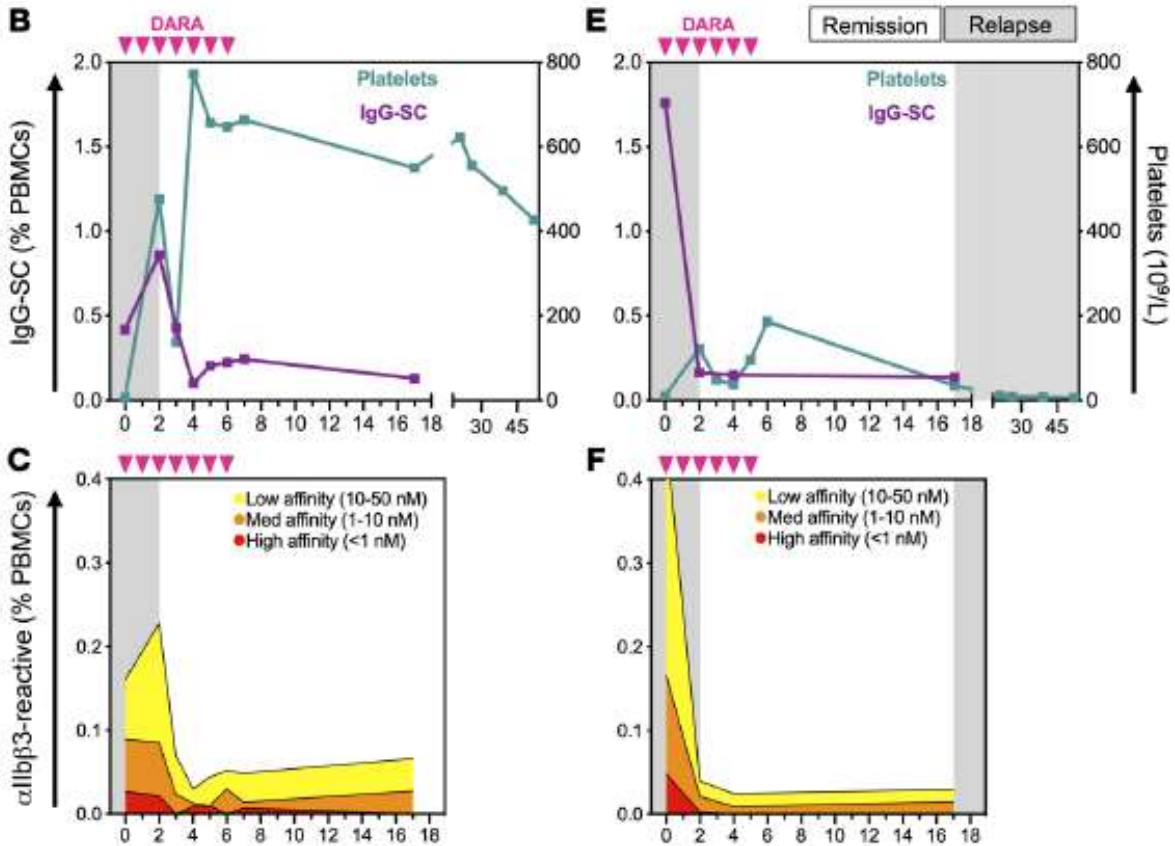
Ostendorf, Nat com 2026

Plasmocytes circulants,
patients répondeurs

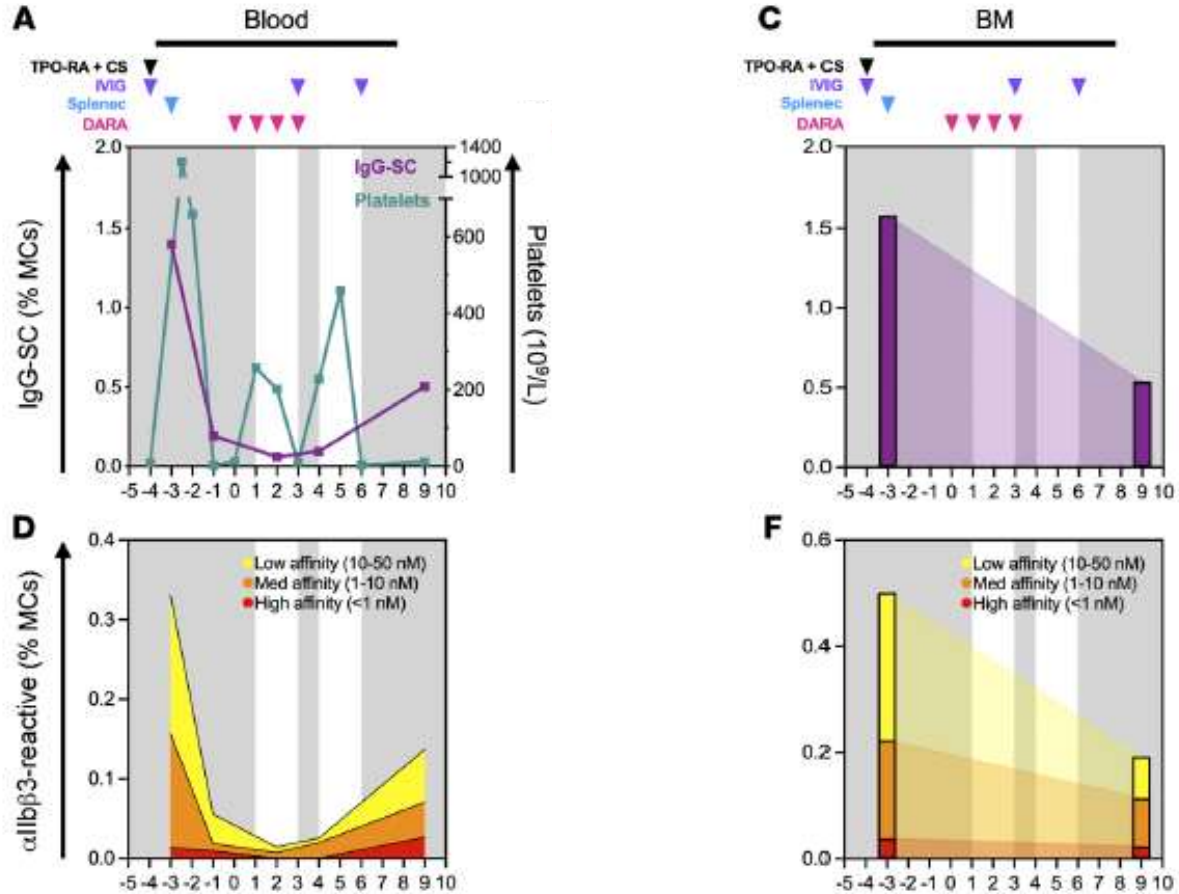


Canales, JCI 2022

Plasmocytes circulants,
patients répondeurs



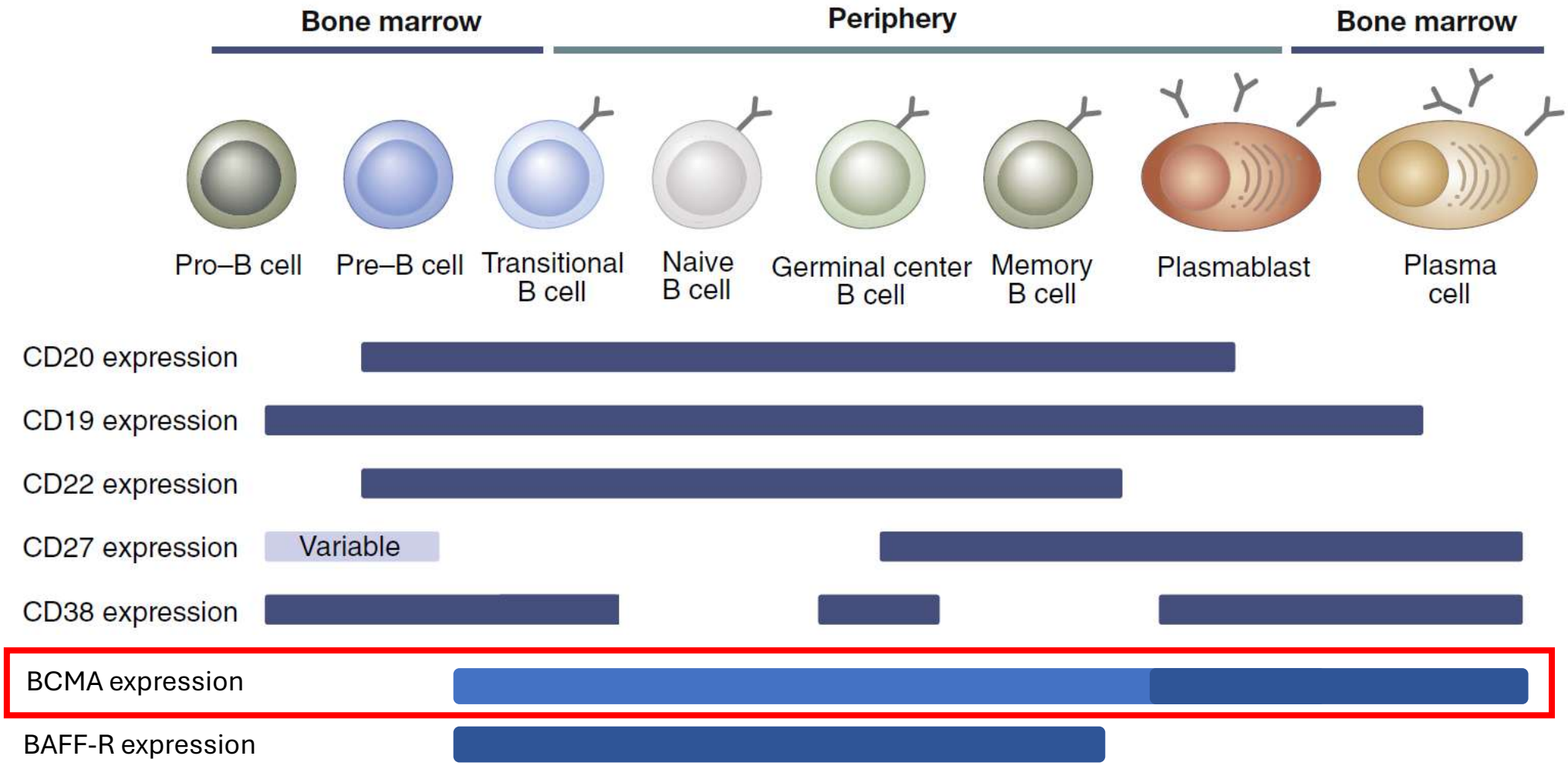
Plasmocytes circulants/médullaires,
patient réfractaire



Plasmocytes persistants sous Dara : traitement insuffisamment long ? Mécanisme de résistance ?

Canales, JCI 2022

Cibler le lymphocyte B et le plasmocyte



Anti-BCMA BiTEs (teclistamab, elranatamab)

- Nombreux case reports
- Efficacité très rapide (et systématique ?)
- CRS (peu sévères) et hypogammaglobulinémie++

Table 1. Characteristics of the Patients at Baseline and after Teclistamab Therapy.*

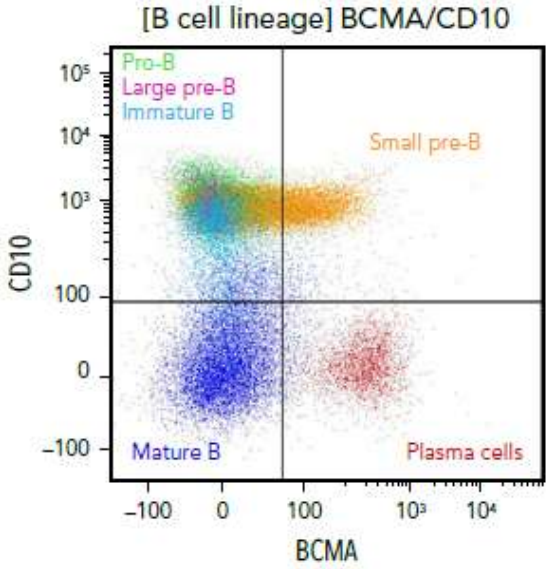
Variable	Patient Number									
	1	5	6	2	3	8	4	7	9	10
At baseline										
Disease diagnosis	Systemic sclerosis	Systemic sclerosis	Systemic sclerosis	Primary Sjögren's syndrome	Idiopathic inflammatory myositis	Idiopathic inflammatory myositis	Rheumatoid arthritis	Graves disease	IgG4-related disease	IgG4-related disease
Age — yr	60	61	51	57	24	44	52	31	66	56
Sex	Female	Male	Female	Female	Female	Female	Female	Male	Male	Male
Disease duration — yr	9	2	4	2	3	2	28	1	0.5	8
Arthritis	No	No	No	Yes	Yes	No	Yes	No	No	No
Myositis	No	No	No	Yes	Yes	Yes	No	No	No	No
Skin manifestation	Yes	Yes	Yes	Yes	Yes	No	No	No	No	No
Interstitial lung disease	Yes	Yes	Yes	Yes	Yes	No	Yes	No	No	No
Small-vessel vasculitis	No	No	No	Yes	Yes	No	No	No	No	No
Antinuclear antibodies — titer	1:3200	1:1000	1:3200	1:10,000	0	1:3200	0	0	0	0
Specific autoantibodies	PM-Scl	PM-Scl	PM-Scl, Th/To, Ro	Ro, La, PL-7	MDA 5	Mi-2	CCP2, MCV	TRAK	NA	NA
C-reactive protein — mg/liter	0.7	6.5	8.6	75	10.7	2.3	17.3	0.8	52	46.6
Previous cs/ts/bDMARDs — no.	4	6	5	6	5	5	11	1	3	6
Previous B-cell depletion	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes
Safety analysis results										
Length of follow-up after first dose — mo	15	11	7	13	10	7	11	8	5	5
Cumulative dose — μg	176.3	242.2	220.8	183.3	178.8	183.2	211.2	242.5	263.2	303.6
Grade of cytokine release syndrome	1	2	2	2	0	2	0	1	1	1
Hypogammaglobulinemia†	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Infection	URTI, GI	URTI	URTI	Cutaneous	UTI	URTI	HSV, URTI	URTI, GI	URTI	URTI
Severe infection	GI	NA	NA	NA	Cutaneous	NA	NA	GI	NA	NA
Safety measures at baseline and after therapy‡										
MRSS at baseline — U	39	34	10	NA	NA	NA	NA	NA	NA	NA
MRSS at follow-up — U	24	22	9	NA	NA	NA	NA	NA	NA	NA

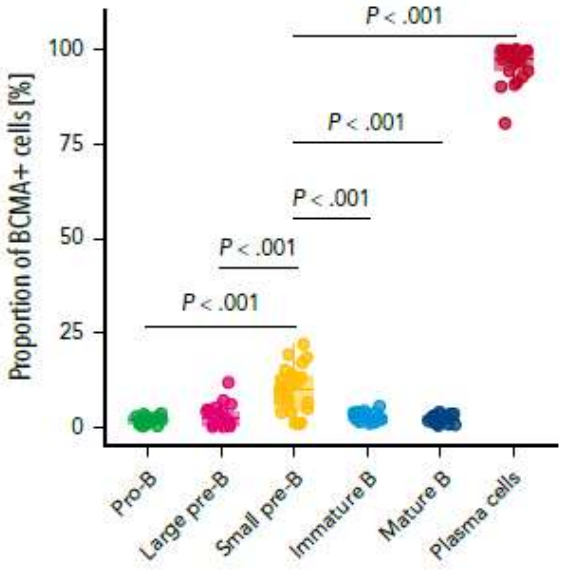
Bucci, NEJM 2025

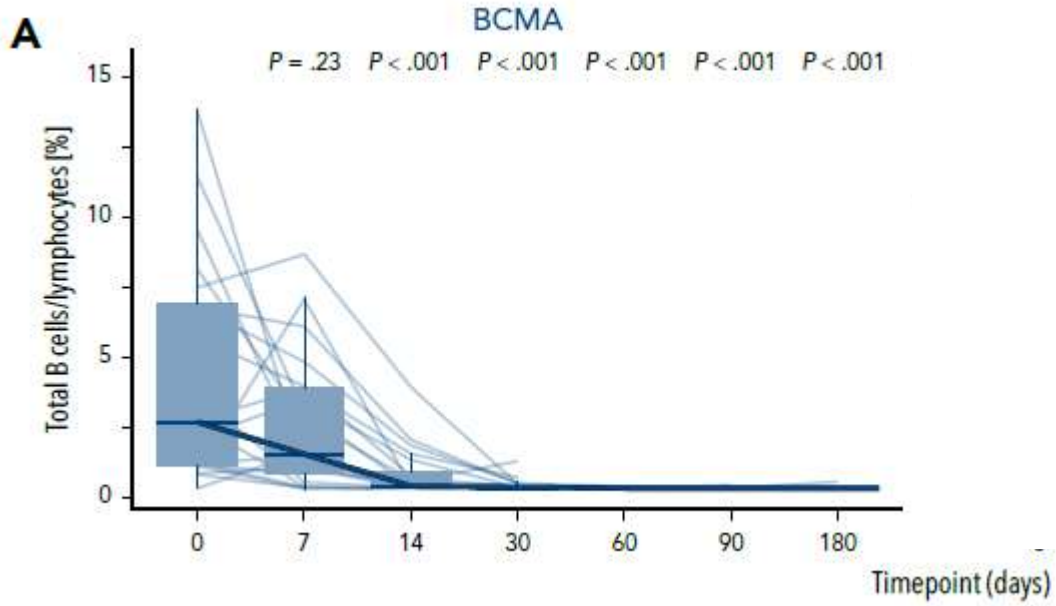
Anti-BCMA – déplétion B

Expression de BCMA sur les précurseurs B

Mais déplétion rapide des B matures après BiTE anti-BCMA

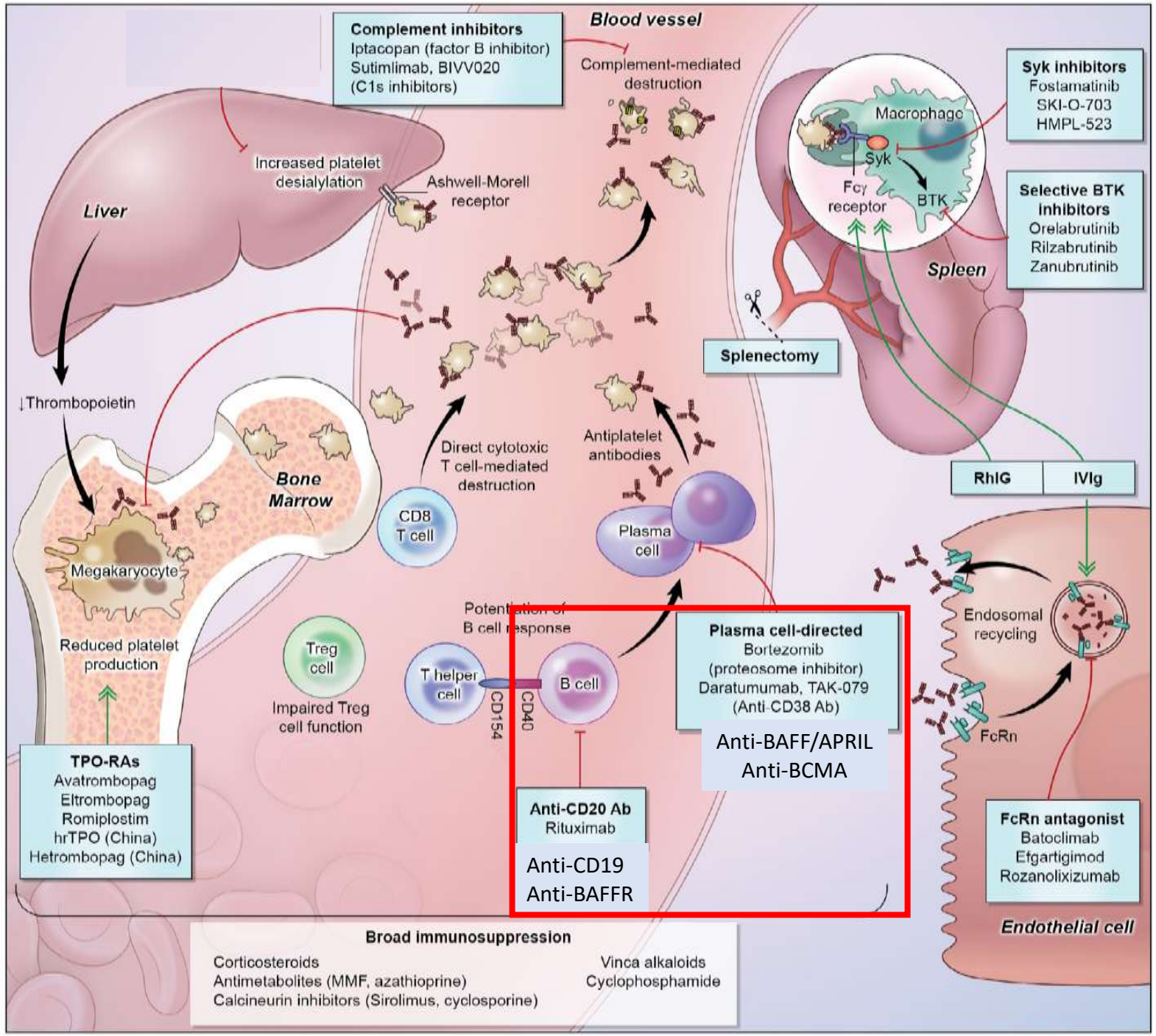






Jelinek, Blood 2026

Autres approches anti-B

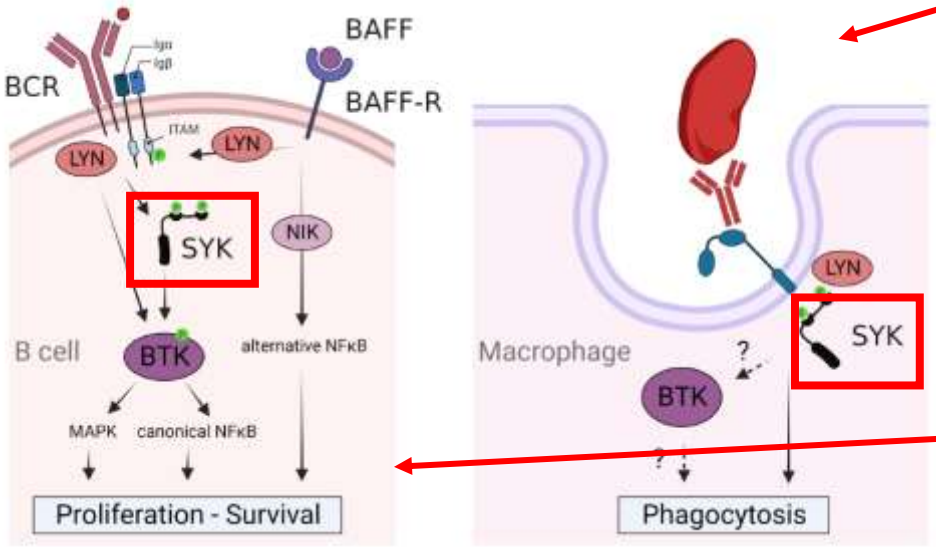


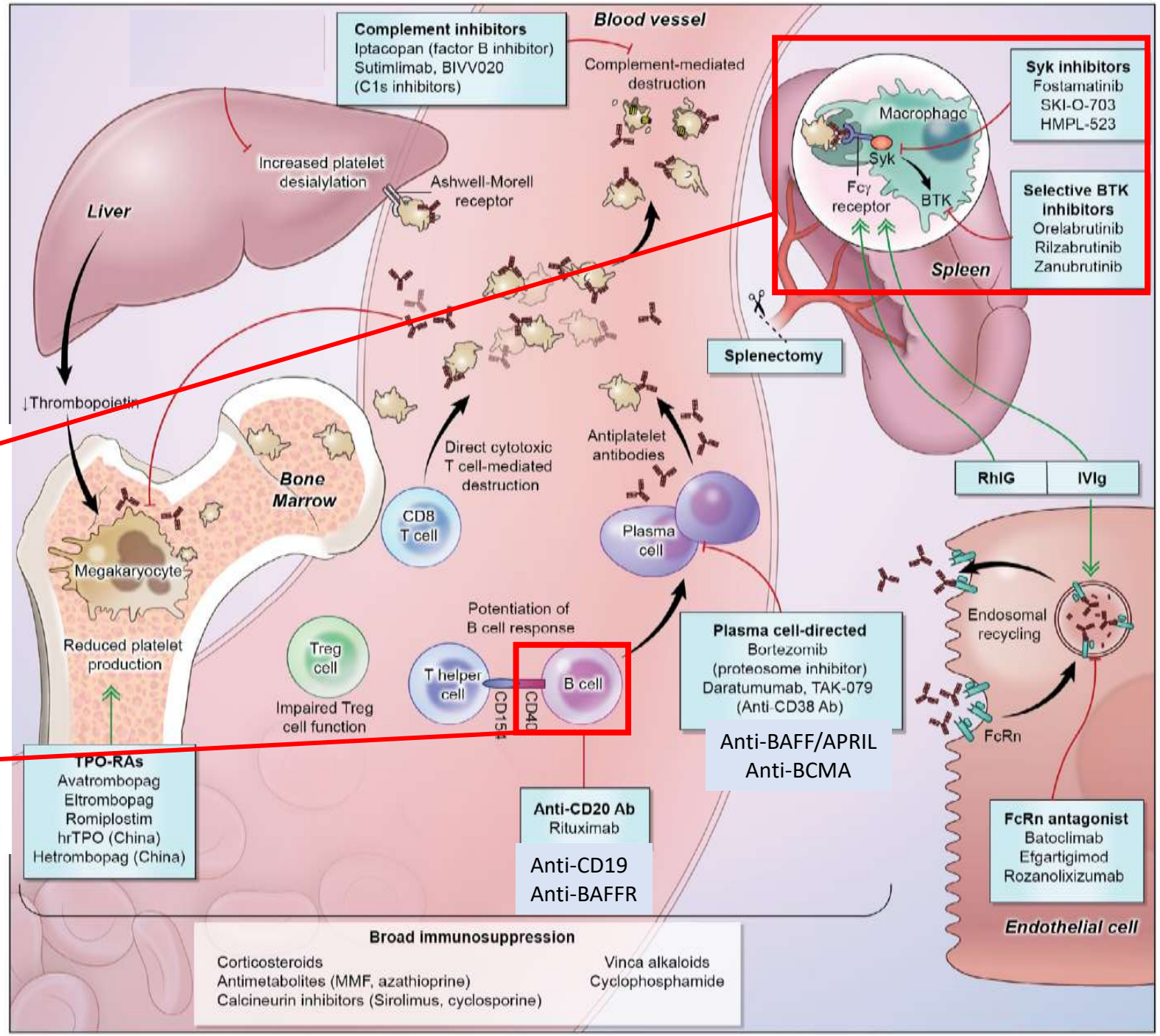
Adapté de Jiang, TMR 2022

Al-Samkary et al, AJH 2024

Anti-SYK

Fostamatinib, Sovleplenib… (PTI)



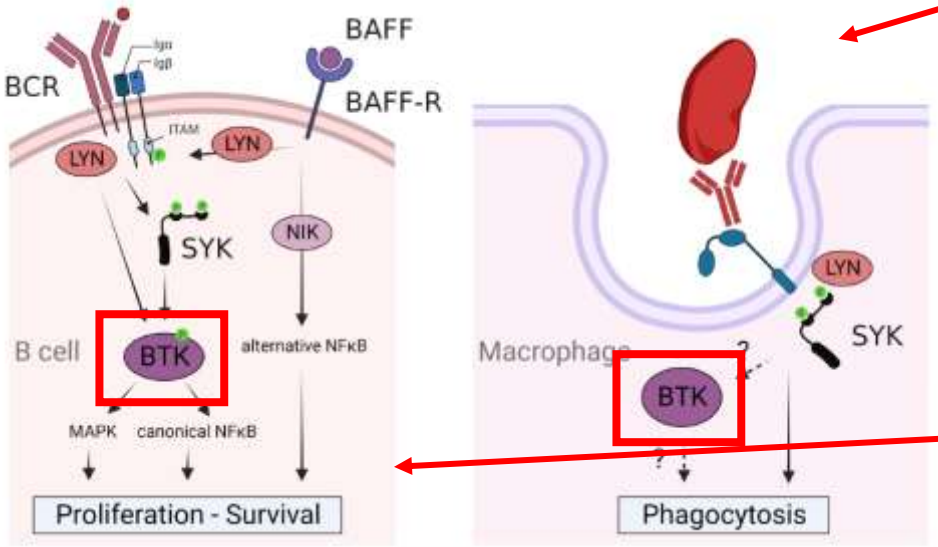


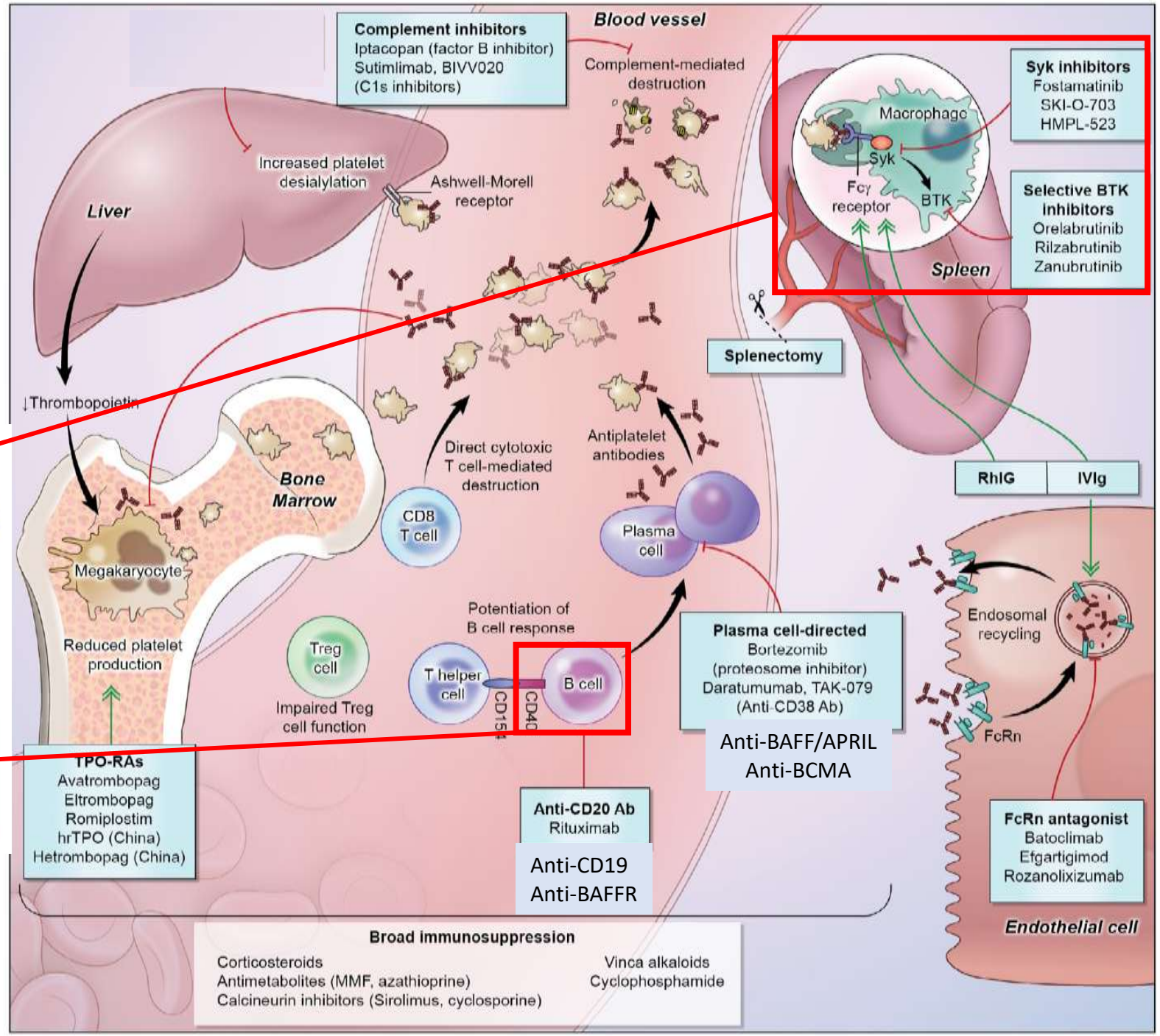
Adapté de Jiang, TMR 2022

Al-Samkary et al, AJH 2024

BTKi

Ibrutinib, rilzabrutinib, zanubrutnib… (PTI)



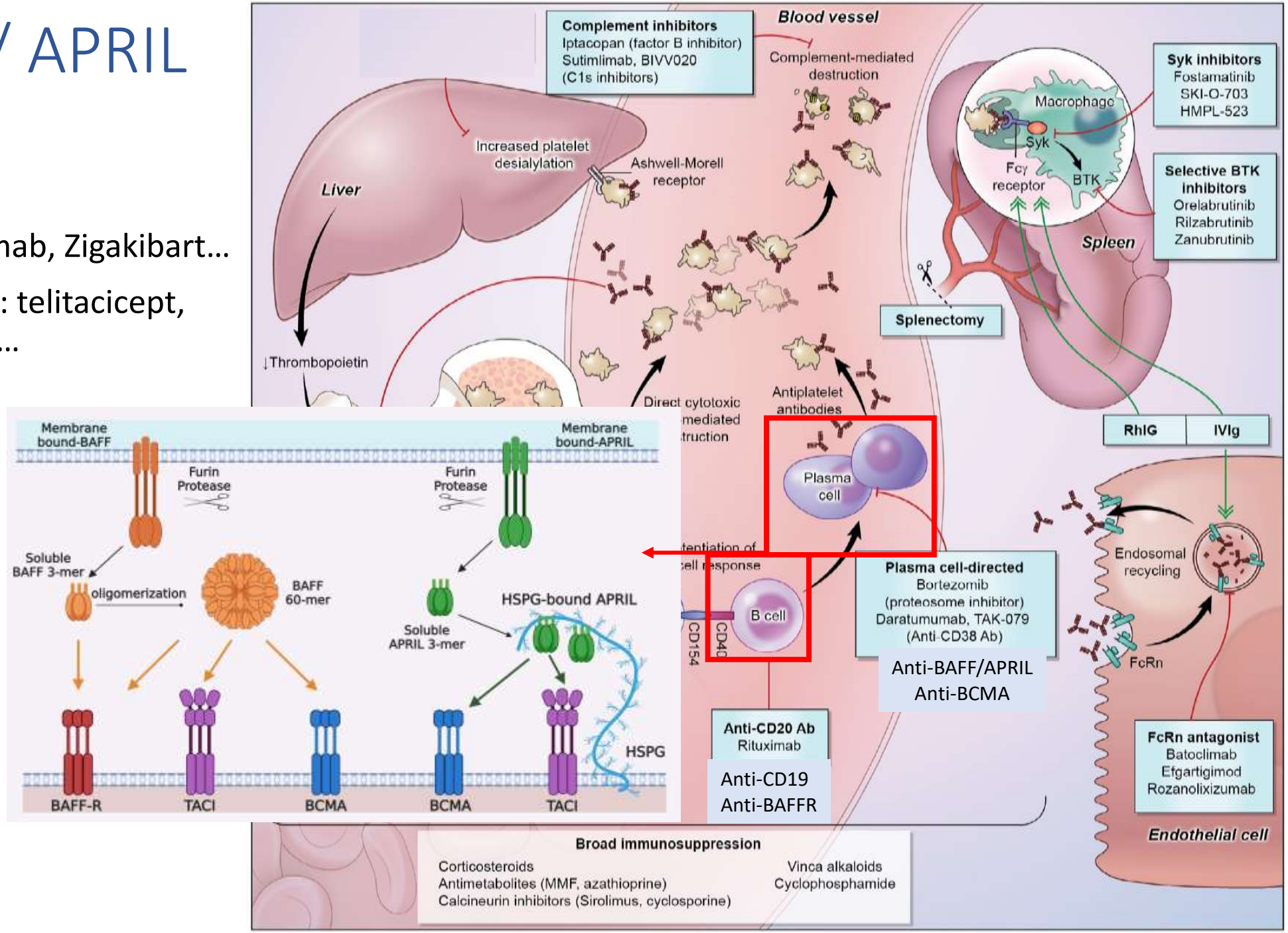


Adapté de Jiang, TMR 2022

Al-Samkary et al, AJH 2024

Anti – BAFF / APRIL

- Anti-BAFF : belimumab
- Anti-APRIL : Sibeprenlimab, Zigakibart…
- Bloqueurs BAFF / APRIL: telitacicept, atacicept, povetacicept…

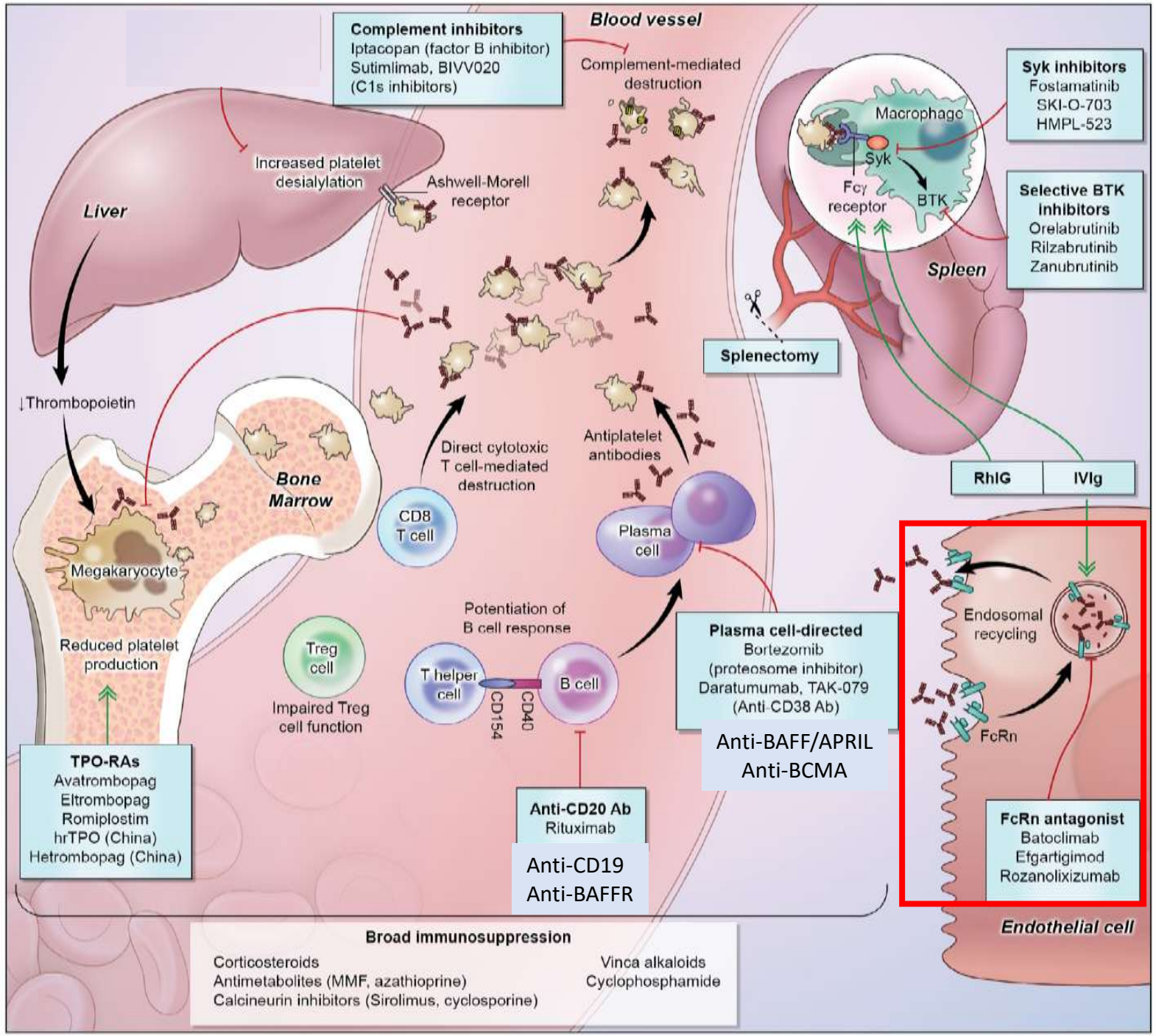


Adapté de Jiang, TMR 2022

Al-Samkary et al, AJH 2024

Anti – FcRn

Nipocalimab, efgartigimod, Rozanolixizumab…

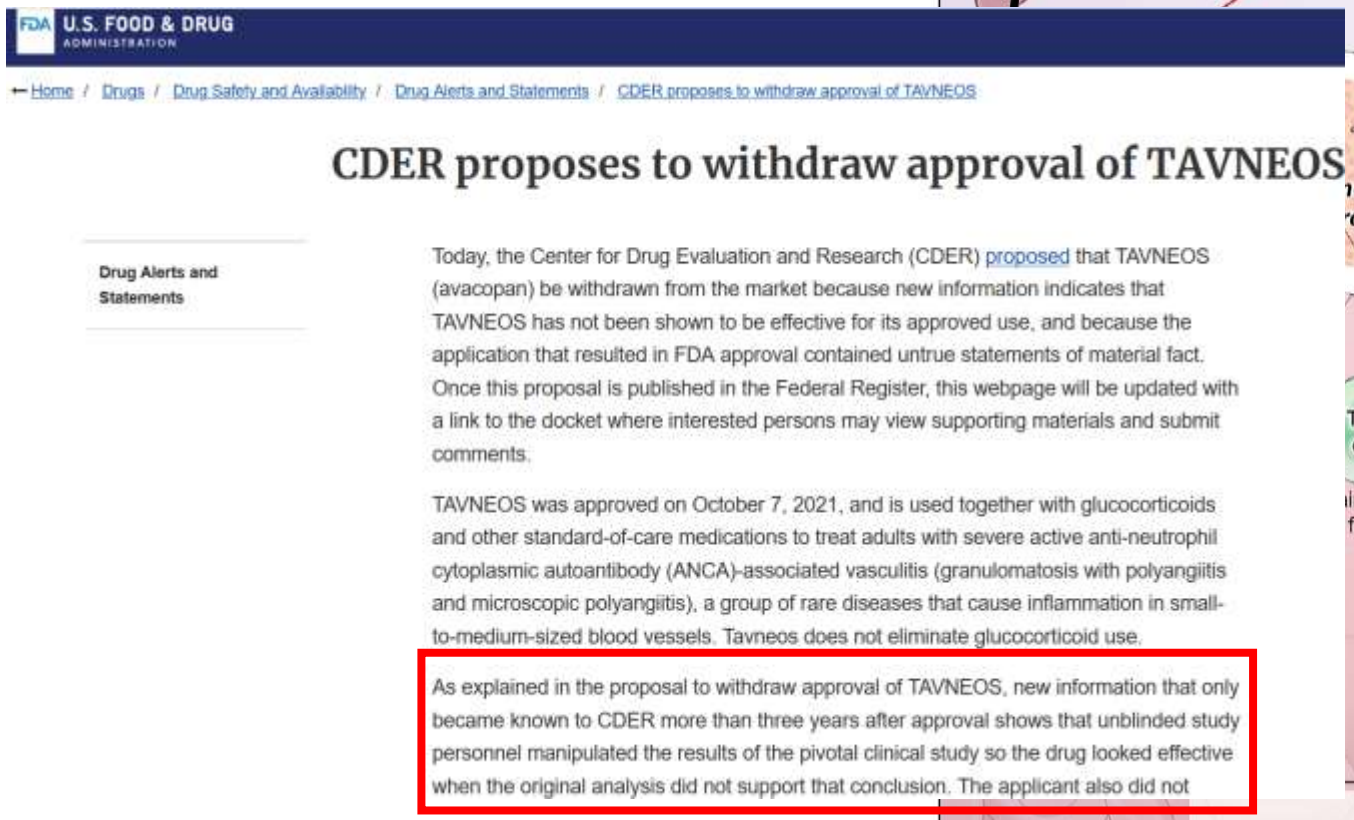


Adapté de Jiang, TMR 2022

Al-Samkary et al, AJH 2024

Anti – complément

Iptacopan (anti-B), Pegcetacoplan (anti-C3), Sutimlimab (anti-C1s), Ravulizumab (anti-C5)…



U.S. FOOD & DRUG ADMINISTRATION

Home / Drugs / Drug Safety and Availability / Drug Alerts and Statements / CDER proposes to withdraw approval of TAVNEOS

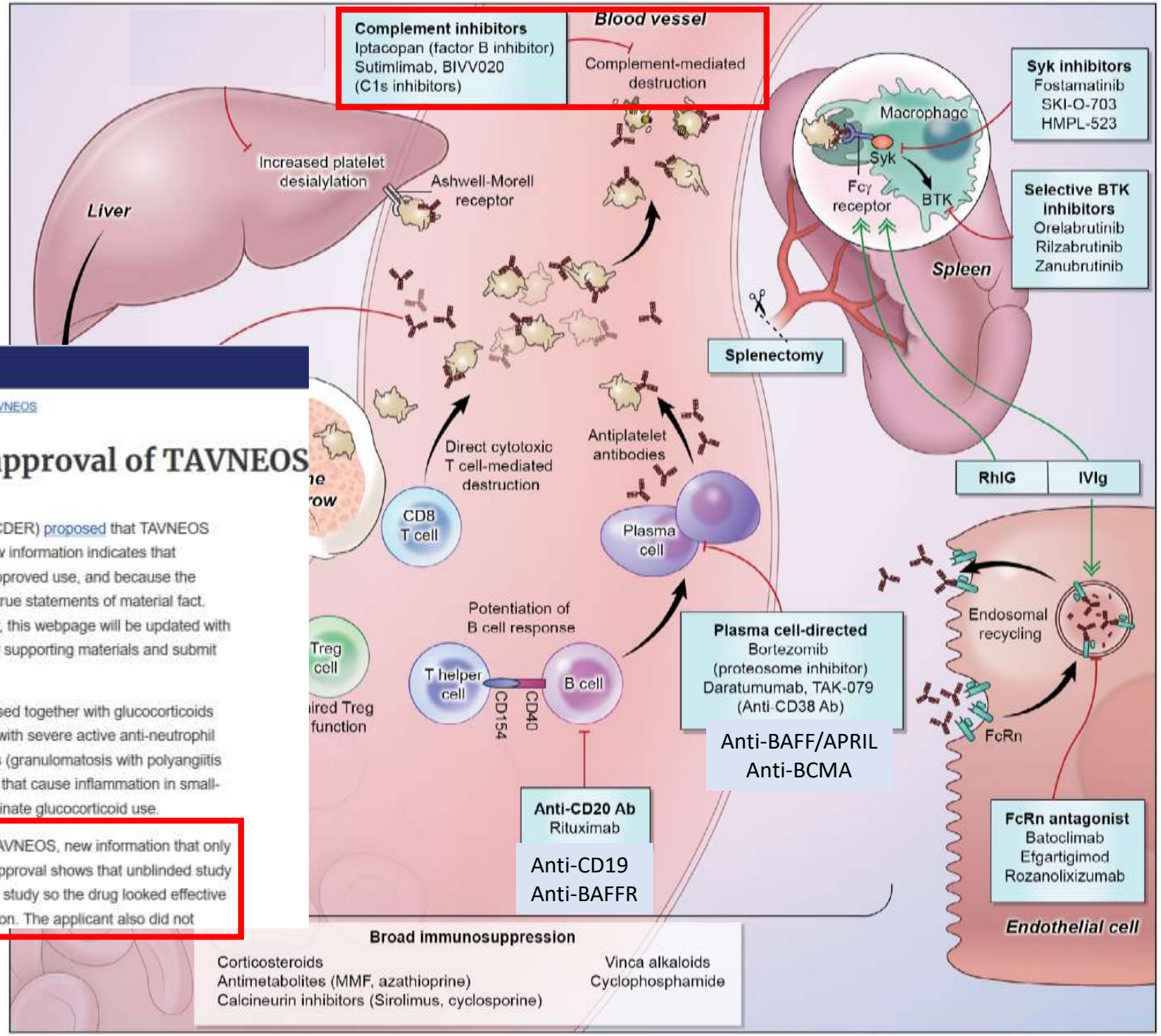
CDER proposes to withdraw approval of TAVNEOS

Drug Alerts and Statements

Today, the Center for Drug Evaluation and Research (CDER) proposed that TAVNEOS (avacopan) be withdrawn from the market because new information indicates that TAVNEOS has not been shown to be effective for its approved use, and because the application that resulted in FDA approval contained untrue statements of material fact. Once this proposal is published in the Federal Register, this webpage will be updated with a link to the docket where interested persons may view supporting materials and submit comments.

TAVNEOS was approved on October 7, 2021, and is used together with glucocorticoids and other standard-of-care medications to treat adults with severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (granulomatosis with polyangiitis and microscopic polyangiitis), a group of rare diseases that cause inflammation in small-to-medium-sized blood vessels. Tavneos does not eliminate glucocorticoid use.

As explained in the proposal to withdraw approval of TAVNEOS, new information that only became known to CDER more than three years after approval shows that unblinded study personnel manipulated the results of the pivotal clinical study so the drug looked effective when the original analysis did not support that conclusion. The applicant also did not



Adapté de Jiang, TMR 2022

Al-Samkary et al, AJH 2024

Quel choix de traitement ?

- Choisir la bonne cible pour la bonne maladie

Quel choix de traitement ?

- Choisir la bonne cible pour la bonne maladie
- Choisir le bon traitement pour le bon patient

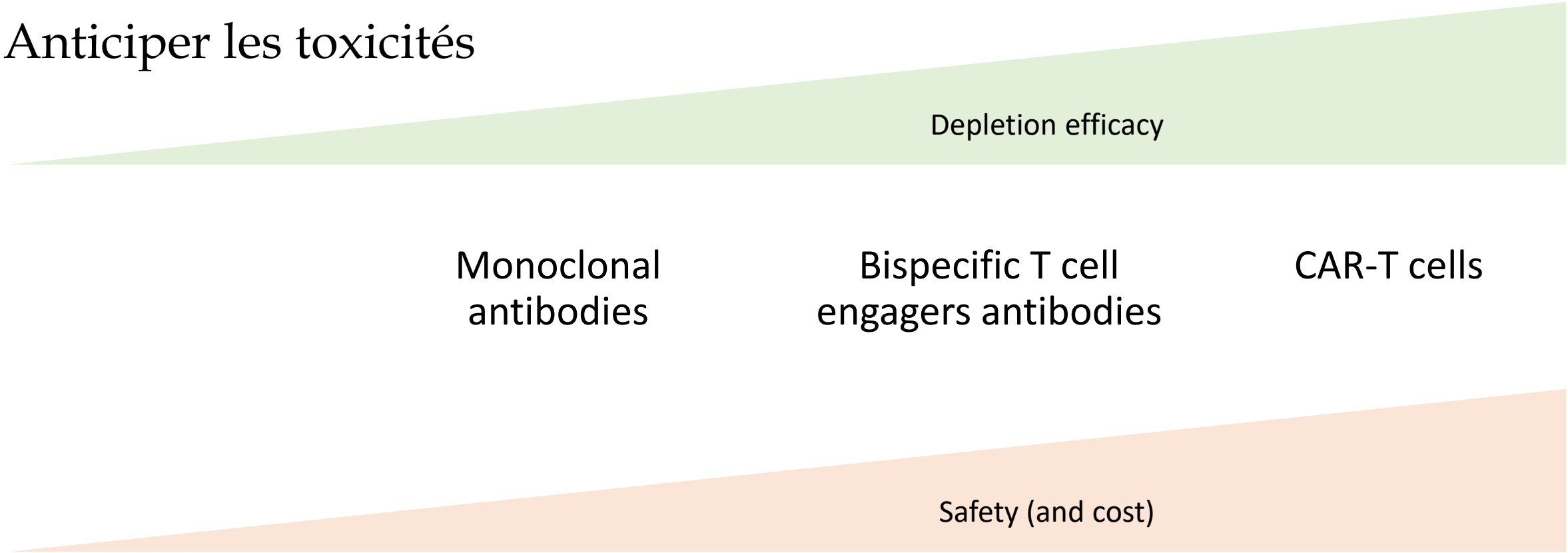
Monoclonal antibodies

Bispecific T cell engagers antibodies

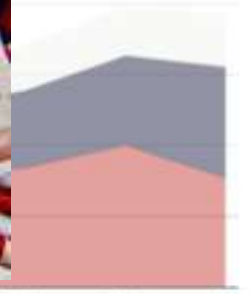
CAR-T cells

Quel choix de traitement ?

- Choisir la bonne cible pour la bonne maladie
- Choisir le bon traitement pour le bon patient
- Anticiper les toxicités



Nouvelles thérapeutiques ? A quel prix ?



Source: GlobalData

Drug name

Adaptive immunity

BIIB059

Obinutuzumab

Tofacitinib anti-JAK1/3

BMS-986165 anti-TYK2

Deucravacitinib anti-TYK2

Upadacitinib anti-JAK1

Indirect impact on B cells

Anifrolumab anti-IFNAR

Secukinumab anti-IL17A

Ustekinumab anti-IL12/23

T03616912

T03616964

sni et al. (109)

T03943147

T04857034

T03978520

ie et al. (94)

rand et al. (95)

T05138133

T04181762

Vollenhoven et al. (110)

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CDER proposes to withdraw approval of TAVNEOS

Drug Alerts and Statements

Today, the Center for Drug Evaluation and Research (CDER) proposed that TAVNEOS (avacopan) be withdrawn from the market because new information indicates that TAVNEOS has not been shown to be effective for its approved use, and because the application that resulted in FDA approval contained untrue statements of material fact. Once this proposal is published in the Federal Register, this webpage will be updated with a link to the docket where interested persons may view supporting materials and submit comments.

TAVNEOS was approved on October 7, 2021, and is used together with glucocorticoids and other standard-of-care medications to treat adults with severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (granulomatosis with polyangiitis and microscopic polyangiitis), a group of rare diseases that cause inflammation in small-to-medium-sized blood vessels. Tavneos does not eliminate glucocorticoid use.

As explained in the proposal to withdraw approval of TAVNEOS, new information that only became known to CDER more than three years after approval shows that unblinded study personnel manipulated the results of the pivotal clinical study so the drug looked effective when the original analysis did not support that conclusion. The applicant also did not

Conclusions

- Une myriade de nouveaux traitements anti-B en concurrence pour une meilleure déplétion
- Des traitements anti-plasmocytaires rapidement efficaces chez des patients réfractaires

Mais au-delà des effets d'annonce…

- Une preuve de supériorité par rapport au RTX restant à faire dans beaucoup d'indications
- Une sécurité d'emploi à moyen/long terme à démontrer
- Un cout important pour la société
- Une corticophobie au cœur des préoccupations, mais ne devant pas tout justifier
- Il reste du travail pour optimiser les traitements existants…