2ND meeting of the European Research Consortium on ITP

NEW INSIGHTS INTO IMMUNE THROMBOCYTOPENIA

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Targeting BAFF/BAFF-R in ITP

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Outlines:

- Role of BAFF and BAFF-R in the pathophysiology of ITP
- Inhibition of BAFF with Belimumab
- Inhibition of BAFF-R with Ianalumab

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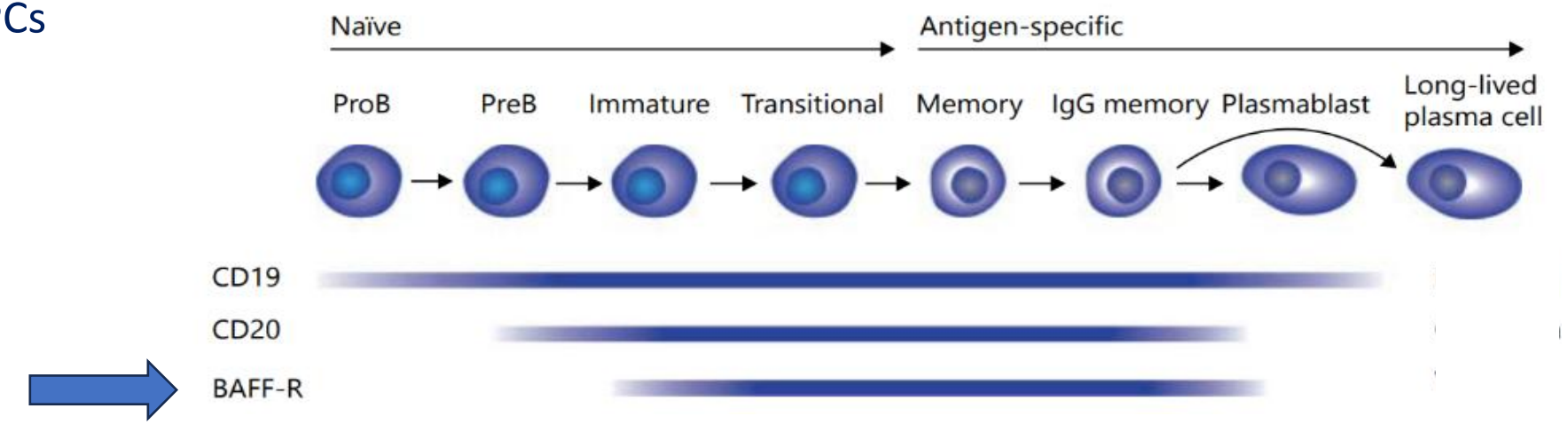
Role BAFF level in the pathophysiology of auto-immune disorders

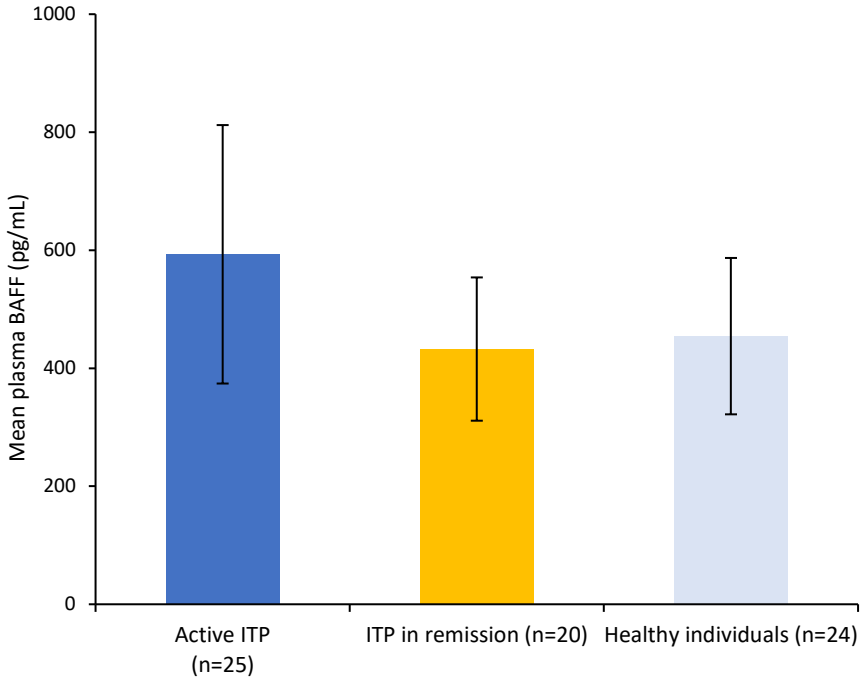
BAFF (B cell activating factor) is a cytokine critical for B cell homeostasis:

- promotes B cell maturation and survival, counters B cell apoptosis
- promotes B cell differentiation to Ig producing PCs
- increases autoreactive B cell survival pivotal in producing anti-platelet autoantibodies

BAFF-R is present on immature and mature B cells,including plasmablasts and some plasma cells, but excluding long lived PCs

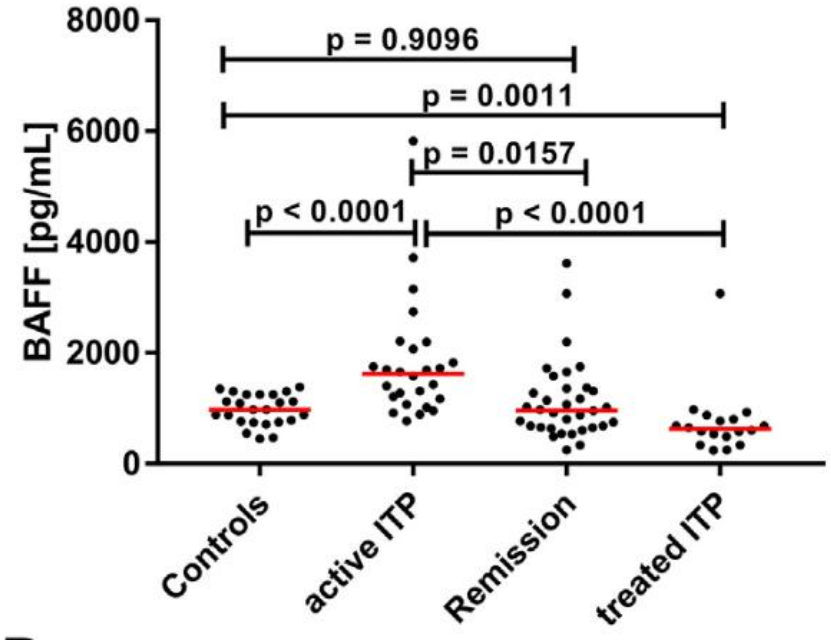


Serum BAFF level in ITP



Plasma BAFF and BAFF mRNA in ITP patients and controls

Zhu X-J et al, Blood 2009



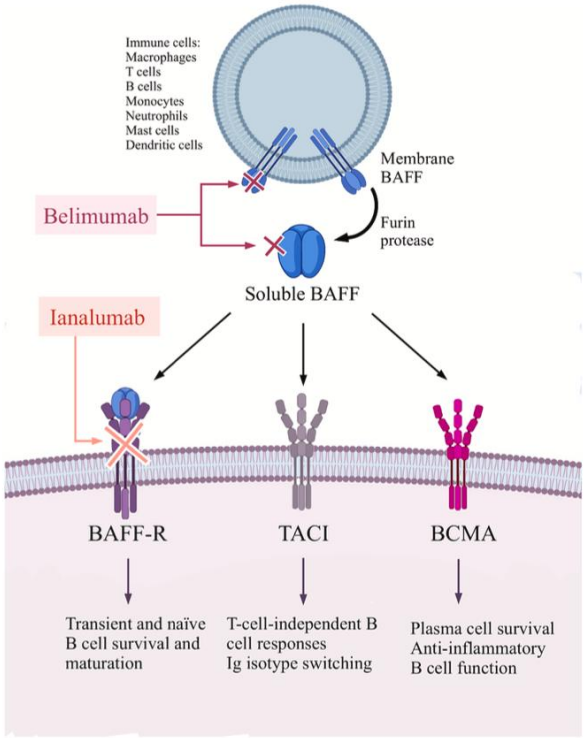
Kamhieh-Milz J et al. Clin Immunol 2017

The mechanism of action of BAFF/BAFF-R signaling

BAFF is the natural ligand of 3 TNF receptors: BAFF-R, TACI, and BCMA

- **BAFF-R:** triggers the survival and maturation of naïve B cells
- **BCMA**: increased long-lived PCs survival in the bone marrow
- **TACI:** T-cell-independent B cell responses and isotype switching

- **BAFF-R, TACI and BCMA:** are found on the surface of mature B cells
- **BAFF-R and TACI** are found on THF and activated T-cells

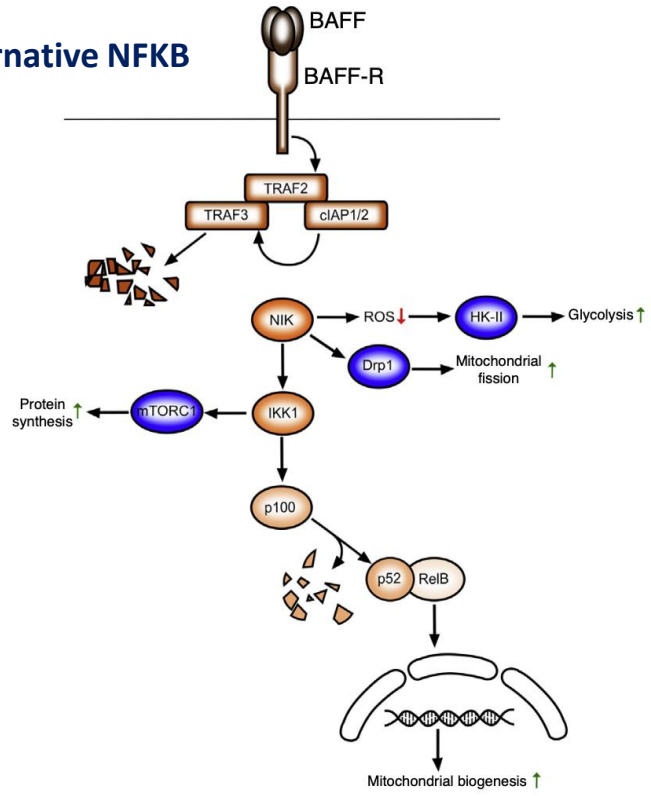


Nilforoushzadeh MA et al 2024, Semple JW 2009

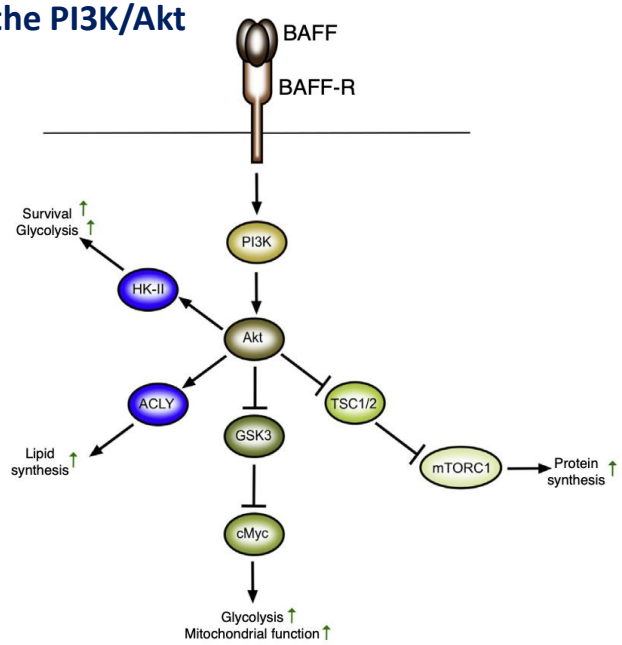
BAFF/BAFF-R signaling

B cell proliferation is an energy demanding process. BAFF lead to higher mitochondrial membrane potential and increased expression of genes supporting glucose uptake and glycolytic metabolism.

via the alternative NFKB

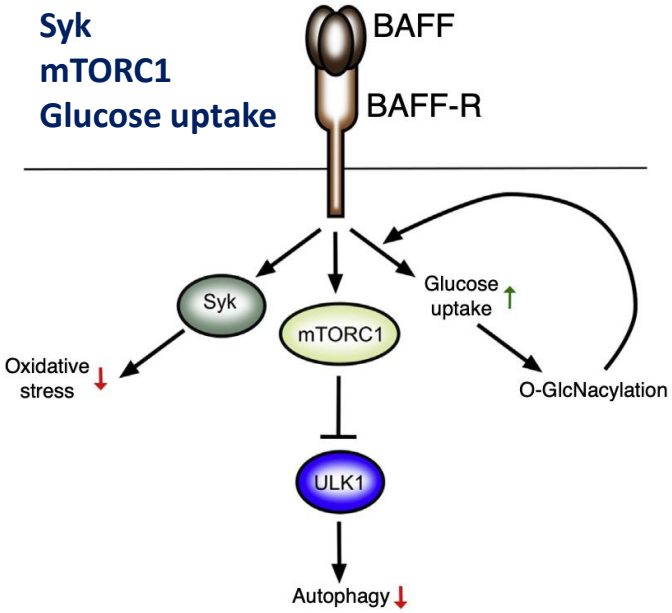


via the PI3K/Akt



- **metabolic changes**

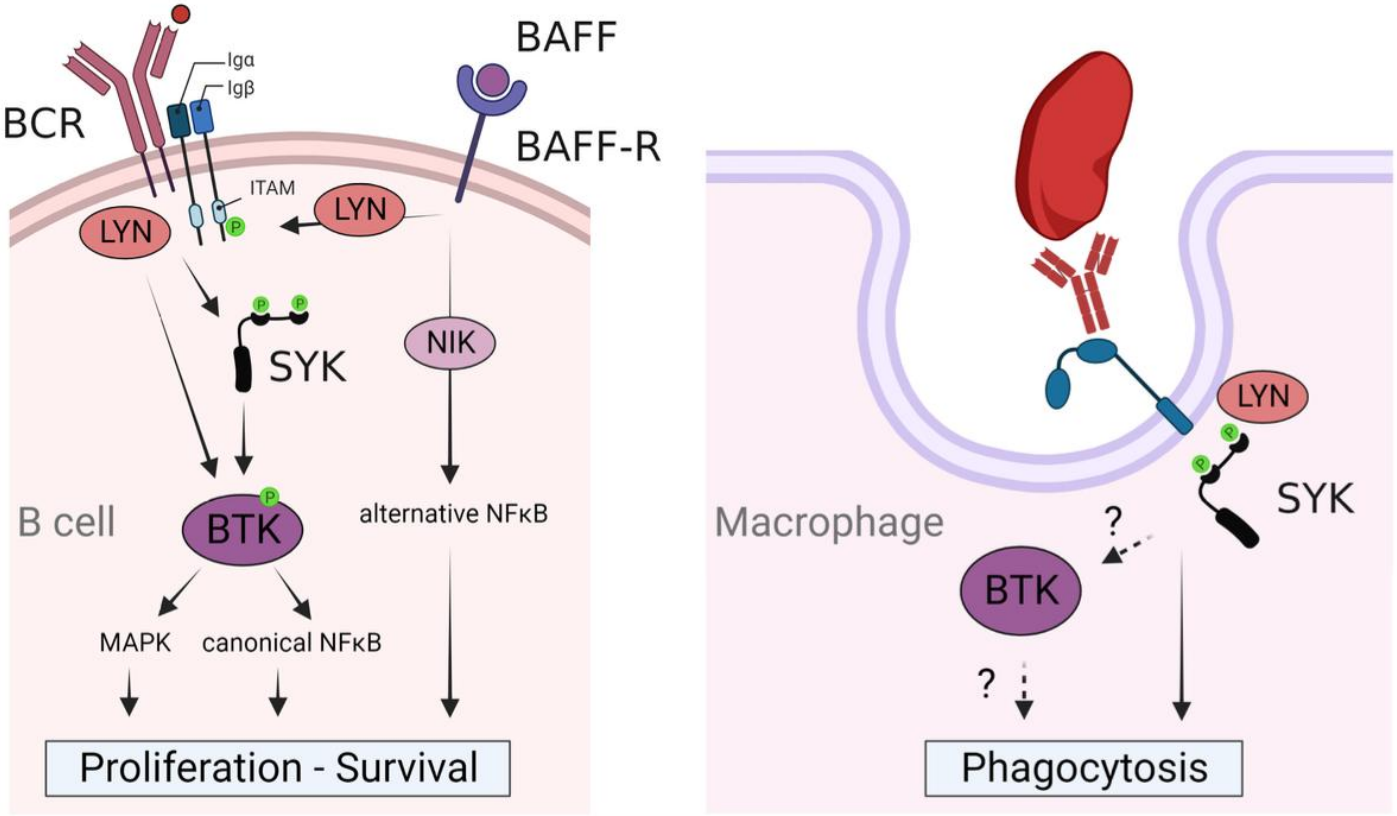
Syk
mTORC1
Glucose uptake



- autophagy,
- redox balance
- glucose usage

McAllister E et al 2021

BAFF/BAFF-R signaling

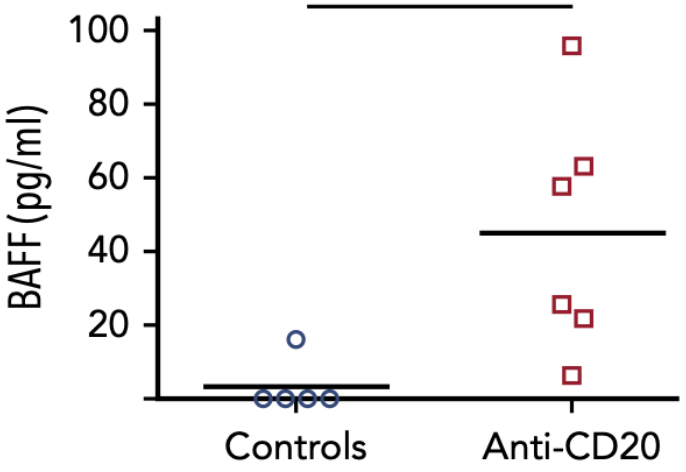


BAFF/BAFF-R signaling leads to the phosphorylation of Igα and SYK and transduces signals via the BCR

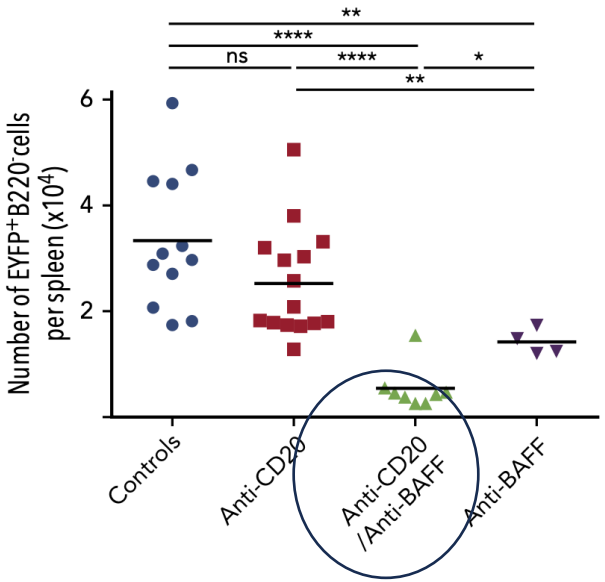
Schweighoffer E at al. 2013; Roeser A et al BJH 2023

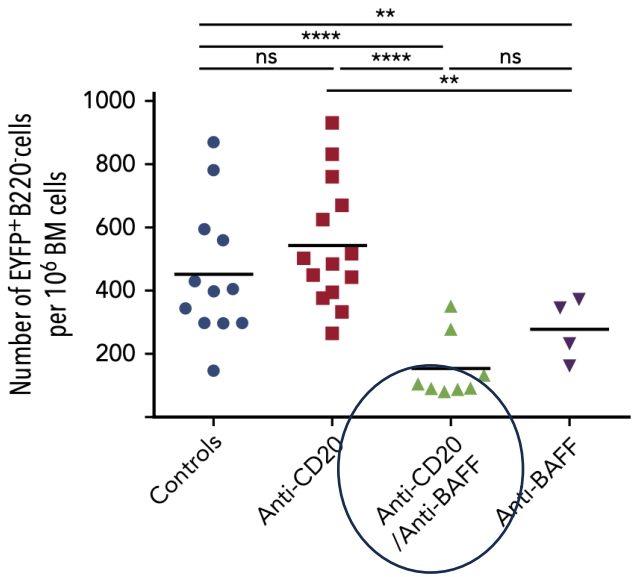
The B-cell depletion paradox

BAFF in culture supernatants of spleen cells



Quantification of PC (EFYP+B220- cells) in the spleen and BM



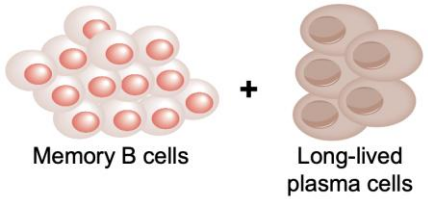


KEY POINTS

- **Modification of the splenic microenvironment induced by B-cell depletion creates a dependence of PCs on BAFF and CD4⁺ T cells.**
- **Combining anti-CD20 and anti-BAFF reduces the number of splenic PCs, opening therapeutic perspectives for antibody-mediated cytopenia.**

B-cell depletion induced by rituximab may promote new environmental conditions suitable for the maturation and survival of autoimmune long-lived splenic plasmacell

autoreactive B-cell clones



Mahevas M et al 2013, Thai LH et al Blood 2018

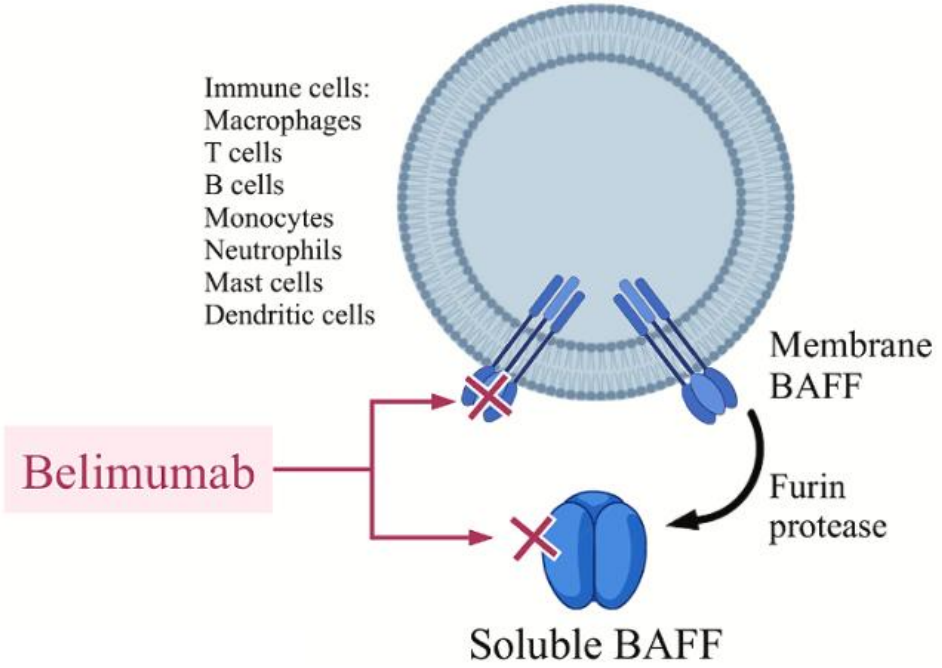
Outlines:

- Role of BAFF in the pathophysiology of ITP
- Inhibition of BAFF with Belimumab
- Inhibition of BAFF-R with Ianalumab

Belimumab

- Fully human IgG1/λ monoclonal antibody
- Binds to the soluble BAFF with high affinity

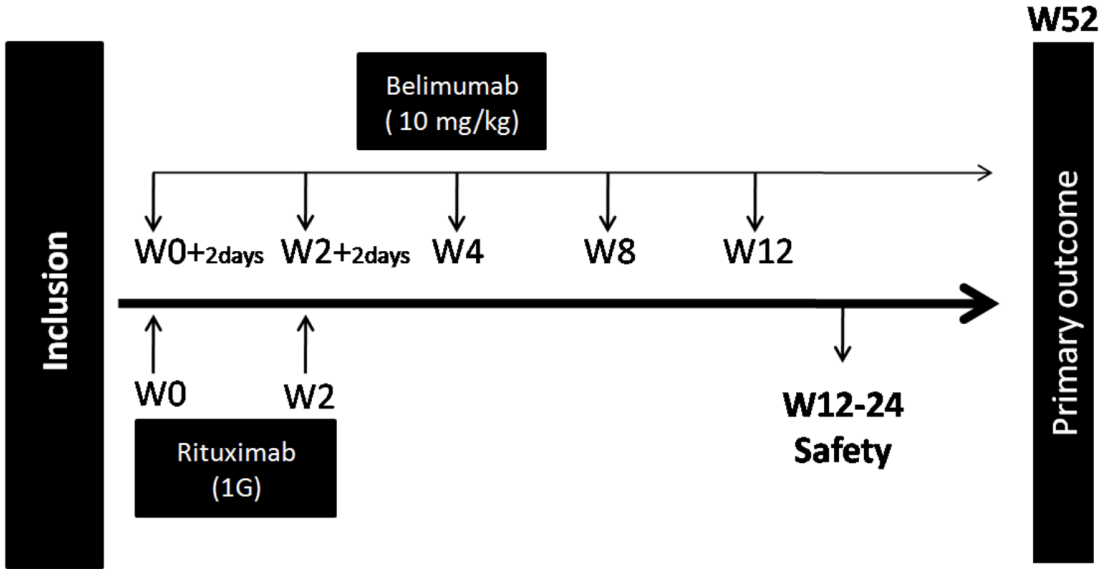
1. **Interferes with the interaction of BAFF with all 3 BAFF receptors (BAFF-R, TACI, BCMA)**



Efficacy, safety and immunological profile of combining rituximab with belimumab for adults with persistent or chronic immune thrombocytopenia: results from a prospective phase IIb trial

- Single arm, prospective, phase 2 trial in adult patients with persistent or chronic ITP
- Primary endpoint**: overall response at week 52 according to IWG criteria**

Patients	15 (12F, 3M)
Median age, yr (range)	50 (20-70)
Median PLT count, x 10^9/L (range)	16 (3-28)
Median duration of ITP, months (range)	11 (4-52)
Persistent/Chronic ITP	60% / 40%



Mahevas M et al Haematologica 2021

Rituximab plus belimumab in ITP

Efficacy

- ORR at week 12: 87% (13/15), with 60% CR
- **ORR at week 52: 80% (12/15), with 66% CR**

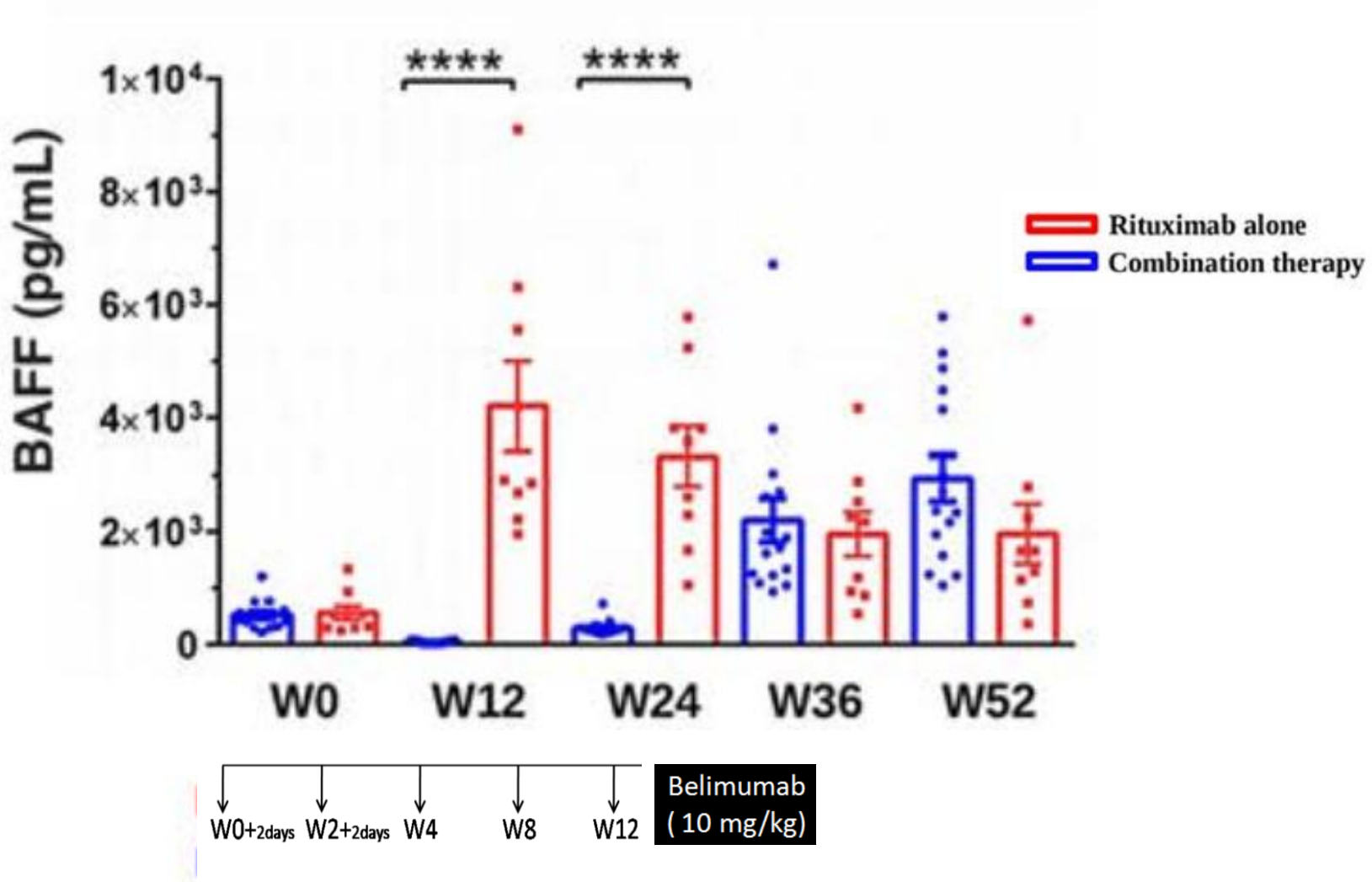
Among responders, one patient in CR relapsed after a follow-up of 18 months

Outcome at W12	Outcome at W24	Outcome at W36	Outcome at W52
9 CR	9 CR	10 CR	10 CR
4 R	4 R	2 R	2 R
2 NR	2 NR	3 NR	3 NR

Mahevas M et al Haematologica 2021

AE, adverse event; NR, no response.

Mahévas M, et al. Haematologica 2021



Mahevas M et al Haematologica 2021

Safety:

- No infusion-related reactions with belimumab
- No severe infections
- No severe hypogammaglobulinemia, although significant decrease in IgG and IgM titres

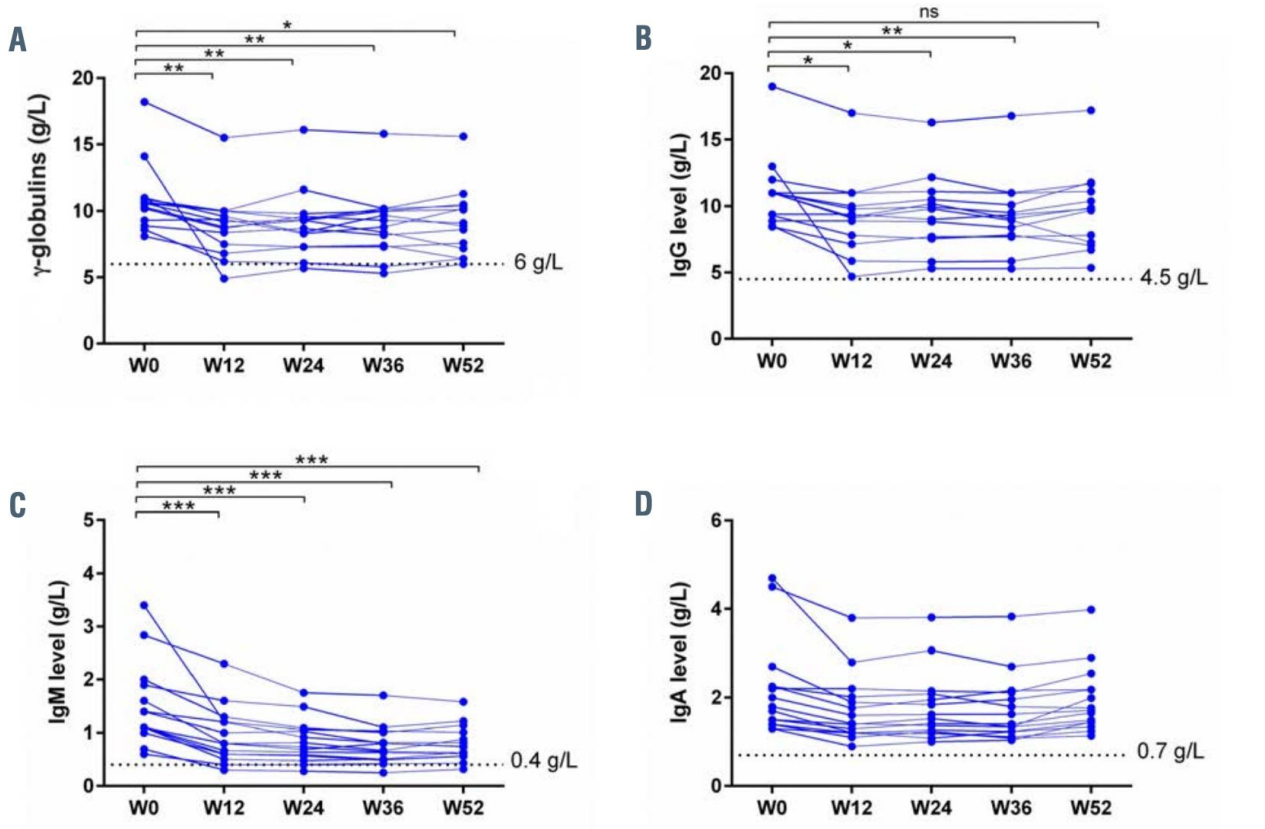


Figure 1. Serum level of total γ-globulins and immunoglobulin isotypes (IgG, IgA, IgM) during the study of rituximab and belimumab combined. Serum level of total γ-globulins (A) and IgG (B), IgM (C), and IgA (D) were assessed by nephelometry at week 12 (W12), W24, W36, W52. Dotted line represents normal threshold for each isotype. *P<0.05, **P<0.01, ***P<0.001; ns: not significant.

Mahevas M et al Haematologica 2021

MAIPA	W0	W24	Clinical outcome at W24	W52	Clinical outcome at W52
Anti-GpIIb/IIIa	9	Neg: 4 Pos: 5	CR: 3, NR: 1 CR: 4, R: 1	Neg: 7 Pos: 2	CR: 6, NR: 1 CR: 1, R: 1
Anti-GpIb/IX	1	Neg: 1	R: 1	Neg: 1	R: 1
Negative Undetermined	3 1	Neg: 3 Not performed: 1	CR: 2, NR: 1 CR: 1	Neg: 3 Not performed: 1	CR:2, NR: 1 CR: 1
Not performed	1	Neg: 1	CR: 1	Neg: 1	CR: 1

Mahevas M et al Haematologica 2021

RITUX-PLUS 2 CLINICAL TRIAL SUMMARY

The RITUX-PLUS 2 clinical trial is an international multicentre institutional trial sponsored by the Assistance Publique – Hôpitaux de Paris (AP-HP) [Paris Public Hospitals].

Title: A phase 3 randomized and double-blind controlled trial comparing the efficacy and safety of subcutaneous Belimumab or placebo in addition to Rituximab in adult patients with persistent or chronic immune thrombocytopenia (ITP).

Population: Adults ≥18 years of age with a definitive diagnosis of ITP.

Primary objective:
To evaluate the superiority, after 52 weeks, of treatment with weekly subcutaneous injections of **Belimumab** for 24 weeks (arm A) or **placebo** (arm B) combined with **Rituximab** (Mabthera© or biosimilar) at a fixed dose of 1000 mg on days 7 and 21.

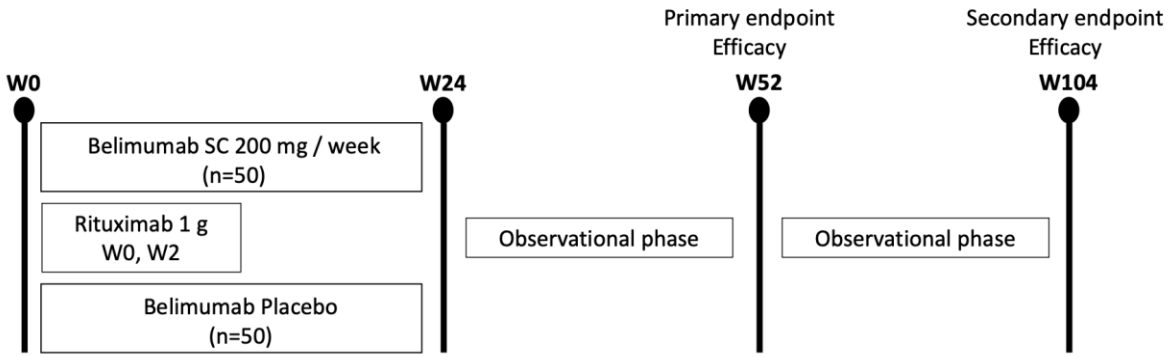
Number of patients: 132
Number of participating sites: 31, of which 23 in France, 4 in Italy, 4 in Spain

Total study duration: 60 months

- Duration of enrolment: 36 months (planned at the start of the research)
- Duration of participation for each patient: 24 months

Treatment regimen:

- **Arm A: Belimumab** 200 mg – 1 SC injection per week for 24 weeks
- **Arm B: Belimumab PLACEBO** 200 mg – 1 SC injection per week for 24 weeks



Outlines:

- Role of BAFF in the pathophysiology of ITP
- Inhibition of BAFF with Belimumab
- Inhibition of BAFF-R with Ianalumab

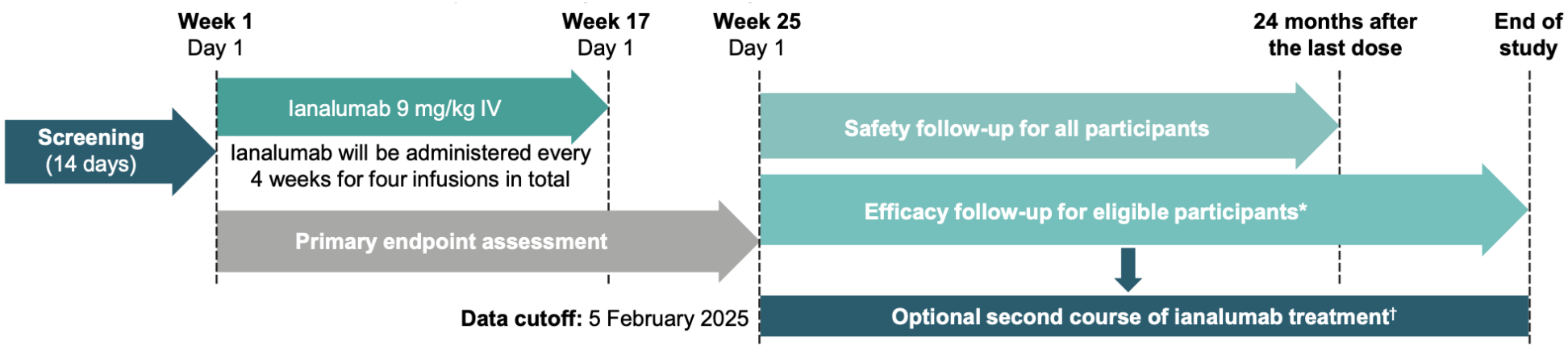
There are four trials investigating ianalumab in primary ITP

	VAYHIT1[1,2]	VAYHIT2[3,4]	VAYHIT3[5,6]	VAY RE-HIT[7,8]
Type	Randomized, double-blind, placebo-controlled trial	Randomized, double-blind, placebo-controlled trial	Open-label, single-arm trial	Double-blind, exploratory trial
Phase	III	III	II	II
Active treatment	Ianalumab in addition to corticosteroids	Ianalumab in addition to eltrombopag	Ianalumab[§]	Ianalumab
Ianalumab dosing	IV every 4 weeks for four infusions in total	IV every 4 weeks for four infusions in total	IV every 4 weeks for four infusions in total	IV every 4 weeks for four infusions in total
Treatment setting	1L	2L	3L+ (patients who have been treated with at least one corticosteroid and one TPO-RA)	Patients previously treated with ianalumab
Primary endpoint	Time from randomization to treatment failure (TTF)*	Time from randomization to treatment failure (TTF)*	Confirmed response (ConfR)[‖]	Proportion of patients who are free from treatment failure* at 12 months
Key secondary endpoint	Response rate and complete response rate[†]	Stable response at 6 months[‡]	Response rate and complete response rate[†]	Response rate and complete response rate[†]
NCT number	NCT05653349	NCT05653219	NCT05885555	NCT07039422
Presented/published		ASH 2025 and NEJM 2025	ASH 2024 and 2025	Propsed at ASH 2025

VAYHIT3, a phase 2 study of Ianalumab in primary ITP patients previously treated with at least two lines of therapy

Key inclusion criteria

- ≥18 years with primary ITP treated with at least a corticosteroid (±IVIg) and aTPO-RA, with no previous splenectomy
- Loss of response, no or insufficient response or intolerance to the last ITP therapy
- Platelet count of <30G/L and assessed by the investigator as needing treatment

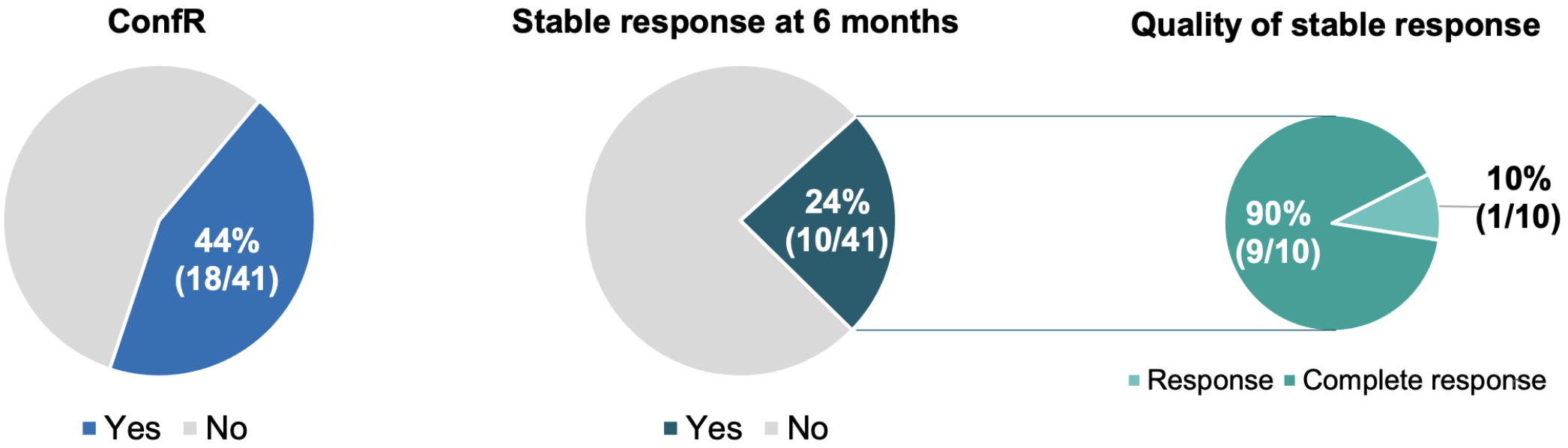


Primary endpoint: confirmed response (ConfR) platelet count of ≥50 G/L at ≥2 consecutive assessments that are at least 7 days apart between Week 1 and Week 25 in the absence of rescue treatment

Choi P et al. ASH 2025

VAYHIT3

- 41 patients
- median age: 55 y, median n. of prior lines of therapy: 6 (2–13), 88% having received ≥4 prior lines
- 38 (93%) received all four planned infusions of ianalumab



- **Eight** patients achieved a **ConfR** in the **first 4 weeks of treatment**, with the **remaining** patients achieving this between **Week 4 and Week 8 (n=5)** or **Week 8 and Week 20 (n=5)**[1]
- **Median time to ConfR** was **6 weeks** among patients with a ConfR[1]
- ConfR rates **across all subgroups** analyzed were: **prior ITP treatments** (2–3: 40%; 4–5: 67%; ≥6: 33%), **age** (18–<65 years: 42%; ≥65 years: 50%), and **sex** (female: 48%; male: 40%)[2]

Choi P et al. ASH 2025

VAYHIT3: safety profile analysis

Overview of on-treatment AEs*,[1]

n (%)	Ianalumab (N=41)	
	All grades	Grade ≥3
AEs	35 (85)	9 (22)
Ianalumab related	15 (37)	1 (2)
SAEs	6 (15)	6 (15)
Ianalumab related	0	0
Fatal AEs	0	0
AEs leading to study drug discontinuation	0	0

On-treatment SAEs*,[1]

n (%)	Ianalumab (N=41)	
	All grades	Grade 3/4
Thrombocytopenia	2 (5)	2 (5)
Allergy to immunoglobulin therapy	1 (2)	1 (2)
Arterial disorder	1 (2)	1 (2)
Chronic kidney disease	1 (2)	1 (2)
Liver disorder	1 (2)	1 (2)
Upper gastrointestinal hemorrhage	1 (2)	1 (2)

- **No new safety concerns**† were detected with **ianalumab** in the primary analysis of **VAYHIT3**[1]
- **Most frequent on-treatment AEs** (occurring in >10% of patients) were **headache** (22%), **contusion**, **petechiae**, **purpura** (each 20%), **IRR** (15%) and **upper respiratory tract infection** (12%); all were **Grade 1 or Grade 2**[1]
- **IRRs** were reported in **six patients** (15%), all of which were **Grade 1 or Grade 2**; there were **no discontinuations because of IRRs**[1]
- On-treatment **infections** were reported in **15 patients** (37%); **one patient** (2%) experienced a **Grade 3 infection** (*Clostridium difficile*)[1]
- **One patient died** in the post-treatment follow-up period because of an **AE of pulmonary edema**; this was assessed by the investigator as being **unrelated to ianalumab**[1]
- No opportunistic infections observed[2]

VAYHIT2

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Ianalumab plus Eltrombopag in Immune Thrombocytopenia

A. Cuker,[1] T. Stauch,[2,3] N. Cooper,[4] H. Al-Samkari,[5] M. Michel,[6] W. Ghanima,[7,8] P. Urban,[9] J. Fronczek,[9] M. Foster,[10] M. Weill,[9] L. Zhang,[11] M. Hou,[12] T. Zander,[13] A. Sharif,[14] J. Sun,[15] U.K. Nath,[16] R. Schutgens,[17] E. Rossi,[18] L. Deleu,[19] L. Červinek,[20] J.-H. Yoon,[21] H. Chang,[22-24] T. Ruchutrakool,[25] M. Iino,[26] T. Goto,[27] and F. Zaja,[28] for the VAYHIT2 Investigators*

New England Journal of Medicine 2025 Dec 9

ESTIT - Study design

Start of treatment

Treatment

Eltrombopag 50 mg/day, then adjusted according to platelet count (50–150 x 10^9/L)

NR → OFF study

Week 24

Tapering

Dose reduction of 25 mg every 2 weeks, up to a minimum of 25 mg every 4 days, then STOP

CR or R

Week 32

Observation

- **Patients who achieved SROT: 25%** (13/51)
  - 38% of responders (13/34)
  - 50% of complete responders (9/18)

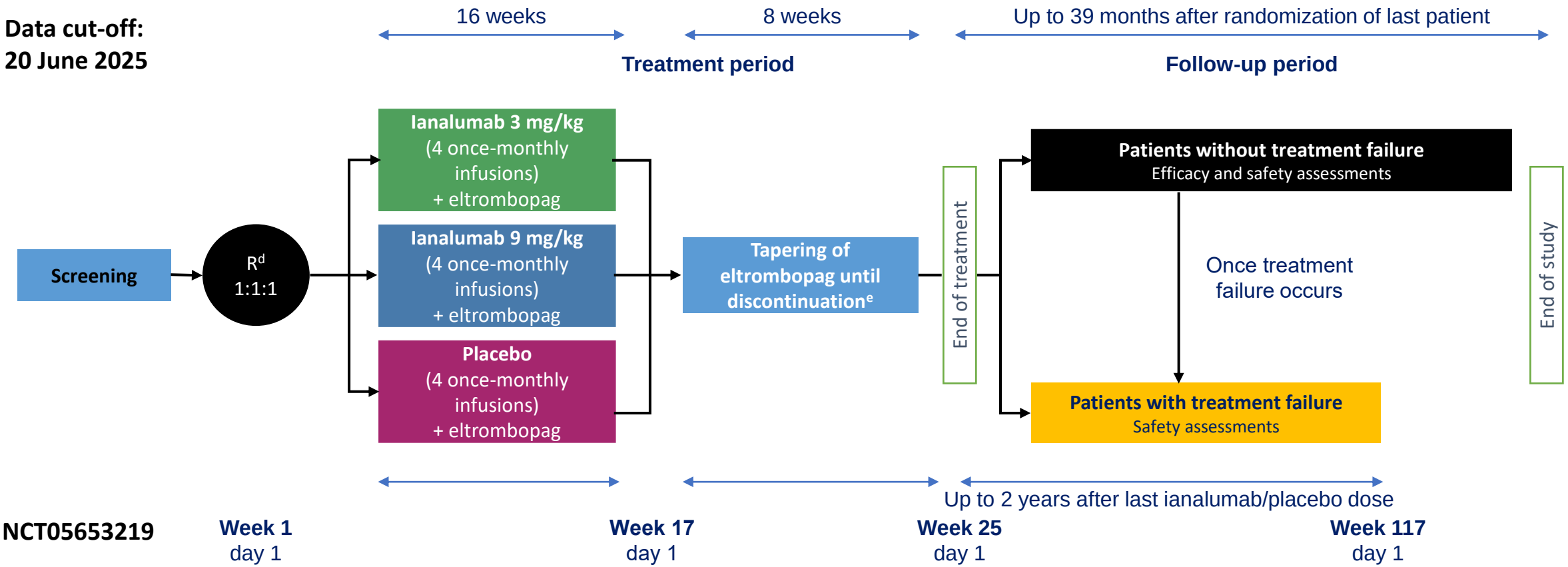
Week 52

Lucchini E et al BJH 2021

VAYHIT2 Study Design

- Adults with primary ITP previously treated with only corticosteroids[a] (+/- IVIG), who had an insufficient response[b] or relapsed[c]
- Platelet counts <30 × 10^9/L
- No prior second-line therapy and indication to initiate eltrombopag treatment

Data cut-off:
20 June 2025



VAYHIT2 : Endpoints and Statistical Analysis

Primary endpoint

Time to treatment failure (TTF): Time from randomization until the first occurrence of any of the 4 following events that reflect key treatment needs of patients with ITP:

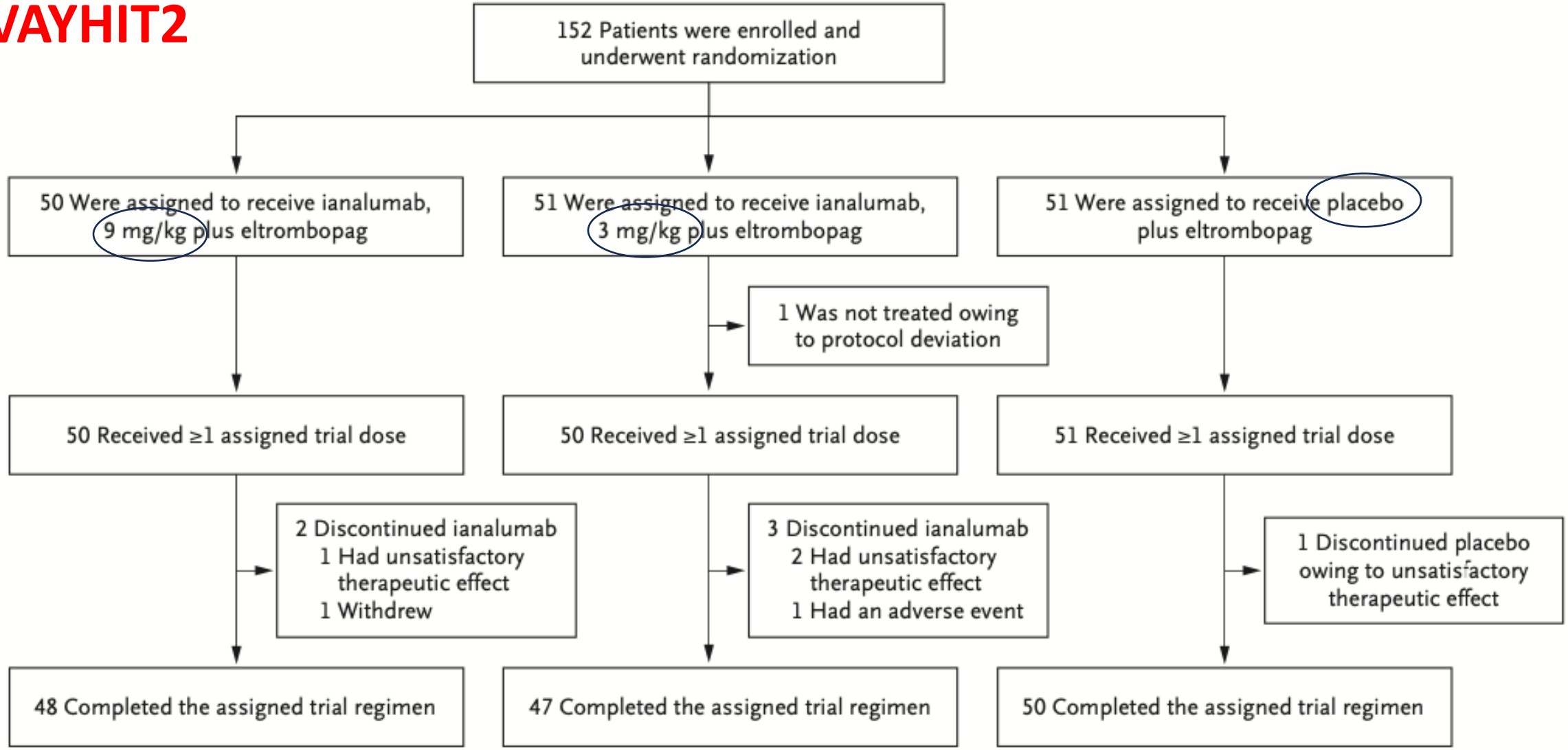
1. Platelet counts <30 × 10^9/L or start of rescue therapy beyond 8 weeks from randomization
2. Start of a new ITP therapy at any time
3. Inability to taper or discontinue eltrombopag
4. Death

Key secondary endpoint

Stable response at 6 months (SR6): Proportion of patients with:

1. Platelet count ≥50 × 10^9/L on ≥75% of planned bi-weekly assessments between Weeks 19 to 25
2. No rescue therapy within the last 4 weeks or start of new ITP therapy

VAYHIT2



96% 92% 98%

VAYHIT2

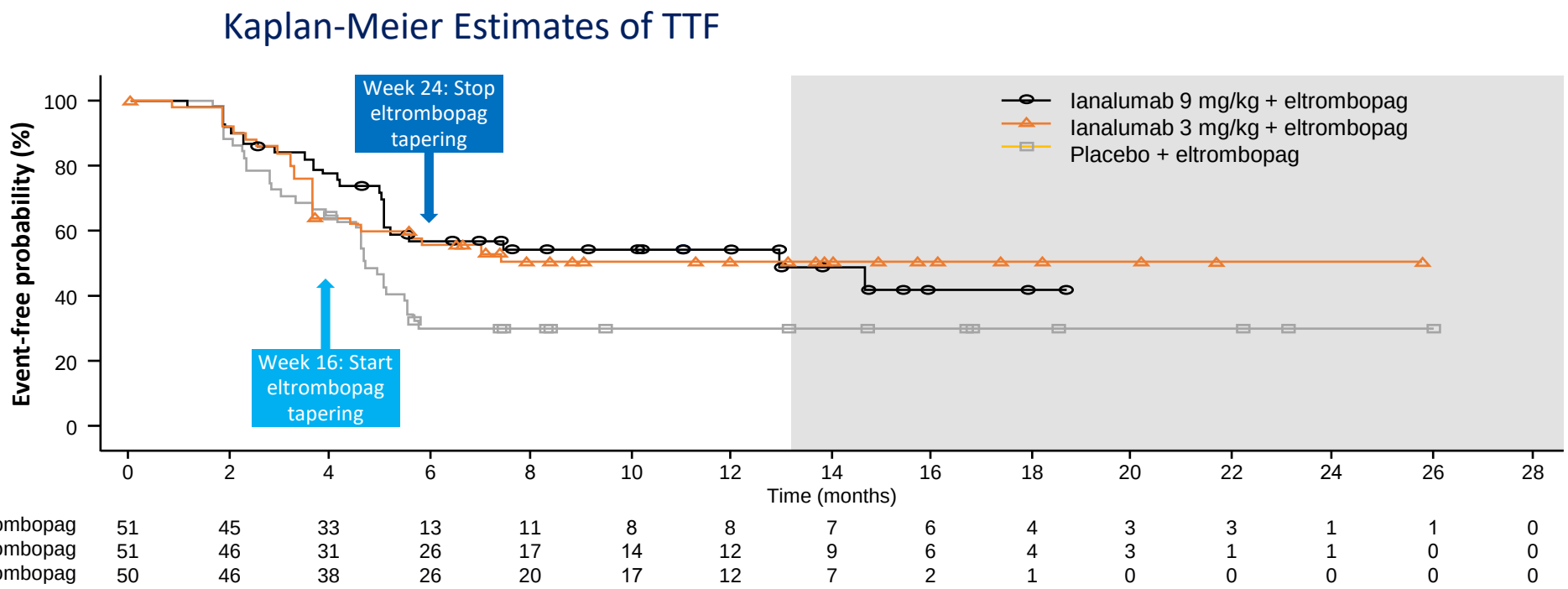
Table 1. Demographic and Clinical Characteristics of the Patients at Baseline.*

Characteristic	Ianalumab, 9 mg/kg (N=50)	Ianalumab, 3 mg/kg (N=51)	Placebo (N=51)
Age — yr	40.2±15.3	45.5±19.7	40.5±16.6
Age group — no. (%)			
18 to <65 yr	48 (96)	43 (84)	46 (90)
65 to <85 yr	2 (4)	8 (16)	5 (10)
Female sex — no. (%)	33 (66)	31 (61)	35 (69)
Race or ethnic group — no. (%)†			
White	25 (50)	26 (51)	22 (43)
Asian	22 (44)	24 (47)	25 (49)
American Indian or Alaska Native	0	1 (2)	3 (6)
Unknown	3 (6)	0	1 (2)
Body-mass index‡	27.7±7.0	25.8±5.5	27.6±7.6
Median time since initial ITP diagnosis (range) — mo§	3.6 (0.4–482.8)	4.2 (0.3–160.8)	3.4 (0.5–259.3)
Received IVIG before screening — no. (%)	17 (34)	15 (29)	11 (22)
Received platelet transfusion before screening — no. (%)	12 (24)	11 (22)	17 (33)
Received TPO-RAs before screening — no. (%)¶	5 (10)	4 (8)	4 (8)

VAYHIT2: Primary Endpoint: Time to Treatment Failure

TTF at 12 months:

- Ian 9 mg/kg + ELT: 54%
- Ian 3 mg/kg + ELT: 51%
- Placebo + ELT: 30%



- **TTF** was longer with ianalumab **9 mg/kg** + eltrombopag (**HR 0.55**, 95% CI 0.32-0.92; ***P*=0.021**) and **3 mg/kg** + eltrombopag (**HR 0.58**, 95% CI 0.34-0.98; ***P*=0.023***) **vs placebo** + eltrombopag
- The **median TTF** was 13.0 months with ianalumab 9 mg/kg + eltrombopag, not reached with ianalumab 3 mg/kg + eltrombopag, and 4.7 months with placebo + eltrombopag

VAYHIT2: Key Secondary Endpoint: stable response at 6 months

Table 2. Stable Response at 6 Months.*

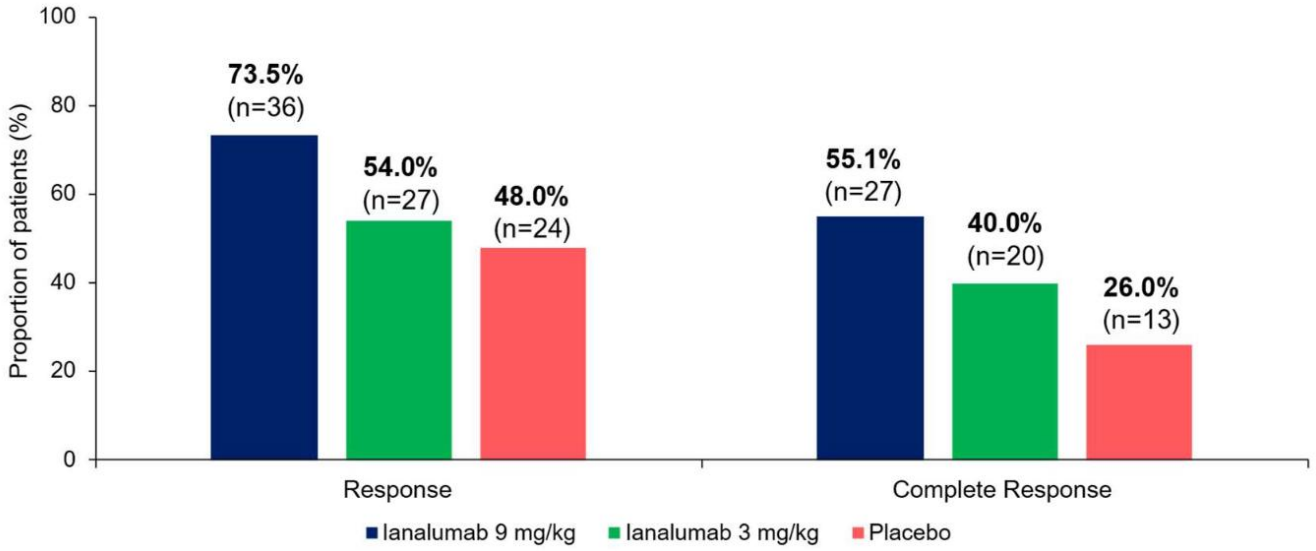
Trial Group	Stable Response at 6 Months		Risk Difference (95% CI)†	P Value‡
	no. with event/ total no.	% with event (95% CI)§		
Ianalumab, 9 mg/kg	31/50	62 (47 to 75)	22.7 (3.8 to 41.5)	0.045
Ianalumab, 3 mg/kg	29/51	57 (42 to 71)	17.7 (–0.9 to 36.2)	0.07
Placebo	20/51	39 (26 to 54)	—	—

SR6: Proportion of patients with:

- Platelet count ≥50 × 10^9/L on ≥75% of planned bi-weekly assessments between Weeks 19 to 25
- No rescue therapy within the last 4 weeks or start of new ITP therapy

VAYHIT2: Other Secondary Endpoints: Response and Bleeding

1. Response and complete response at 6 months



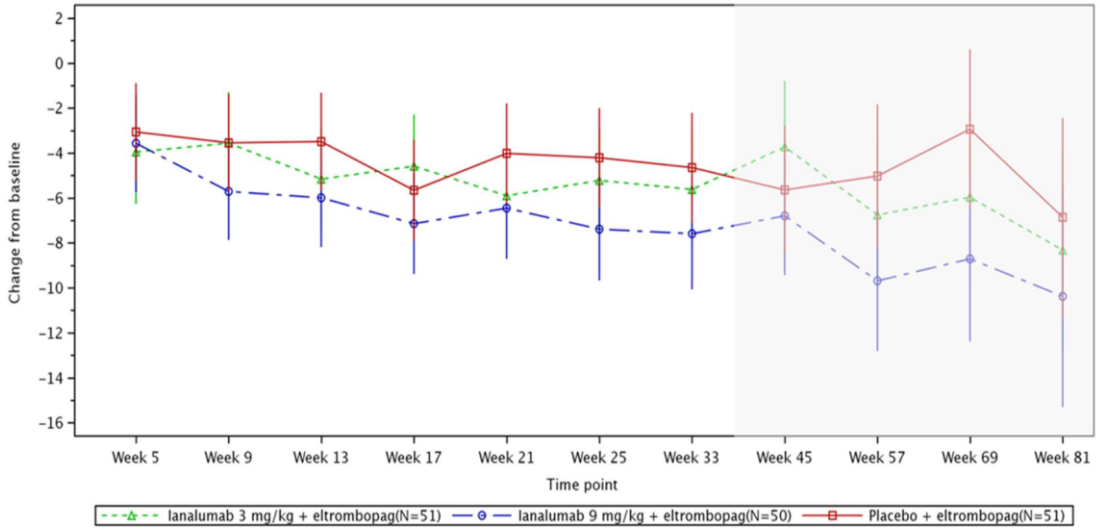
2. Bleeding events

	Baseline (%)	Week 25 (%)
Ianalumab 9 mg/kg	50	10.4
Ianalumab 3 mg/kg	58.8	12.2
Placebo	60.8	20

VAYHIT2: Other Secondary Endpoints: Fatigues

3. Changes in PROMIS-Fatigue Scores from Baseline

Higher score denotes a greater degree of fatigue

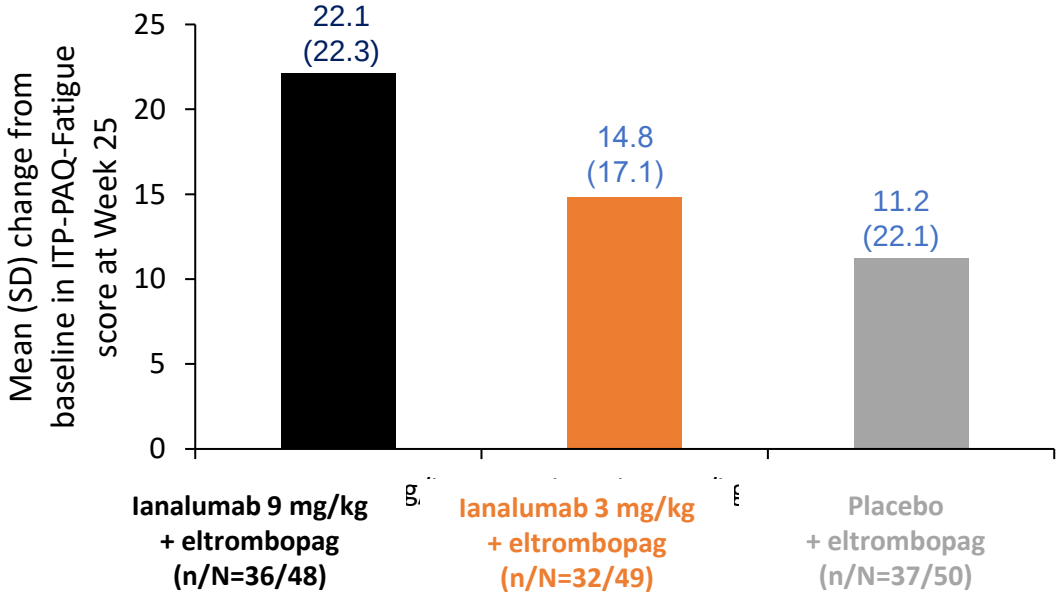


No. of evaluable participants

Pbo	46	46	45	40	42	44	32	22	18	15	9
lana3	40	42	41	40	36	39	28	21	16	13	9
lana9	45	46	44	41	40	40	31	28	18	13	7

4. Changes in ITP-PAQ-Fatigue

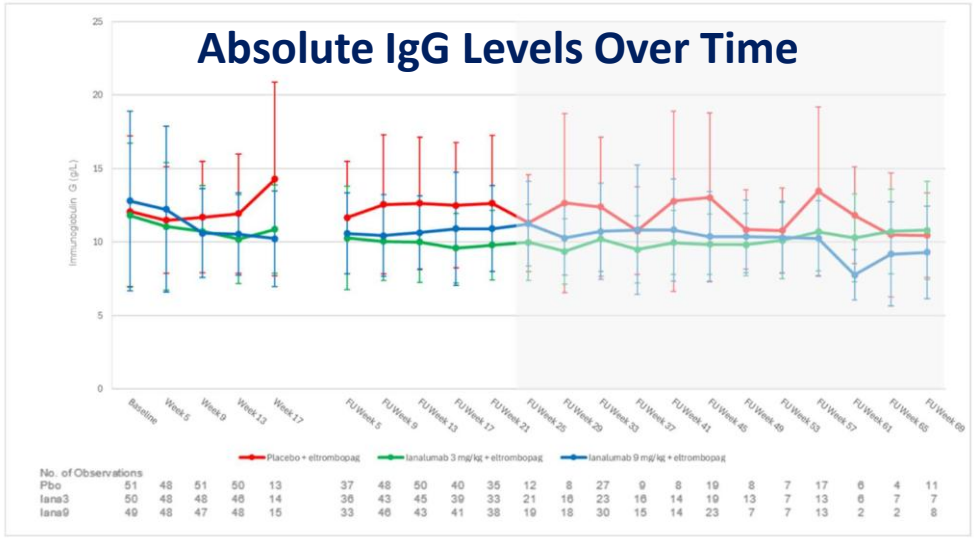
Higher score denotes higher HRQoL

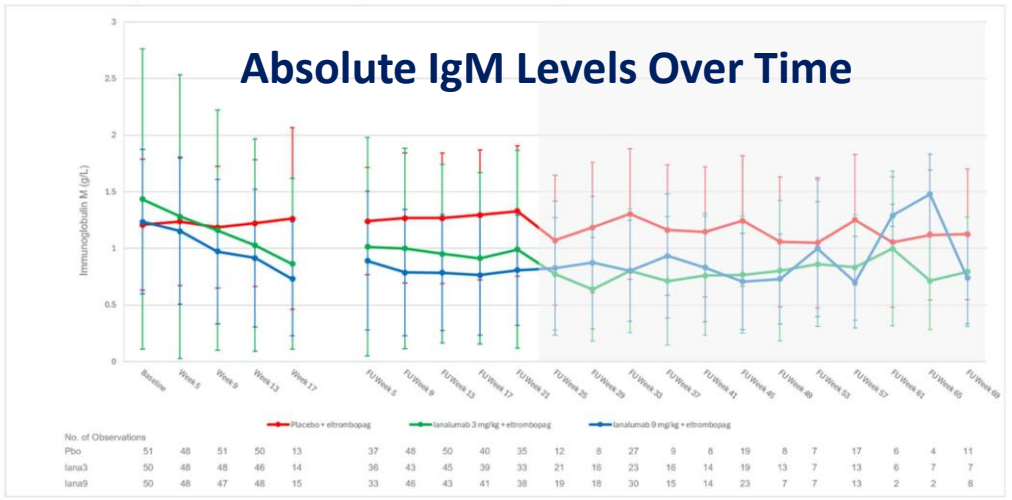


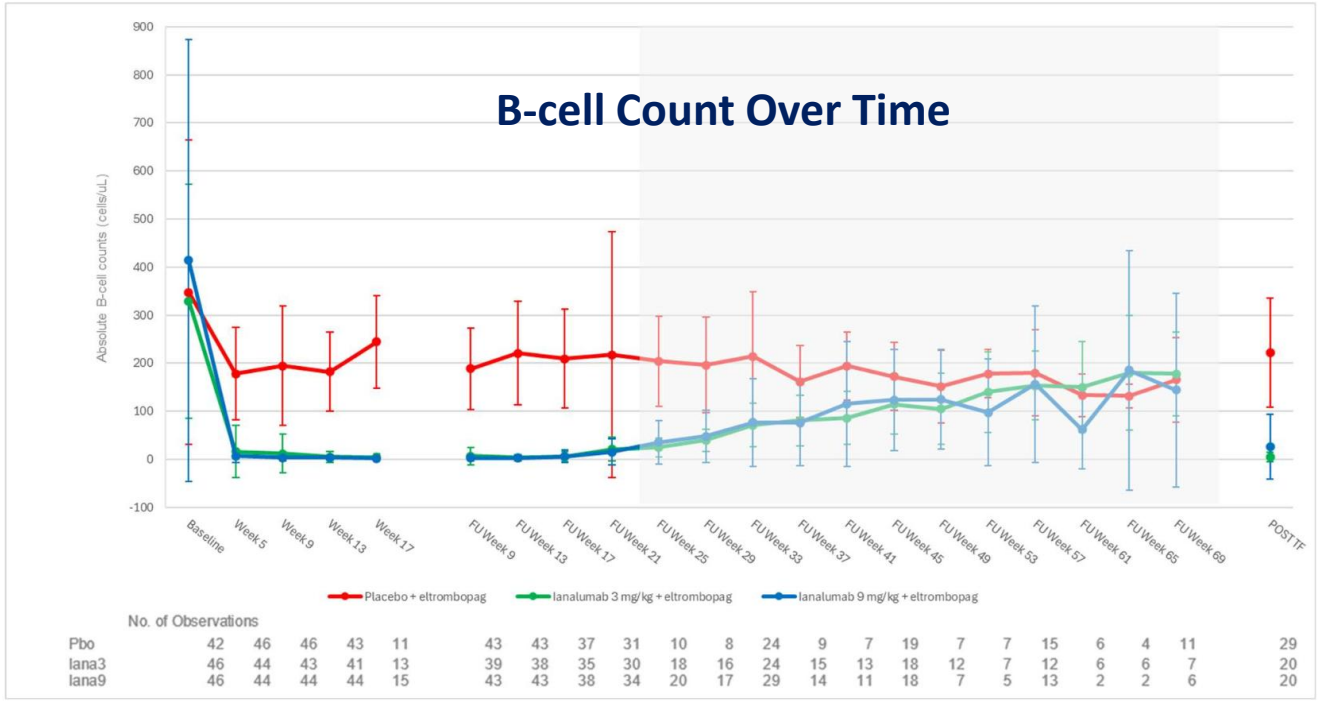
VAYHIT2: On- and Post-Treatment Adverse Events of Special Interest

Category, n (%)	Ianalumab 9 mg/kg + eltrombopag (n=50)		Ianalumab 3 mg/kg + eltrombopag (n=50)		Placebo + eltrombopag (n=51)	
	All grades	Grade ≥3	All grades	Grade ≥3	All grades	Grade ≥3
Infections	24 (48.0)	2 (4.0)	28 (56.0)	1 (2.0)	27 (52.9)	1 (2.0)
Neutropenia	**8 (16.0)**	**7 (14.0)**	**6 (12.0)**	3 (6.0)	1 (2.0)	0
Infusion-related reactions	7 (14.0)	0	4 (8.0)	0	4 (7.8)	0
Hypogamma globulinemia	1 (2.0)	0	0	0	0	0

VAYHIT2: Changes in Ig level and B-cell depletion







VAYHIT2: Eltrombopag Cumulative Dose and Duration of Exposure

	Ianalumab 9 mg/kg (N=50)	Ianalumab 3 mg/kg (N=50)	Placebo (N=51)
Total number of patients receiving eltrombopag, n (%)	50 (100)	49* (98.0)	51 (100)
Cumulative dose, median (IQR), mg	3600.0 (1562.5 to 6700.0)	3375.0 (1787.5 to 6575.0)	4900.0 (2675.0 to 7650.0)
Duration of exposure, mean (±SD), weeks	16.3 (±8.3)	18.1 (±6.9)	19.7 (±6.8)
Duration of exposure, median (IQR), weeks	19.0 (10.1 to 23.9)	20.3 (14.0 to 24.0)	23.6 (18.1 to 24.1)
Duration of exposure, range, weeks	0.4 to 24.4	3.6 to 24.6	2.0 to 25.1

IQR, interquartile range; SD, standard deviation.

*Patient did not receive eltrombopag as they responded well to rescue therapy and maintained platelet counts >100 × 10^9/L throughout the treatment period.

VAYHIT2: Take home messages

- A short course of ianalumab in combination with eltrombopag induced durable disease control in patients with primary ITP previously treated with corticosteroids
    - Ianalumab 9 mg/kg and 3 mg/kg in combination with eltrombopag both significantly prolonged TTF; patients receiving ianalumab 9 mg/kg achieved a significantly higher rate of SR6 vs placebo + eltrombopag
    - More patients treated with ianalumab vs placebo were able to taper and discontinue eltrombopag and maintain safe platelet counts without need for additional ITP therapy or rescue therapy
    - Ianalumab 9 mg/kg vs 3 mg/kg: higher rate of SR6, higher 6 months R and CR, higher neutropenia
    - Fatigue improved in all treatment groups; this trend was more pronounced in patients receiving ianalumab + eltrombopag, particularly the 9 mg/kg group
    - Ianalumab was well tolerated, with similar infection severity and frequency relative to placebo
- Longer-term follow-up is necessary to confirm the disease-modifying impact of ianalumab in primary ITP

Ianalumab in addition to 1L corticosteroids is being investigated as a short-course therapy for patients with primary ITP

VAYHIT1 is a randomized, double-blind, placebo-controlled, Phase III study of ianalumab in addition to 1L corticosteroids in adults with primary ITP[1,2] (NCT05653349)

Screening (≥28 days)

Key inclusion criteria

- Aged ≥18 years
- Primary ITP diagnosed within 3 months of initiating 1L treatment
- Platelet count <30 G/L before starting 1L therapy for ITP
- Response (platelet count ≥50 G/L) to corticosteroids* (±IVIg) prior to randomization

1:1:1

Randomization† (N=225)

Double-blind treatment period (16 weeks)

- Lower ianalumab dose IV and a corticosteroid* (n=75)
- Higher ianalumab dose IV and a corticosteroid* (n=75)
- Placebo IV and a corticosteroid* (n=75)

Ianalumab/placebo will be administered every 4 weeks for four infusions in total

Follow-up period

For patients:

Without treatment failure
Follow-up for efficacy and safety up to 39 months after randomization of the last patient or until treatment failure

With treatment failure
Follow-up for safety for 20 weeks then quarterly for up to 2 years after the last dose of ianalumab or placebo

Primary endpoint: time from randomization to treatment failure (TTF);
treatment failure is defined as platelet count <30 G/L later than 8 weeks from randomization, start of a new ITP treatment, need for rescue therapy (any treatment for ITP given during the study with the aim of rapidly increasing platelet count)‡ later than 8 weeks from randomization, or death

Second-course ianalumab is being investigated in patients with ITP and wAIHA who have previously benefited from ianalumab

VAY RE-HIT is a multicenter, double-blind, exploratory, Phase II study of second-course ianalumab after treatment failure in ITP and wAIHA Phase III trials[1] (NCT07039422)

Screening

ITP-specific key inclusion criteria
- Patients aged ≥18 years
- Previously enrolled and treated with ianalumab or placebo in VAYHIT1 or VAYHIT2
- Treatment failure in VAYHIT1 or VAHIT2 ≥2 years after the last infusion of ianalumab

Double-blind treatment period (16 weeks)

Ianalumab 3 mg/kg IV* (n=30)

Ianalumab 9 mg/kg IV† (n=30)

Ianalumab/placebo will be administered every 4 weeks for four infusions in total

Follow-up period

For patients with ITP:

Without treatment failure
Follow-up for efficacy and safety up to 2 years after last dose or until treatment failure

With treatment failure
Follow-up for safety up to 2 years after the last dose of ianalumab

Primary endpoint for patients with ITP: proportion of patients who are free from treatment failure 12 months after the start of second-course ianalumab (treatment failure defined as in VAYHIT1 and VAYHIT2)[2,3]

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Thank you for your attention