

# Long-term efficacy of Syk-inhibition in ITP. Real-world data and the importance of tailored therapy.

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# DISCLOSURES

- Grant/ Research support

Sanofi, Novartis, Takeda, Amgen, Novonordisk

- Advisory board

Boheringer, Novartis, Sanofi, Sobi, Takeda, Grifols, Amgen, Shiomi, Novonordisk

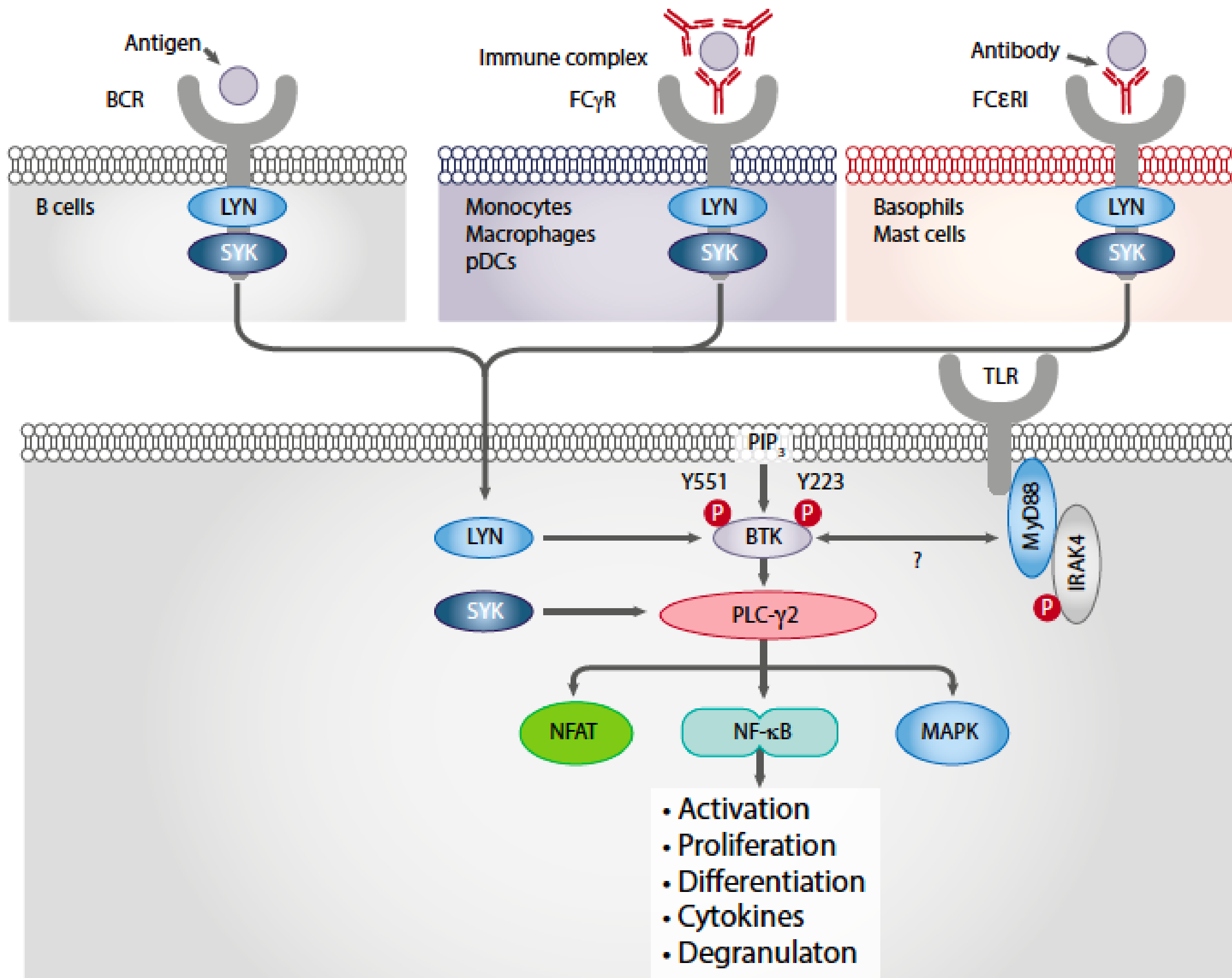
- Consultant

Member of director Committee Scientific of SETH (Sociedad Española de Trombosis y Hemostasia), Member of director Committee of Fundación Victoria Eugenia, Member of director Committee of CAT, Member of director Committee of GEPTI, Member of director Committee of REPTT-GEA

- Speaker bureau

Boheringer, Novartis, Sanofi, Sobi, Takeda, Grifols, Amgen, Shiomi, Novonordisk

# What is Spleen Tyrosine Kinase (SYK)?



- Spleen tyrosine kinase (SYK).
- Chromosome 9q22, 635 aa, 72 kDa.
- FcγRs active SYK
- SYK active a signs cascade
- Change in cytoskeleton and phagocytosis
- SYK Induces:
  - Lymphocyte B activation
  - Antibodies production
  - Activation fo GPVI y CLEC-2 (platelet activity)

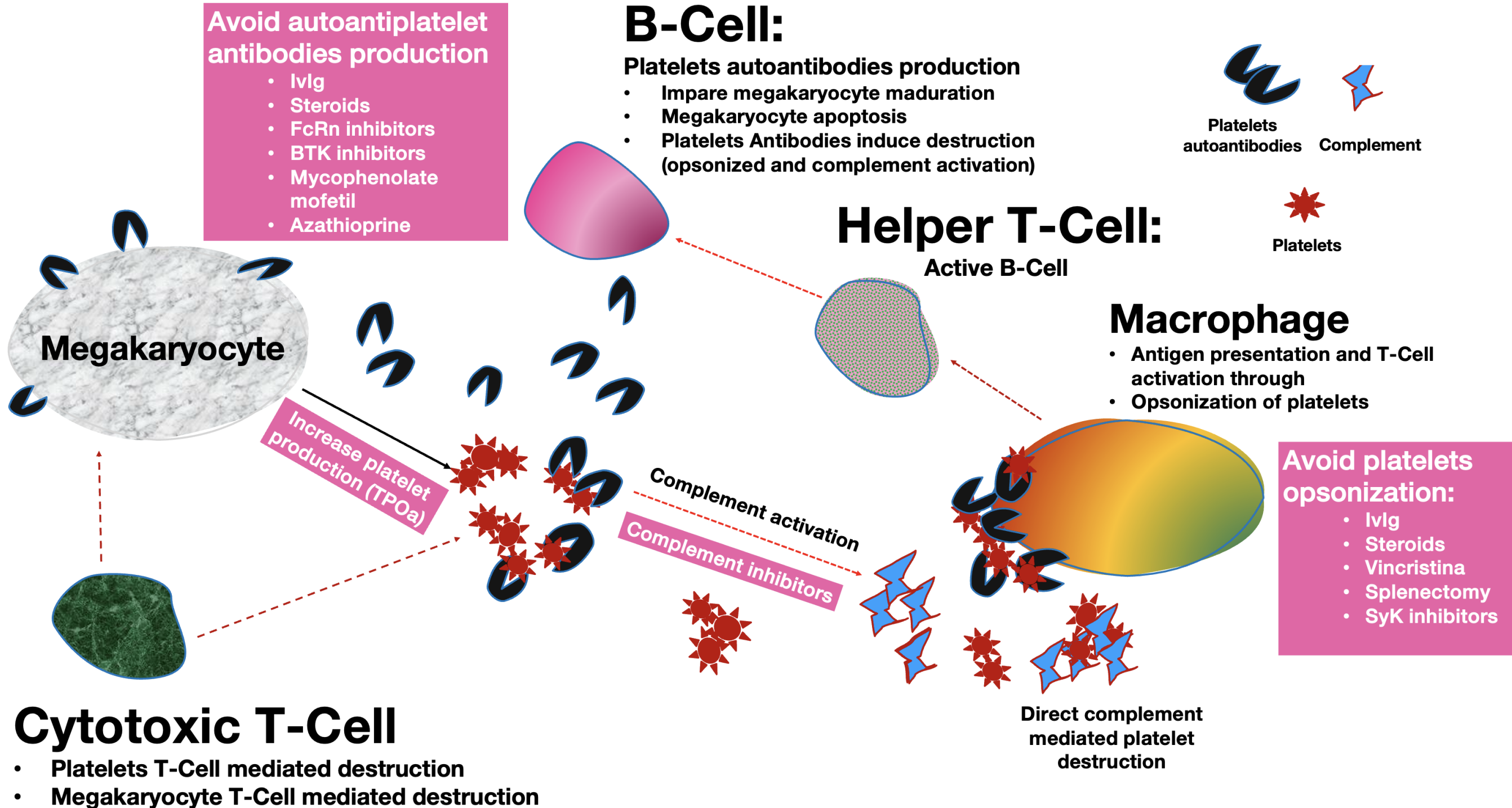
# Syk inhibitors portfolio

|               | ITP      | RA      | wAIHA   | CLL     | AML     | B-cell lymphoma | Hematologic malignancies | COVID-19 | CLE     | Sjögren's |
|---------------|----------|---------|---------|---------|---------|-----------------|--------------------------|----------|---------|-----------|
| Fostamatinib  | Approved |         |         |         |         |                 |                          |          |         |           |
| Entospletinib |          | Phase 2 |         | Phase 2 | Phase 2 | Phase 2         | Phase 2                  | Phase 2  |         |           |
| HMPL-523      | Phase 3  |         | Phase 2 |         |         | Phase 2         |                          |          |         |           |
| GSK2646264    |          |         |         |         |         |                 |                          | Phase 1  | Phase 2 | Phase 2   |
| Lanraplenib   |          | Phase 2 |         |         |         |                 | Phase 2                  |          |         |           |
| Ceviplenib    |          |         |         | Phase 1 |         |                 |                          |          |         |           |

ITP:

Avoid autoantibodies

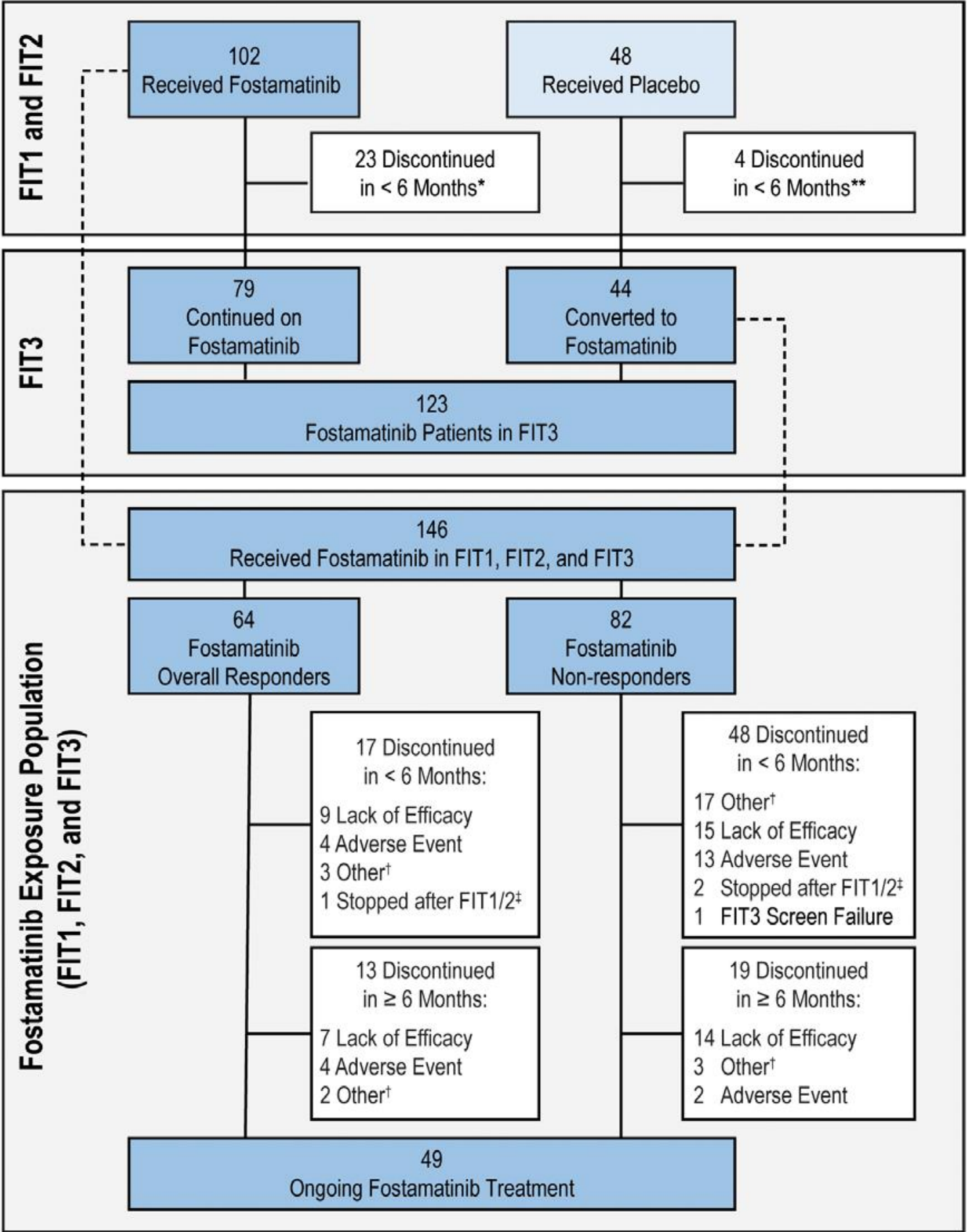
Decrease Macrophage activity



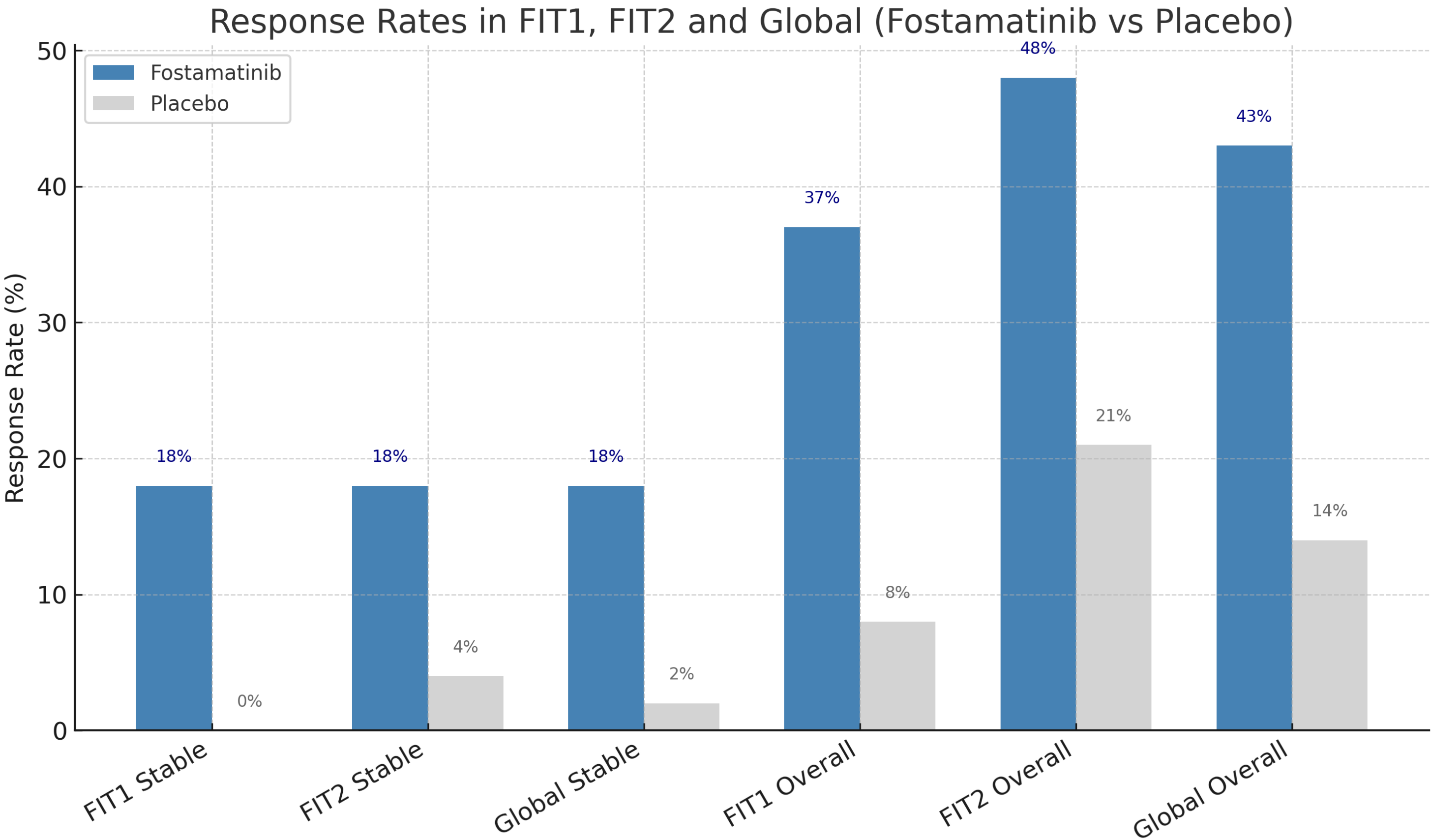
Cooper N, et al. Platelets. 2023 Dec;34(1):2131751;  
Mingot-Castellano ME, et al. Pharmaceuticals (Basel).  
2022 Jun 23;15(7):779

# FOSTAMATINIB: STUDIES FIT-1/FIT-2

FIT-1/FIT-2: Randomized control/placebo, doble blinded



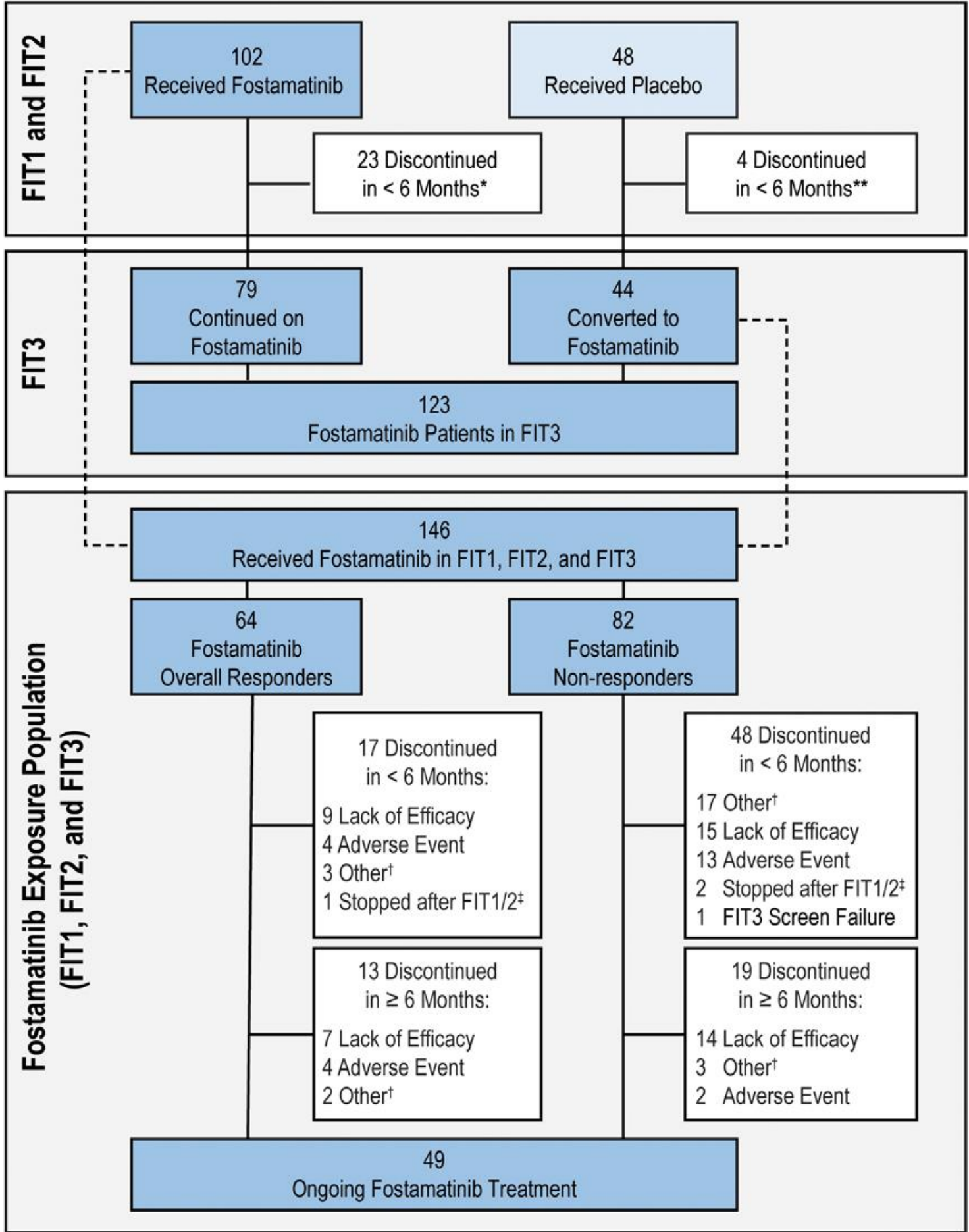
\* Reasons for discontinuation included in total fostamatinib exposure population information  
\*\*4 discontinued due to AEs  
† Other may include: lost to follow-up, non-compliance, physician decision, subject decision  
‡ After completing initial study (FIT1 or FIT2), patient chose not to enter extension study



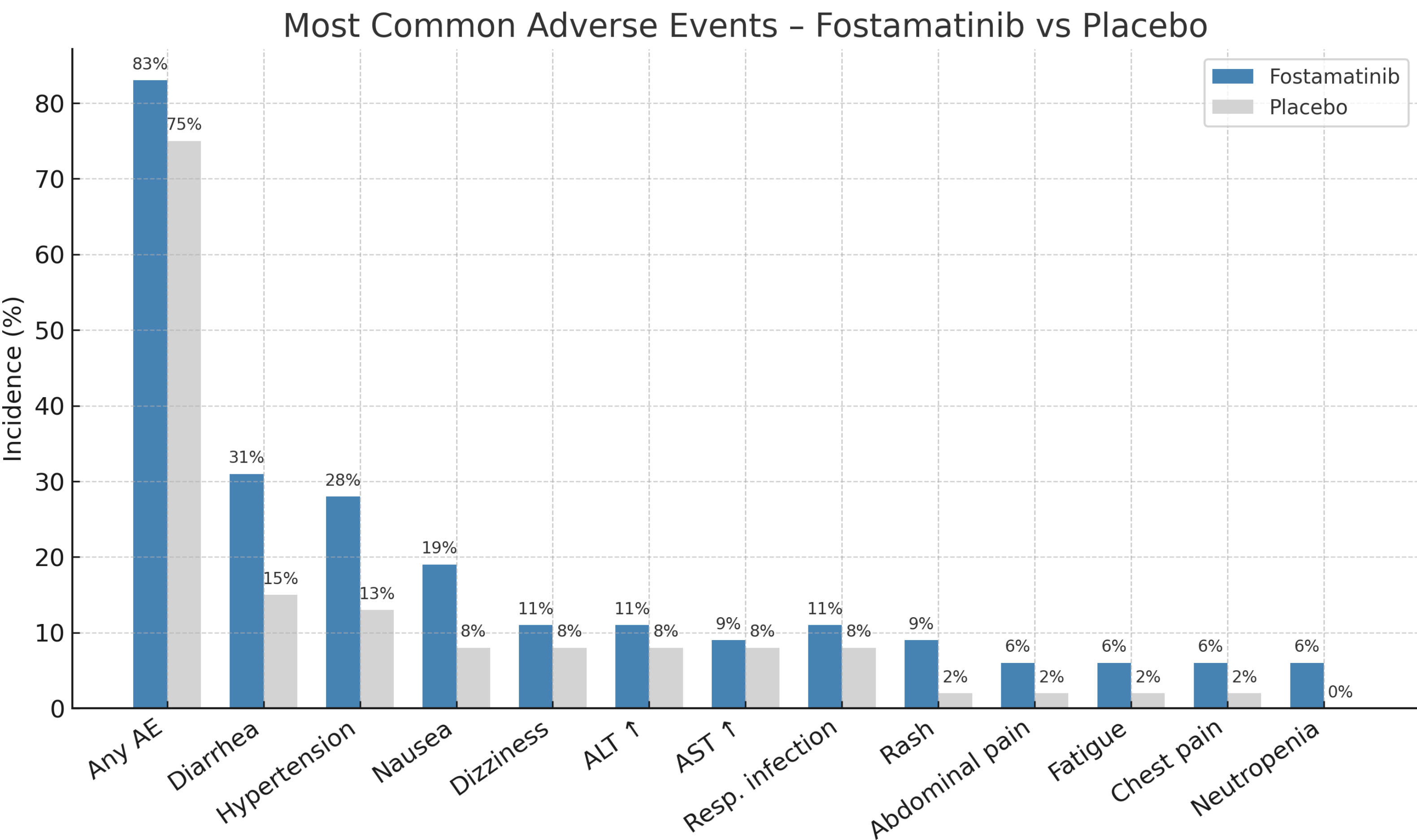
No difference in response in less than 3 years from diagnose

# FOSTAMATINIB: STUDIES FIT-1/FIT-2

FIT-1/FIT-2: Randomized control/placebo, doble blinded



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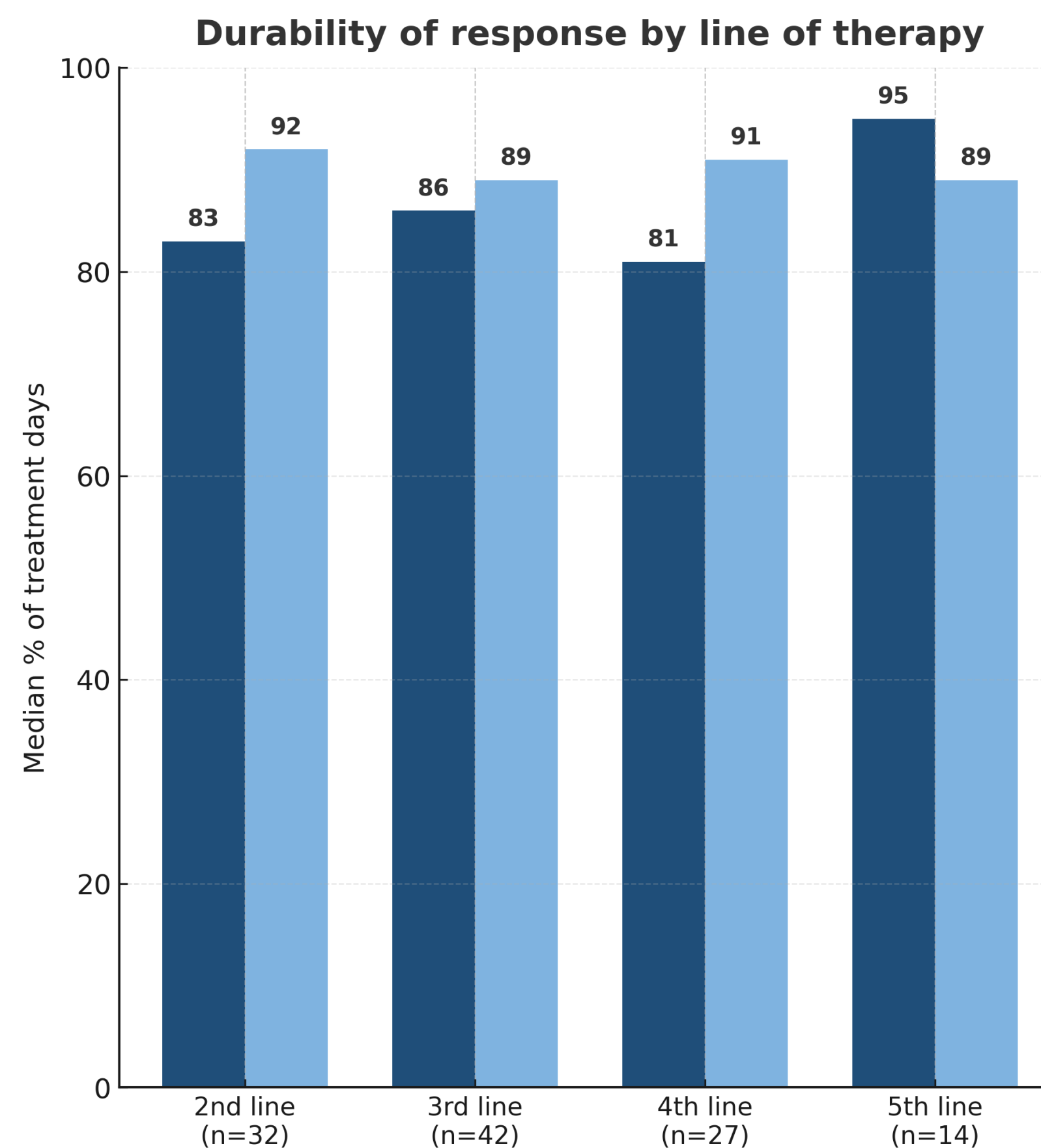
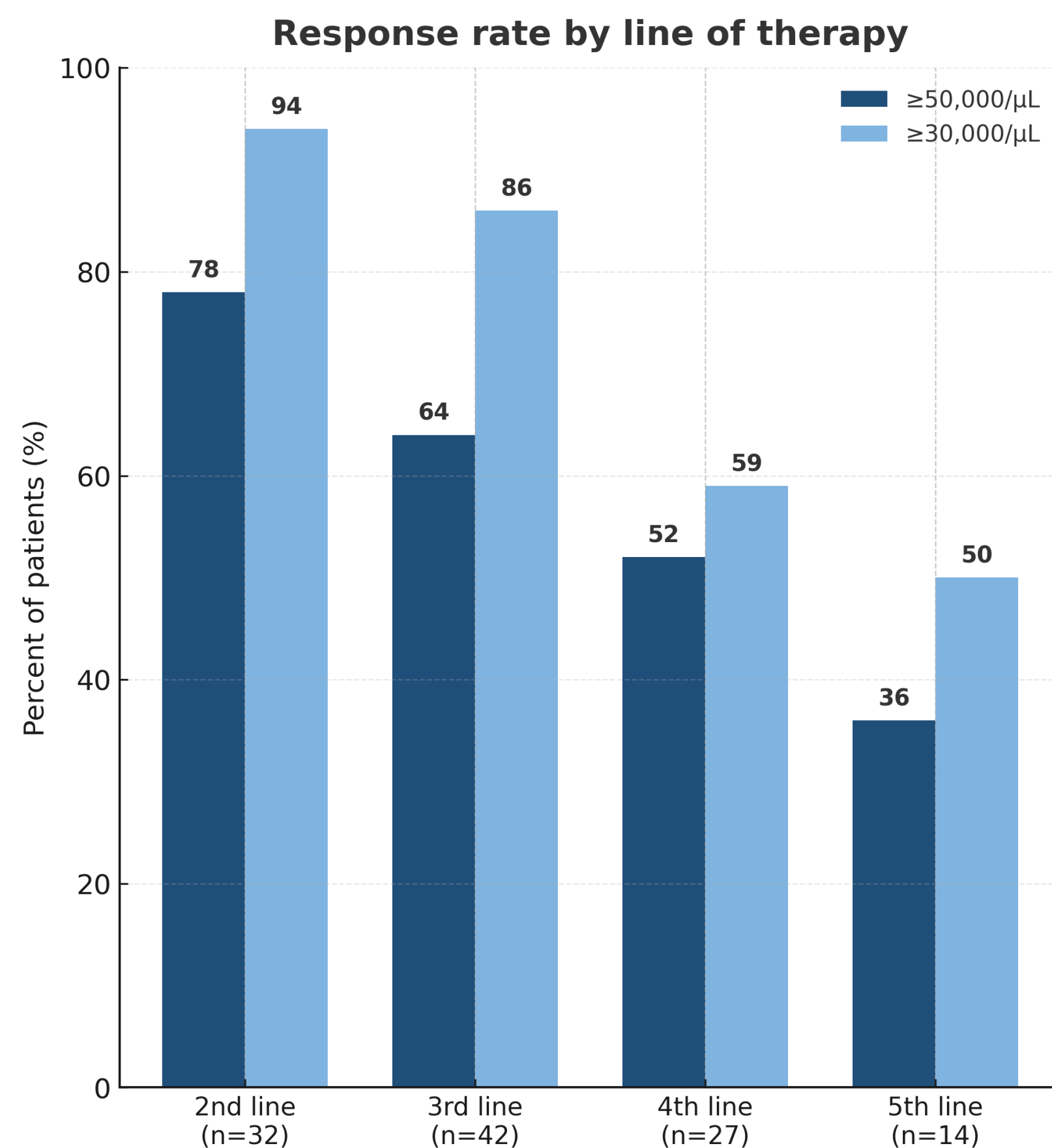
1. Bussel J, et al. *Am J Hematol.* 2018;93(7):921-30. 2. Cooper N, et al. *Ther Adv Hematol.* 2021;12:1-12 3. Bussel JB, et al. *Am J Hematol.* 2019;94(5):546-53.



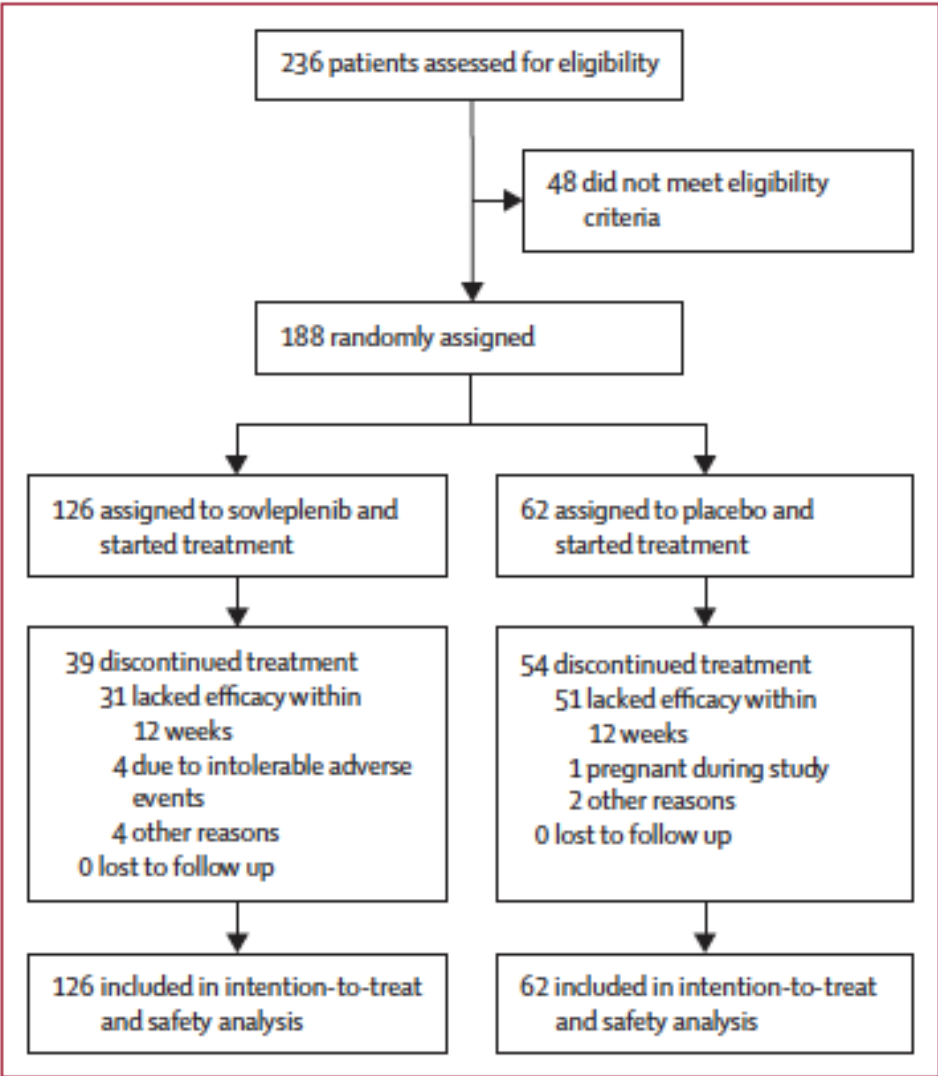
# What to wait from Fostamatinib

- The sooner the better
- Patients who response maintained this response, high stability

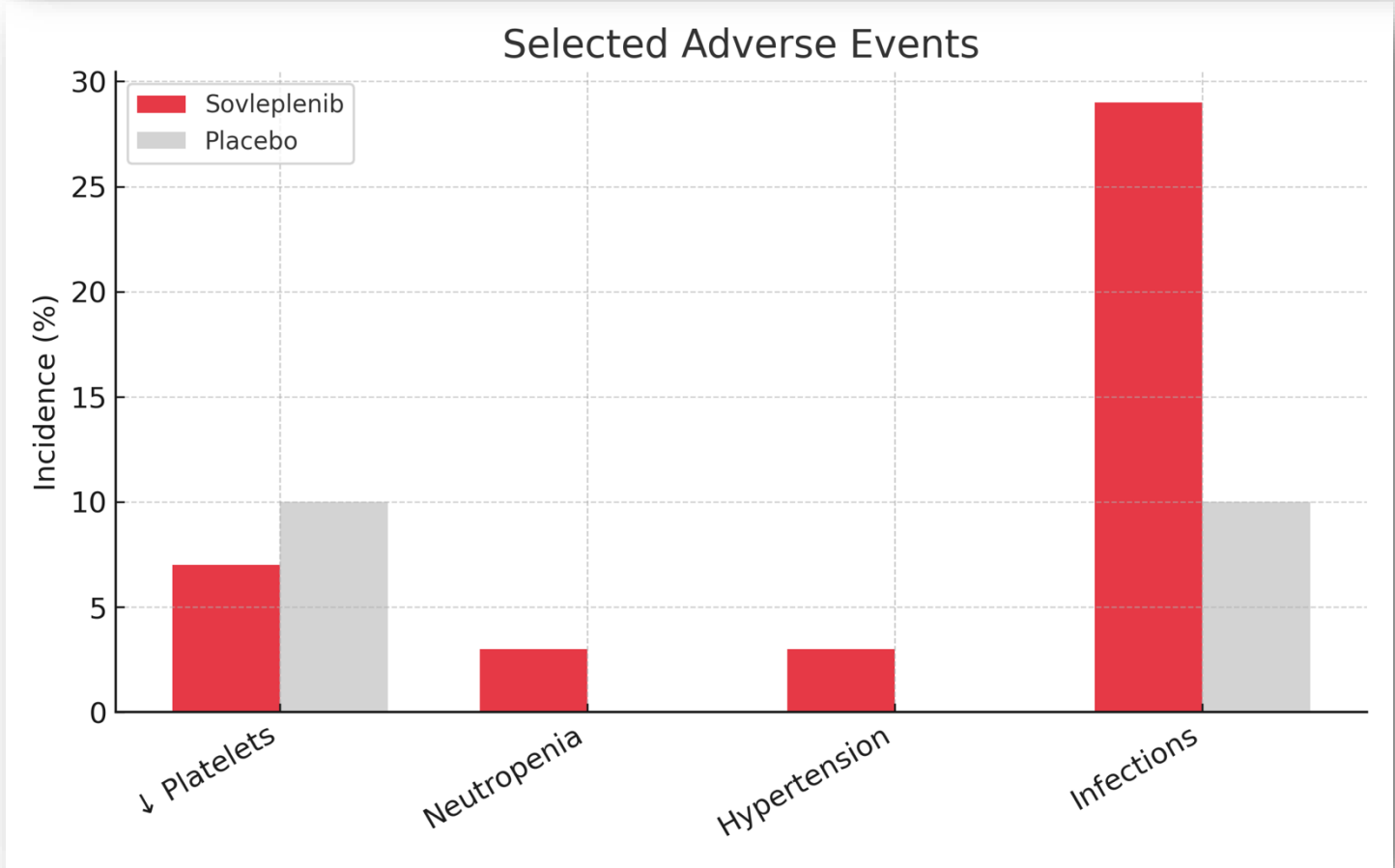
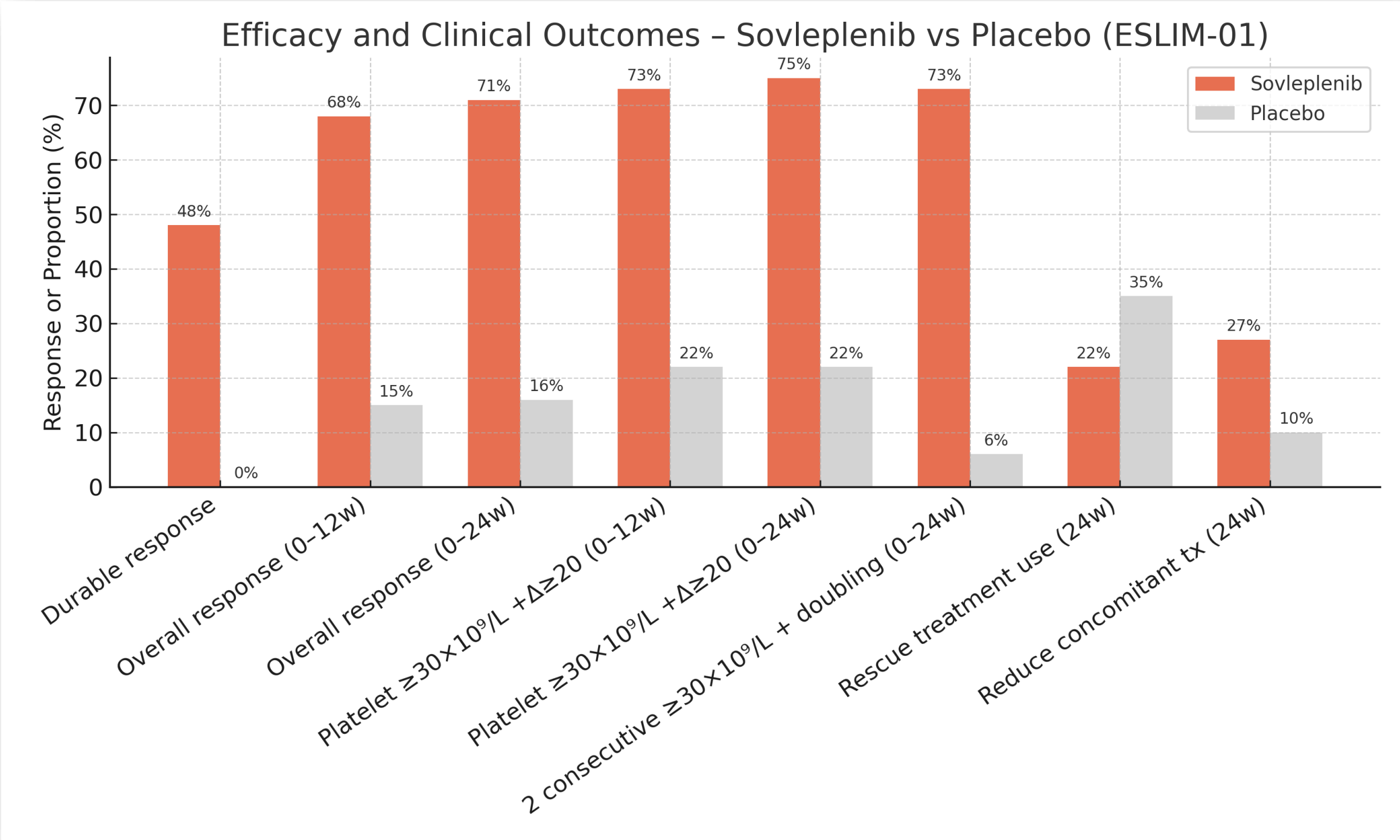
**Fostamatinib - Response and Durability by Line of Therapy**



# Sovleplenib, fase 3 study in ITP

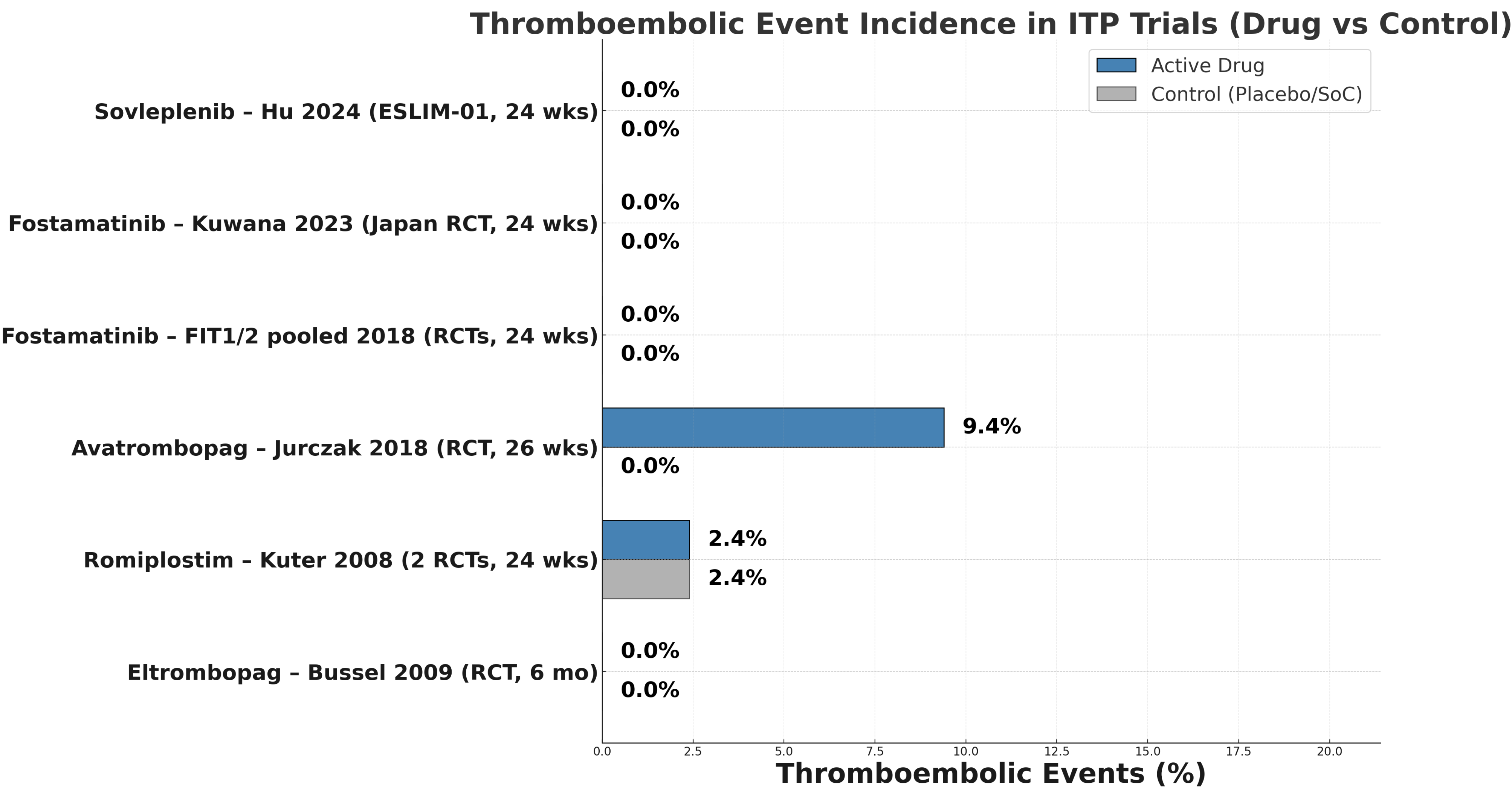


|                                                                                 |            |           |
|---------------------------------------------------------------------------------|------------|-----------|
| Baseline platelet count                                                         |            |           |
| <15 × 10 <sup>9</sup> /L                                                        | 75 (60%)   | 37 (60%)  |
| ≥15 × 10 <sup>9</sup> /L                                                        | 51 (40%)   | 25 (40%)  |
| Previous splenectomy                                                            |            |           |
| Yes                                                                             | 5 (4%)     | 3 (5%)    |
| No                                                                              | 121 (96%)  | 59 (95%)  |
| Concomitant anti-immune thrombocytopenia therapy at baseline                    |            |           |
| Yes                                                                             | 41 (33%)   | 20 (32%)  |
| No                                                                              | 85 (67%)   | 42 (68%)  |
| Lines of previous anti-immune thrombocytopenia therapies†                       |            |           |
|                                                                                 | 4-0 (1-10) | 4-0 (1-9) |
| Therapy type (≥10%)                                                             |            |           |
| Glucocorticoid                                                                  | 121 (96%)  | 60 (97%)  |
| Traditional Chinese medicine                                                    | 74 (59%)   | 37 (60%)  |
| Thrombopoietin receptor agonists                                                | 65 (52%)   | 32 (52%)  |
| Intravenous immunoglobulin                                                      | 63 (50%)   | 29 (47%)  |
| Thrombopoietin                                                                  | 60 (48%)   | 21 (34%)  |
| Platelet transfusion                                                            | 53 (42%)   | 13 (21%)  |
| Danazol/Stanozolol                                                              | 41 (33%)   | 21 (34%)  |
| Caffeic acid                                                                    | 23 (18%)   | 11 (18%)  |
| Anti-CD20 antibody                                                              | 20 (16%)   | 7 (11%)   |
| Other‡                                                                          | 19 (15%)   | 8 (13%)   |
| Ciclosporin                                                                     | 18 (14%)   | 10 (16%)  |
| IL-11                                                                           | 16 (13%)   | 10 (16%)  |
| Previous thrombopoietin or thrombopoietin receptor agonists medication, or both |            |           |
| Yes                                                                             | 94 (75%)   | 40 (65%)  |
| No                                                                              | 32 (25%)   | 22 (35%)  |



**No better response:**  
Splenectomized  
ECOG 1  
(few patients?)

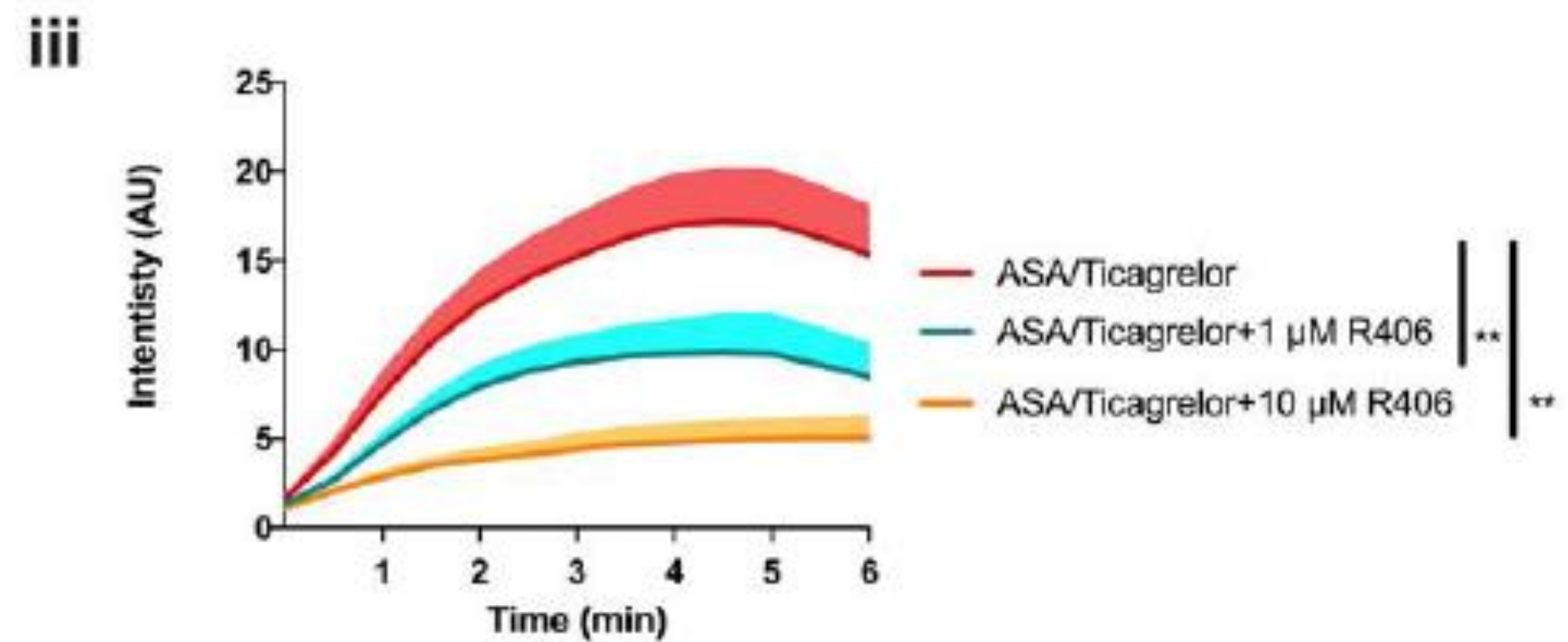
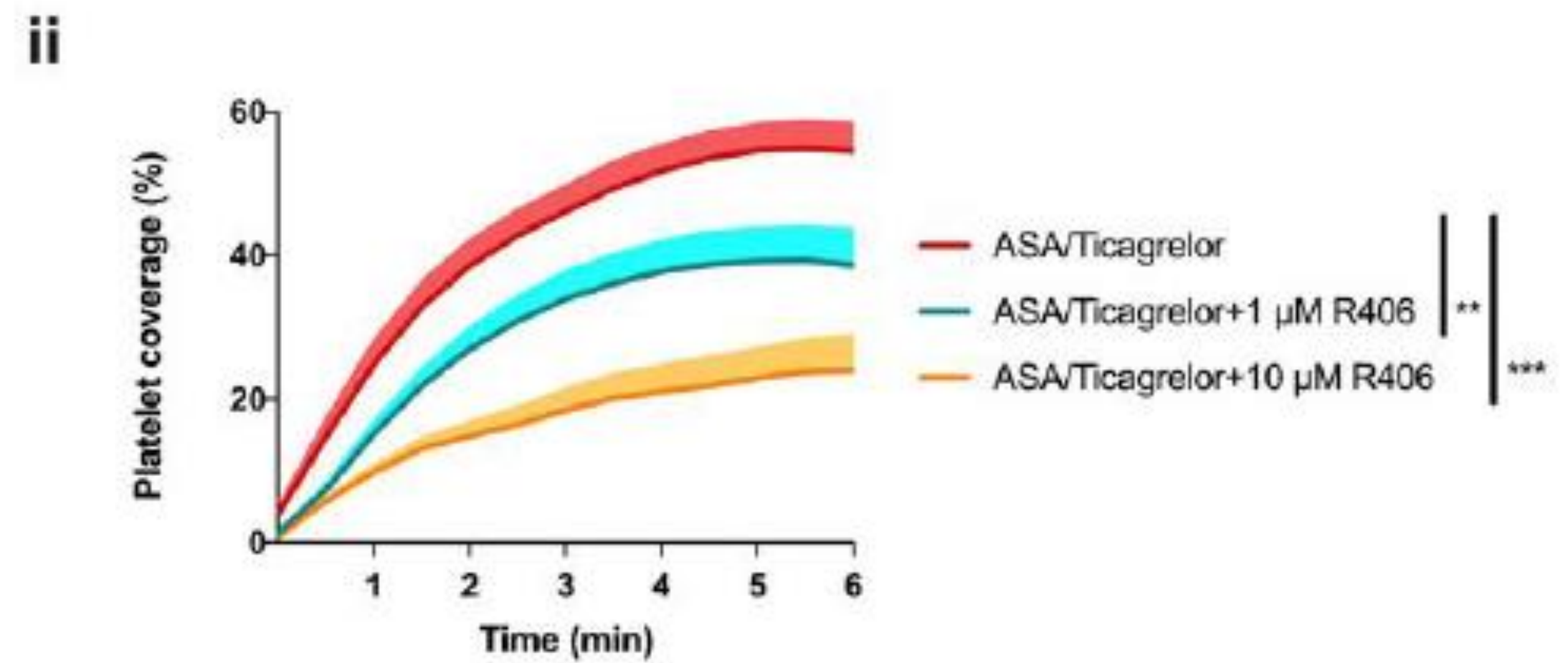
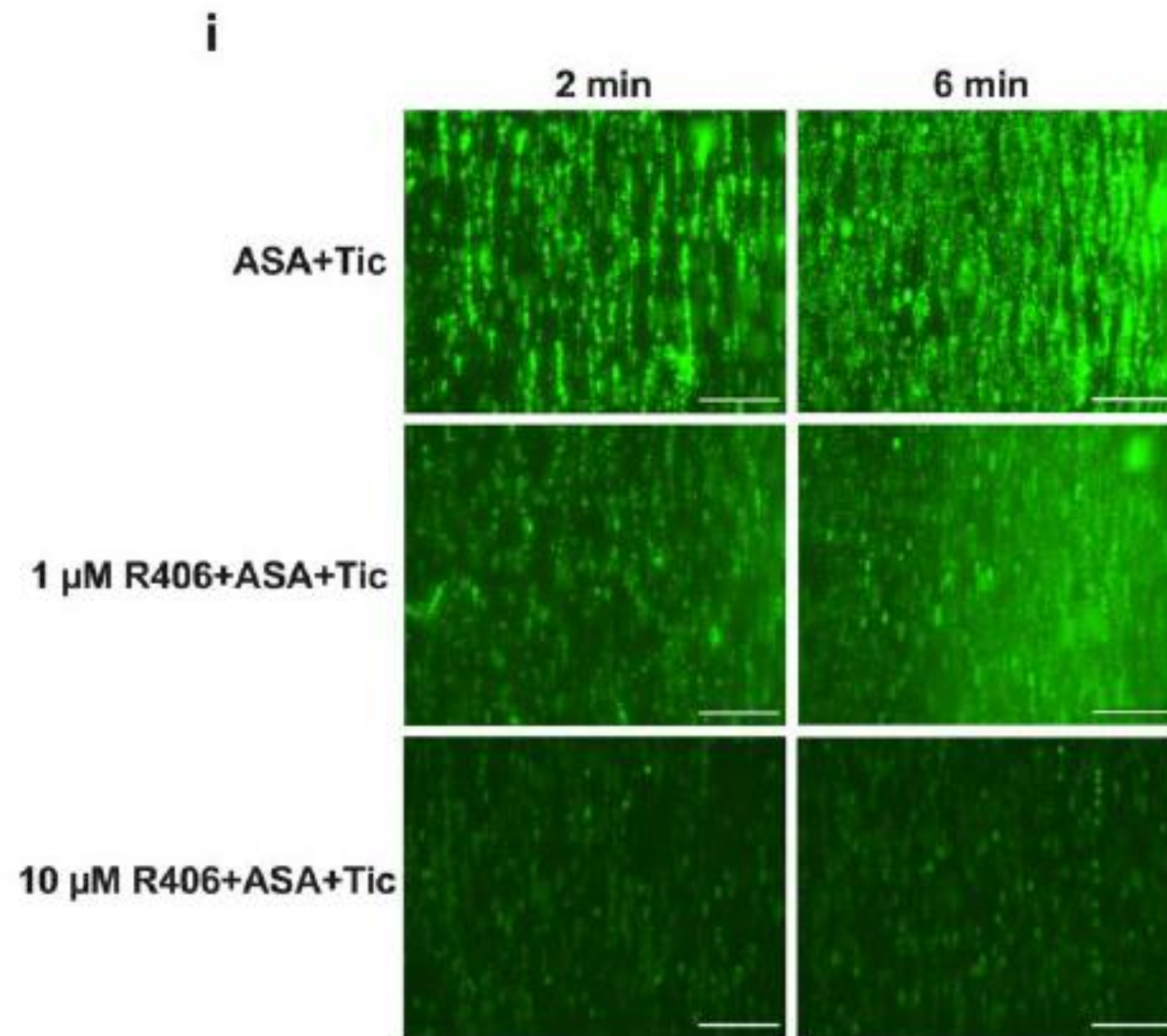
# Fostamatinib and thromboembolic events



Bussel JB, et al. *Lancet*. 2009;373:641-648; Kuter DJ, et al. *Lancet*. 2008;371:395-403; Jurczak W, et al. *Br J Haematol*. 2018;183:479-490; Bussel JB, et al. *Am J Hematol*. 2018;93:921-930; Kuwana M, et al. *Br J Haematol*. 2023;200:802-811; Hu Y, et al. *Lancet Haematol*. 2024;11:e567–e579.



# Fostamatinib and haemostasis



# Fostamatinib in real world: Efficacy

Fostamatinib Studies – Comparative Summary

| Variable                         | FOSTAMES –<br>González-López et al.,<br>2024 (Spain) | FOSTASUR –<br>Jiménez-Bárceñas 2024<br>(Andalusia, Spain) | Moore et al., 2024 (USA,<br>single-center)                                  | Kuwana & Tomiyama,<br>2025 (Japan extension) | GIMEMA ITP1122 –<br>Lucchini et al., 2025<br>(Italy) |
|----------------------------------|------------------------------------------------------|-----------------------------------------------------------|-----------------------------------------------------------------------------|----------------------------------------------|------------------------------------------------------|
| N                                | 138                                                  | 44                                                        | 31                                                                          | 33                                           | 95                                                   |
| Median prior lines               | 4 (IQR 2–5)                                          | 4 (range 1–7)                                             | 4 (2–7)                                                                     | NR                                           | 4                                                    |
| Median age (y)                   | 66 (IQR 56–80)                                       | 58                                                        | 50 (25–88)                                                                  | 62 (25–81)                                   | 64                                                   |
| Women (%)                        | 55.8%                                                | 47.7%                                                     | 58%                                                                         | 79%                                          | 59%                                                  |
| ITP type                         | Primary 88%, Secondary<br>11%                        | Primary (ND 6.8%, P<br>13.6%, C 79.5%)                    | Refractory chronic ITP                                                      | Primary ITP                                  | Primary (ND 0%, P 11%,<br>C 89%); Secondary 6%       |
| Overall response (%)             | 79%                                                  | 70% (end of study)                                        | 45%                                                                         | 55% (≥30k); 48% (≥50k)                       | 68% (≤12 weeks)                                      |
| Complete response (%)            | 53.6%                                                | 47.5% (end of study)                                      | NR                                                                          | NR                                           | 32%                                                  |
| Time to first response<br>(days) | 11 (IQR 7–21)                                        | (56.8% by week 2)                                         | 9 (4–55)                                                                    | NR                                           | median 4.6 weeks;<br>range 1–56 wks                  |
| Relapse after response<br>(%)    | 13.8%                                                | 6.8% (3/44)                                               | NR                                                                          | 18%                                          | 17.6% (12/68)                                        |
| Median follow-up                 | Observation window 27<br>mo                          | Study window 15 mo                                        | NR                                                                          | Exposure median 771<br>days                  | ≥6 months (per protocol)                             |
| Duration of response             | Time in response 83.3%<br>over 27 mo; median NR      | 6 months<br>(Range: 1-14)                                 | Durable response 32%;<br>70% of durable<br>responses maintained at<br>24 mo | Median 589 days (≥50k)                       | 3.5 months<br>(IQR 1.18 – 10.13)                     |

NR: Non reported;



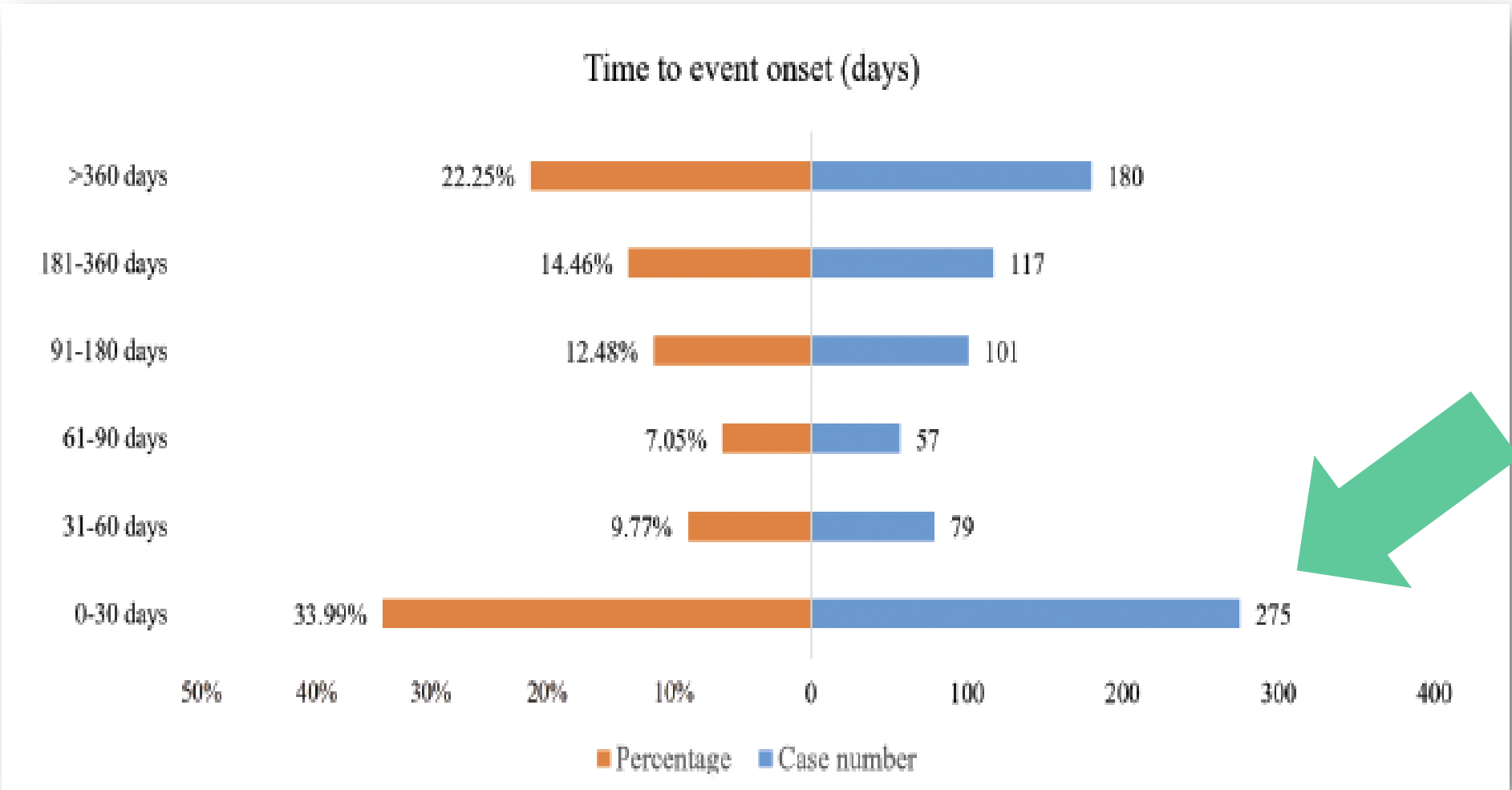
# Fostamatinib in real world: Safety

|                           | González-López 2024<br>Fostames (Spain) | Jiménez-Bárcenas<br>2024 FOSTASUR<br>(Spain, Andalusia) | Kuwana 2025<br>(Japan) | GIMEMA ITP1122 2025<br>(Italy) |
|---------------------------|-----------------------------------------|---------------------------------------------------------|------------------------|--------------------------------|
| Diarrhea                  | 15.2%                                   | 13.6%                                                   | 30%                    | 37.5%                          |
| Hypertension              | 10.7%                                   | 4.5%                                                    | 30%                    | 21.8%                          |
| Transaminase<br>elevation | 4.3%                                    | 4.5%                                                    | NR                     | 21.8%                          |
| Neutropenia               | NR                                      | NR                                                      | NR                     | 9.3%                           |
| Headache                  | 7.8%                                    | 2.3%                                                    | NR                     | 3.0%                           |
| Infections                | NR                                      | NR                                                      | NR                     | NR                             |

González-López TJ, et al. *Blood*. 2024;144(6):646-657; Jiménez-Bárcenas R, et al. *Br J Haematol*. 2024;00:1-9.; Kuwana M, et al. *Int J Hematol*. 2025;121:356-362; Lucchini E et al. *Br J Haematol*. 2025 Aug 25. doi: 10.1111/bjh.70069. Epub ahead of print. PMID: 40855761.



# Fostamatinib in real world: Safety



| SOC                                        | PT                                             | N   | ROR (95%two-sided CI) |   |
|--------------------------------------------|------------------------------------------------|-----|-----------------------|---|
| Vascular disorders                         | Hypertension                                   | 131 | 3.94(3.31-4.69)       | • |
|                                            | Intestinal mass                                | 3   | 13.04(4.19-40.61)     | ← |
|                                            | Faeces soft                                    | 9   | 5.56(2.89-10.7)       | + |
|                                            | Diarrhoea                                      | 533 | 5.3(4.84-5.81)        | • |
|                                            | Food poisoning                                 | 5   | 5.24(2.18-12.61)      | ← |
|                                            | Frequent bowel movements                       | 25  | 4.88(3.29-7.24)       | • |
|                                            | Anal incontinence                              | 10  | 4.88(2.62-9.08)       | ← |
|                                            | Flatulence                                     | 29  | 3.40(2.36-4.9)        | • |
| Surgical and medical procedures            | Prostatic operation                            | 3   | 16.18(5.19-50.41)     | ← |
|                                            | Hospitalisation                                | 250 | 8.77(7.71-9.98)       | • |
|                                            | Eye operation                                  | 5   | 6.02(2.5-14.49)       | ← |
|                                            | Cholecystectomy                                | 7   | 5.01(2.38-10.53)      | ← |
| Injury, poisoning procedural complications | Vaccination complication                       | 7   | 23.31(11.06-49.13)    | ← |
|                                            | Product prescribing issue                      | 44  | 11.30(8.39-15.23)     | + |
|                                            | Product dose omission issue                    | 385 | 5.39(4.85-5.99)       | • |
|                                            | Contusion                                      | 72  | 4.83(3.82-6.1)        | • |
| Nervous system                             | Intentional product misuse                     | 71  | 4.6(3.64-5.82)        | • |
|                                            | Product dose omission                          | 109 | 3.99(3.29-4.83)       | • |
|                                            | Cerebral thrombosis <sup>a</sup>               | 4   | 10.58(3.96-28.28)     | ← |
|                                            | Blood pressure increased                       | 167 | 6.45(5.52-7.53)       | • |
| Investigations                             | Blood pressure abnormal                        | 16  | 4.19(2.56-6.85)       | • |
|                                            | Hepatic enzyme increased                       | 37  | 3.25(2.35-4.5)        | • |
| Infections and infestations                | Necrotising soft tissue infection <sup>a</sup> | 3   | 49.18(15.64-154.61)   | ← |

ROR

# Real-World Use of Fostamatinib in the world

## SAFETY INFORMATION

| Parameter, <i>n</i> (%)                  | Fostamatinib<br>( <i>n</i> = 51) | Eltrombopag<br>( <i>n</i> = 87) | Romiplostim<br>( <i>n</i> = 127) | Avatrombopag<br>( <i>n</i> = 44) |
|------------------------------------------|----------------------------------|---------------------------------|----------------------------------|----------------------------------|
| AEs reported during therapy              | 46 (90.2)                        | 27 (31.0)                       | 53 (41.7)                        | 24 (54.5)                        |
| AEs associated with drug discontinuation | 4 (7.8)                          | 13 (14.9)                       | 6 (4.7)                          | 5 (11.4)                         |
| AEs leading to unplanned clinic visit    | 1 (2.0)                          | 2 (2.3)                         | 1 (0.8)                          | 2 (4.5)                          |
| AEs leading to ER visit                  | 2 (4.0)                          | 1 (1.1)                         | 6 (4.7)                          | 0 (0.0)                          |
| AEs leading to hospital visit            | 5 (9.8)                          | 2 (2.3)                         | 8 (6.3)                          | 0 (0.0)                          |
| Type of AE                               |                                  |                                 |                                  |                                  |
| Diarrhea                                 | 9 (17.6)                         | 4 (4.6)                         | 3 (2.4)                          | 0 (0.0)                          |
| Fatigue                                  | 6 (11.8)                         | 6 (6.9)                         | 13 (10.2)                        | 5 (11.4)                         |
| Headache                                 | 5 (9.8)                          | 2 (2.3)                         | 6 (4.7)                          | 4 (9.1)                          |
| Nausea                                   | 5 (9.8)                          | 2 (2.3)                         | 4 (3.1)                          | 3 (6.8)                          |
| Hypertension                             | 4 (7.8)                          | 0 (0.0)                         | 0 (0.0)                          | 0 (0.0)                          |
| Abdominal pain                           | 2 (3.9)                          | 1 (1.1)                         | 4 (3.1)                          | 0 (0.0)                          |
| Rash                                     | 1 (2.0)                          | 1 (1.1)                         | 4 (3.1)                          | 2 (4.5)                          |
| Chest pain                               | 1 (2.0)                          | 0 (0.0)                         | 0 (0.0))                         | 0 (0.0)                          |
| Neutropenia                              | 1 (2.0)                          | 0 (0.0)                         | 0 (0.0)                          | 0 (0.0)                          |
| Other <sup>1</sup>                       | 12 (23.5)                        | 11 (12.6)                       | 19 (15.0)                        | 10 (22.7)                        |
| Thromboembolic events                    | 2 (3.9)                          | 8 (9.2)                         | 6 (4.7)                          | 5 (11.4)                         |

AEs, adverse events; ER, emergency room. <sup>1</sup>These include transaminitis, hematuria, muscle aches, constipation, fluid retention, leg swelling, loss of taste, pancytopenia, dizziness, edema, and vomiting.



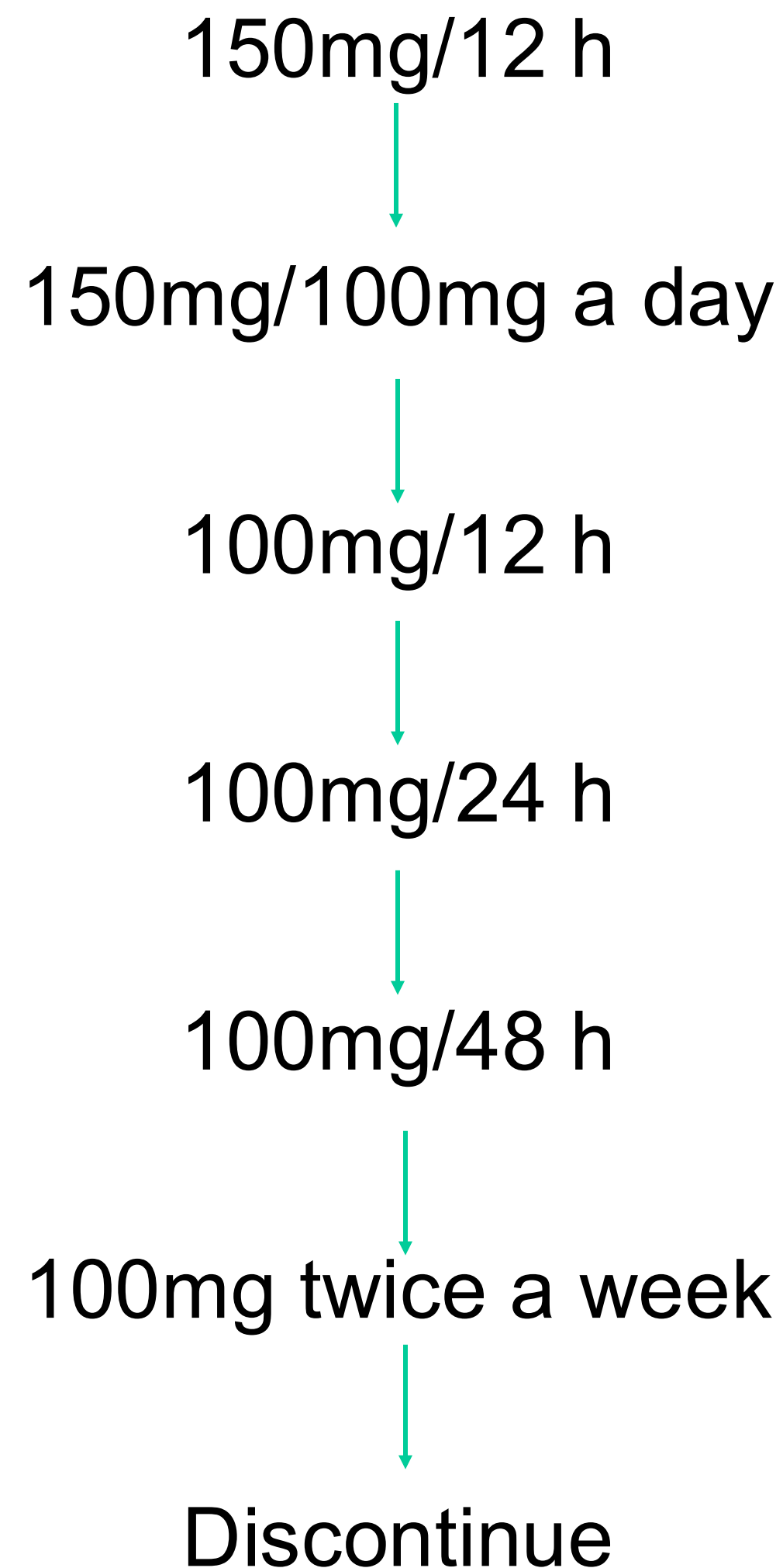
# Fostamatinib: Tapering and Sustained Response

| Study                          | N with sustained response off treatment                  | Time on fostamatinib until discontinuation                 | ITP Type (chronic / persistent / ND)  |
|--------------------------------|----------------------------------------------------------|------------------------------------------------------------|---------------------------------------|
| Auteri 2023                    | 1                                                        | ≈4 years before taper/stop                                 | Chronic ITP                           |
| Ghanima 2025                   | 4 (case series)                                          | Case-specific: 7 weeks; ~2.5 months; 6 months; ~13 months  | 3 Chronic; 1 Persistent               |
| González-López 2024 (FOSTAMES) | 5/138(>9 months off drug)                                | NR                                                         | Among SROT: 3 Chronic; 2 Persistent   |
| Mingot-Castellano 2024         | 7 of 9 who discontinued (2 relapses)<br>7 in 61 patients | Median: 116 d to start taper + 112.5 d taper ≈ 229 d total | Chronic ITP                           |
| Lee 2020                       | 0 (long-term on-therapy responses)                       | NR (no discontinuation)                                    | Chronic ITP                           |
| GIMEMA ITP1122 2025            | 2 in 95 patients                                         | NR (endpoint not reported)                                 | Chronic ITP cohort; detailed split NR |

Auteri G, et al. Heliyon. 2023 Feb 4;9(2):e13462.  
Ghanima W, et al. Hematology. 2025 Dec;30(1):2456687.  
González-López TJ, et al. Blood. 2024 Aug 8;144(6):646-656.  
Mingot-Castellano ME, et al. J Clin Med. 2024 Oct 22;13(21):6294.  
Lee Ej, et al. Br J Haematol. 2020 Apr;189(2):379-382.  
Lucchini E, et al. Br J Haematol. 2025 Aug 25. doi: 10.1111/bjh.70069. Epub ahead of print.

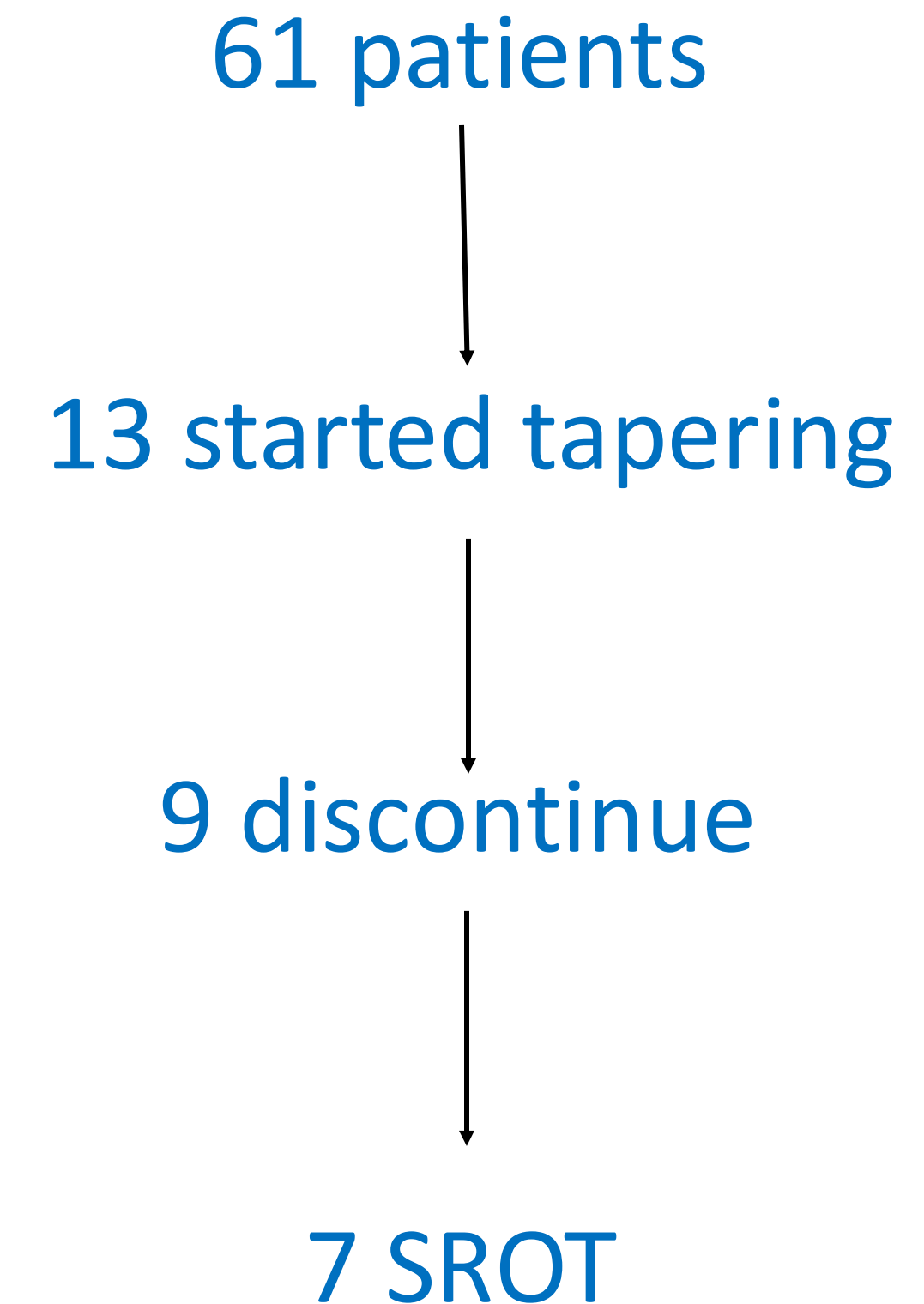


# Fostamatinib: Tapering and Sustained Response



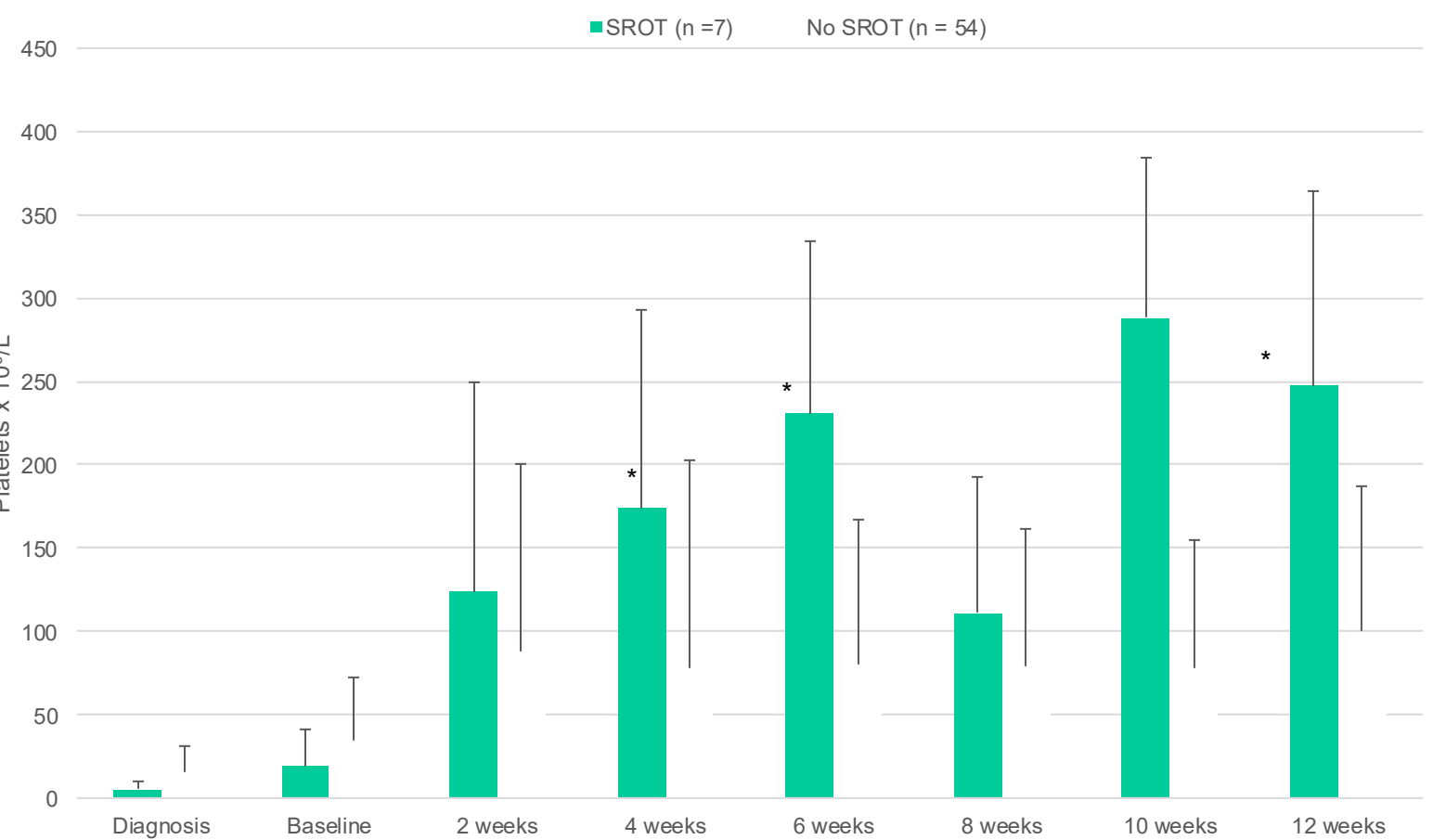
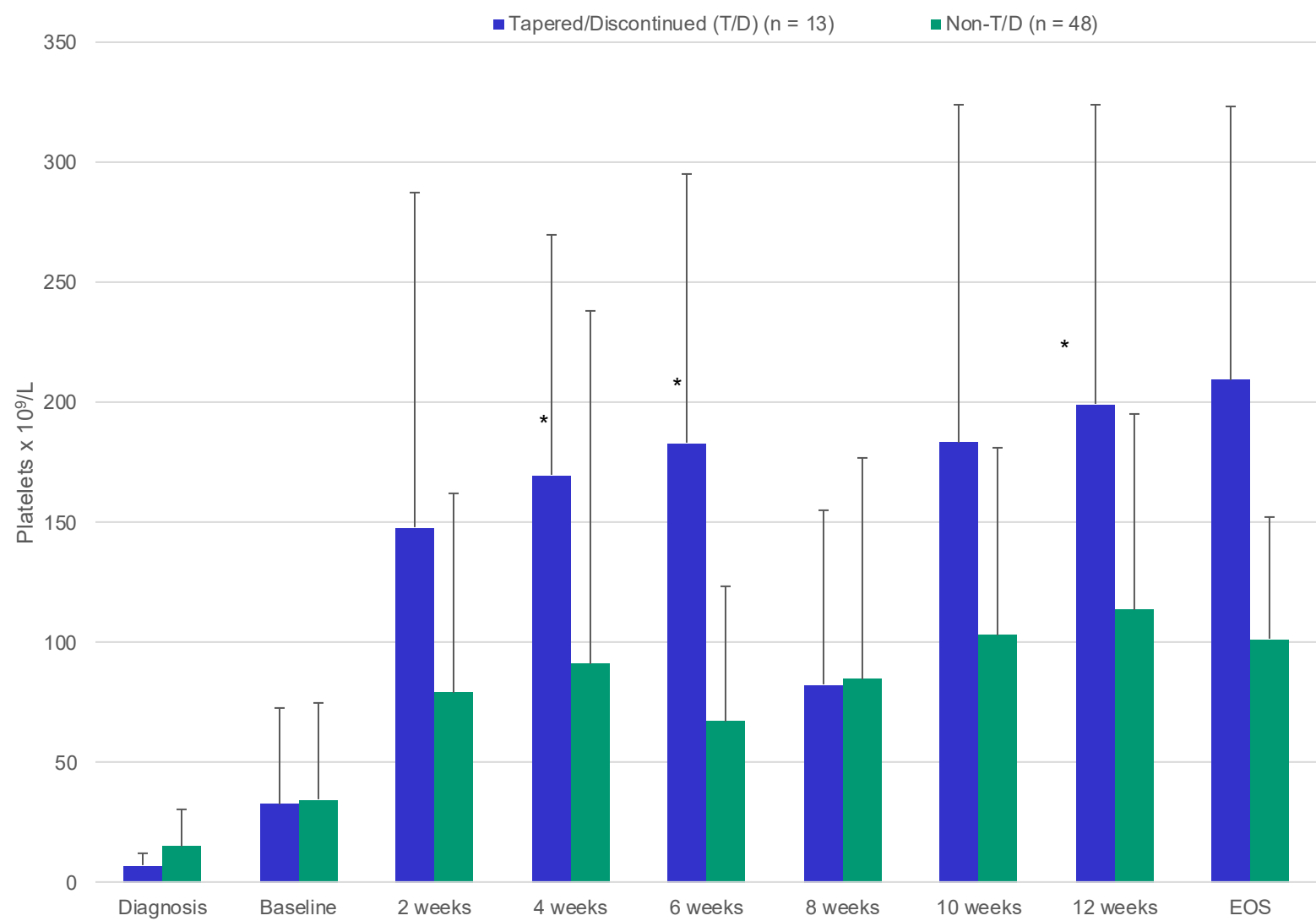
## Tapering:

- Patients under Complete remission
- Patients will be monitor every 2 weeks
- If platelets above  $50 \times 10^9/\text{L}$  after 4 weeks, to to next step



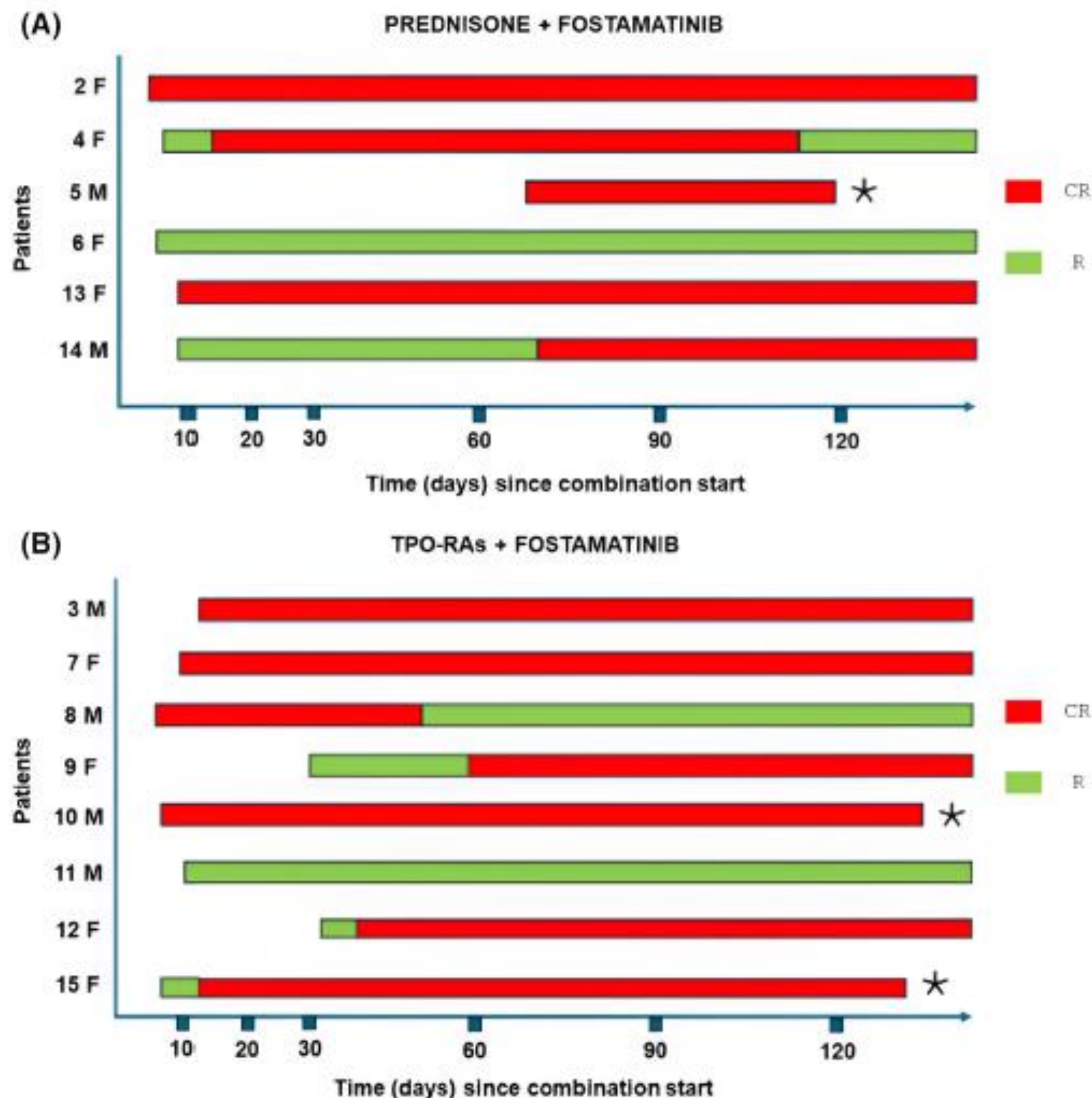
# Fostamatinib: Tapering and Sustained Response

**Platelet > 100x10<sup>9</sup>/L at week 12, only positive predictive factors for tapering and discontinuation**



- Time to start tapering: 116 days (IQR: 42-140)
- Duration of tapering: 112.5 days (IQR 94.5-191).
- Median platelet count at tapering: 232x10<sup>9</sup>/L (IQR 152-345x10<sup>9</sup>/L)
- Median platelet count at discontinuation: 190x10<sup>9</sup>/L (IQR 142.5-316.5x10<sup>9</sup>/L).
- Median follow-up since discontinuation: 263 days (IQR: 247-313 days)
- Only 2 patients relapsed
- Platelet counts higher than 100x10<sup>9</sup>/L at week 12 was the only positive predictive factors for successful tapering and discontinuation.

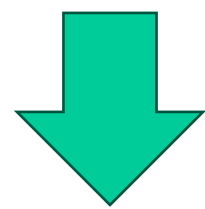
# Combined therapy: Fostamatinib Italian experience



- Fostamatinib was initially 100 mg BID in all patients
- Need increase dose 40% patients
- 80% Response, median time of 9 days (IQR 7–19)
- 73% Complete response, median time 13 days (IQR 9–39)
- 40% discontinued steroids or TPO-RA, median time of 80 days (IQR 43–142)
- 40% no possible discontinued
- Fostamatinib discontinued:
  - 20% for intolerance
  - 13% relapses

# Combined Therapy: Avatrombopag+Fostamatinib

112 treat with AVA



28 no response to AVA

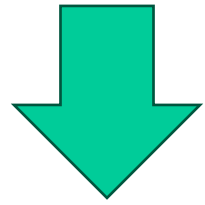


18 treated with AVA-FOS

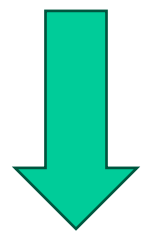
- Median age: 60 years-old (IQR: 37-69)
- 78% males.
- Chronic 12, Persistent 5, 1 Newly diagnose
- median 5 lines of treatment (IQR: 4-7).
- Rituximab 4 patients, 12 eltrombopag, 15 romiplostim
- Overall response of the combination was 83.3% (8 CR, 7 R, 3 NR)
- Median time to maximum response of 15 days (IQR: 8-35 days).
- Median dose at response AVA 280mg a week and FOS 2100mg a week.
- Median dose at last visit AVA was 140mg a week and FOS 1400mg a week.
- 2 relapses in tapering, recovered introducing drug again.

# Fostamatinib in combination: Avatrombopag+Fostamatinib

112 treat with AVA



28 no response to AVA



18 treated with AVA-FOS

**33% AEs**

AVATROMBOPAG:

- Headache 1 patient
- WHO grade 2 liver in 1 patient which was solved after the interruption of AVA for 6 days and reintroduction at a lower dose, from 140mg to 60mg weekly.

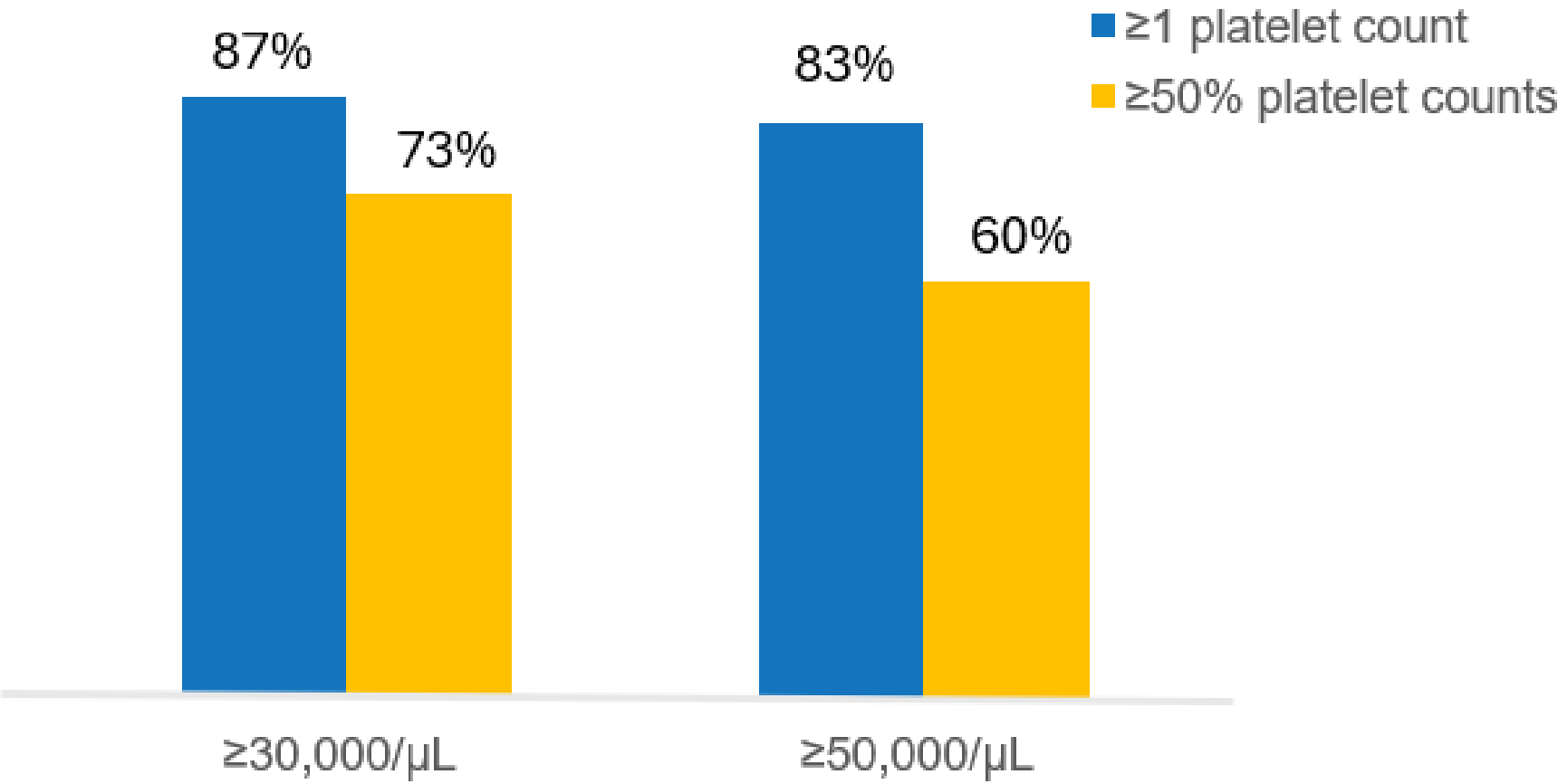
FOSTAMATINIB:

- Diarrhoea grade 1 was communicated in 3 patients
- Neutropenia grade 3 in 2 patient

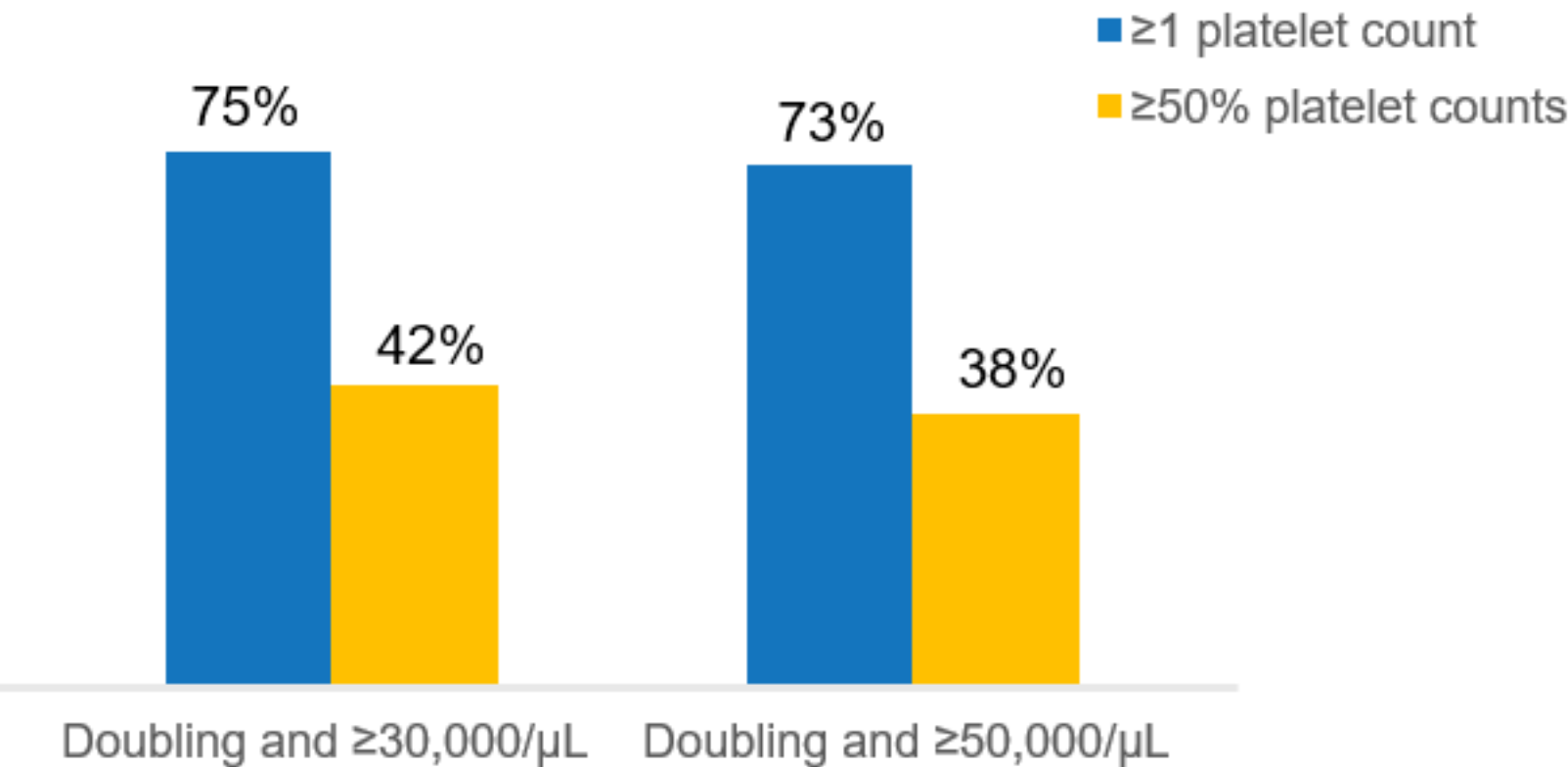
No vascular event or infection

# Fostamatinib in combination: TPOa+Fostamatinib

Proportion of patients with platelet response (n=113)



Proportion of patients with doubling of platelet count and ≥30,000/μL or ≥50,000/μL (n=113)



Patients received fostamatinib for ≥30 days combined with ≥1 dose of TPO-RA.

Median duration of fostamatinib treatment was 6.9 months (range 3.0-70.0).

| Possible AEs             | Patients (%) |
|--------------------------|--------------|
| Diarrhea                 | 23           |
| Increased blood pressure | 18           |
| Bruising/bleeding        | 12           |
| Fatigue                  | 8            |
| Headache                 | 5            |
| Thrombotic event         | 4            |



# Real-World Use of Fostamatinib in the world:

Efficacy No difference

Cost little difference

| Parameter, mean                      | Fostamatinib (n = 51)         | Eltrombopag (n = 87)          | Romiplostim (n = 127)          | Avatrombopag (n = 44)          |
|--------------------------------------|-------------------------------|-------------------------------|--------------------------------|--------------------------------|
| Primary drug therapy <sup>1</sup>    | \$96,401                      | \$89,341                      | \$106,069                      | \$127,247                      |
| Rescue therapy <sup>2</sup>          | \$2,472                       | \$1,830                       | \$1,731                        | \$2,334                        |
| AE management <sup>3</sup>           | \$101.50                      | \$32.56                       | \$62.90                        | \$69.46                        |
| TE management                        | \$234                         | \$1,222                       | \$619                          | \$1,399                        |
| Total mean cost per patient (95% CI) | \$99,209 (\$59,595–\$115,074) | \$92,426 (\$68,331–\$115,519) | \$108,482 (\$84,782–\$132,182) | \$131,050 (\$83,327–\$179,897) |

AE, adverse events; TE, thromboembolic events. <sup>1</sup>Includes the pharmacy dispensing fee in the case of oral agents and the administration fee in the case of subcutaneous romiplostim. <sup>2</sup>Includes infusions of intravenous immune globulin, platelets, and corticosteroids. <sup>3</sup>Consists of resources to manage the drug related adverse events presented in Table 3. Most events were mild to moderate.



# GEPTI recommendations: Spanish guidelines

| Treatment        | TPO-RA                                                         | Fostamatinib                                                                                                                      | Rituximab                                                                                    | Splenectomy                                                                                                           |
|------------------|----------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------|
| Hierarchy        | First Strategy                                                 | First Strategy                                                                                                                    | Second Strategy                                                                              | Second Strategy                                                                                                       |
| Positive Aspects | Response >80%<br>Complete Response >30%<br>Good safety profile | Response >80% as second line treatment, >40% in multirrefractory patients with ITP<br><br>Patients with high cardiovascular risk* | Response 50-60%,<br>Complete response 20%<br>Good tolerance, no need for long-term treatment | Response 50%<br>Complete response 50-70%<br>Low cost Currently the only potentially curative option                   |
| Negative Aspects | Cost                                                           | Cost                                                                                                                              | B cell depletion, neutropenia, hypogammaglobulinemia                                         | Short and long-term effects: thrombosis, infections, need for vaccination, Possibility of postoperative complications |

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