# Insights from EHA and ISTH 2024: How can we optimize care for patients with chronic ITP?

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Recorded following EHA2024 Hybrid Congress, Madrid, Spain, 13–16 June, and ISTH 2024, Bangkok, Thailand, 22–26 June

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# How does ITP impact the patient and their HRQoL?

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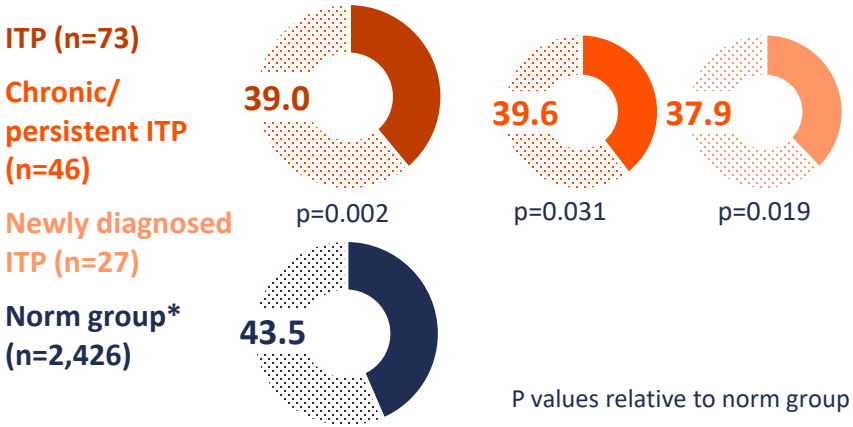
Recorded following EHA2024 Hybrid Congress, Madrid, Spain, 13–16 June, and ISTH 2024, Bangkok, Thailand, 22–26 June

# PB0687: Fatigue in adult patients with primary ITP
## Gebhart J, et al.

### Fatigue outcomes (mean FACIT-F scores)

**Mean total FACIT-F scores (higher scores represent less fatigue)**




**Correlation between fatigue and selected clinical parameters in adults with ITP**


**Ferritin** was the only **significant predictor of fatigue** by regression analysis (p=0.034)

Patients with ITP, including those with chronic ITP, experienced significantly more severe fatigue than the control group. Ferritin levels predict fatigue.

*German Norm Sample Group from 2018.
FACIT-F, Functional Assessment of Chronic Illness Therapy-Fatigue; ITP, immune thrombocytopenia.
Gebhart A, et al. Presented at: ISTH 2024, Bangkok, Thailand. 22–26 June 2024. Poster presentation PB0687.

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# P1630: Incidence, description, and management of venous thromboses in adult patients with ITP. Results from the multicenter prospective registry Carmen-France

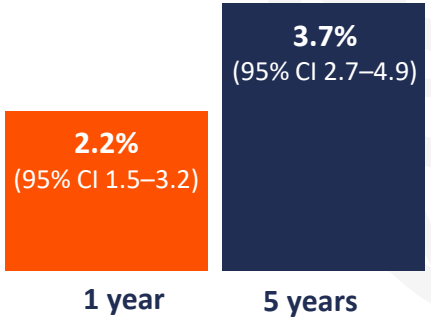
## Therme F, et al.

### Patient demographics and VT incidence

| | VT group (n=53) | Non-VT group (n=1,251) |
|---|---|---|
| Median age, years (Q1–3) | 70 (49–81) | 62 (39–77) |
| History of thrombosis, % | 24.5 | 6.3 |
| Secondary ITP, % | 26.4 | 14.5 |
| Platelets at diagnosis, x $10^9$/L (Q1–3) | 8 (4–24) | 18 (6–46.5) |
| Prothrombotic treatments during FU | | |
| Corticosteroids, % | 94.3 | 81 |
| IVIg, % | 49.1 | 41 |
| ≥1 TPO-RA, % | 62.3 | 28.6 |

Most VT events occurred within **3 months** of ITP diagnosis

**Cumulative incidence rates of VT**




A higher proportion of patients with VT had a history of thrombosis, secondary ITP, more severe disease and were treated with TPO-RAs vs patients who did not experience VT.

Ci, confidence interval; FU, follow up; ITP, immune thrombocytopenia; IVIg, intravenous immunoglobulin; TPO-RA, thrombopoietin receptor agonist; VT, venous thrombosis.

Therme F, et al. Presented at: EHA 2024 Hybrid Congress, Madrid, Spain. 13–16 June 2024. Poster presentation P1630.

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# P1630: Incidence, description, and management of venous thromboses in adult patients with ITP. Results from the multicenter prospective registry Carmen-France

Therme F, et al.

## Description of VT events and management practices


Patients had atypical VT events


Cerebral VT events, all in patients treated with TPO-RAs


Cerebral VT events in patients with platelet count >250 x $10^9$/L

**Bleeding and thrombotic events in patients experiencing VT after receiving anticoagulation for ≤3 or ≥6 months (n=31)**

| | + TPO-RA during anticoagulation | | – TPO-RA during anticoagulation | |
|---|---|---|---|---|
| | Thrombosis | Haemorrhage | Thrombosis | Haemorrhage |
| ≤3 mo | 1 | 0 | 0 | 0 |
| ≥6 mo | 0 | 0 | 0 | 0 |

Patients treated with TPO-RAs had an increased risk of VT at an atypical site. TPO-RAs + anticoagulation was an effective and tolerable management strategy.

ITP, immune thrombocytopenia; mo, month; TPO-RA, thrombopoietin receptor agonist; VT, venous thrombosis.

Therme F, et al. Presented at: EHA 2024 Hybrid Congress, Madrid, Spain. 13–16 June 2024. Poster presentation P1630.

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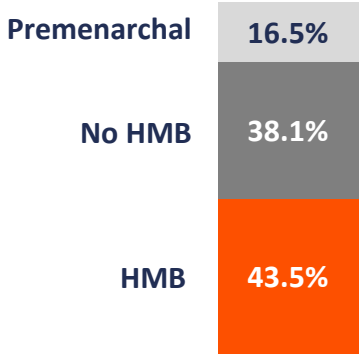
# PB0694: Heavy menstrual bleeding is a common, underrecognized issue in at risk adolescents with ITP and inherited platelet disorders

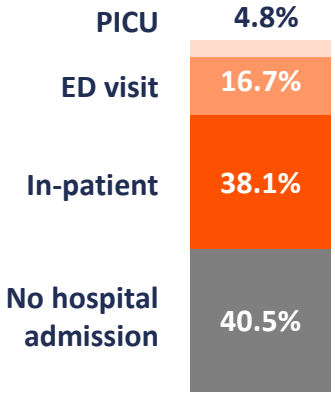
## Doshi BS, et al.

### Frequency and severity of HMB (ITP, n=298; IPD, n=122)

**Incidence of HMB in at-risk patients with ITP (n=85)**




**Hospital management of HMB in patients with ITP (n=42 visits)**




**Treatment of HMB in patients with ITP (n=37):**

- ITP-directed long-term treatment (n=24)
- Hormonal therapy (n=16)


**Of patients with ITP and HMB were iron deficient (n=37)**


**Of patients with ITP or IPD were treated for IDA (n=42)**

HMB is common in female patients with ITP and results in high rates of hospitalization.
Iron deficiency is common in female patients with ITP and HMB.

ED, emergency department; HMB, heavy menstrual bleeding; IDA, iron deficient anaemia; IPD, inherited platelet disorder; ITP, immune thrombocytopenia; PICU, paediatric intensive care unit.

Doshi BS, et al. Presented at: ISTH 2024, Bangkok, Thailand. 22–26 June 2024. Poster presentation PB0694.

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# What are the latest data that inform the use of current treatments for chronic ITP?

**Dr Vickie McDonald**
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London, UK

Recorded following EHA2024 Hybrid Congress, Madrid, Spain, 13–16 June, and ISTH 2024, Bangkok, Thailand, 22–26 June

# P1628: Prolonged response after TPO-RA discontinuation in primary ITP: Long term follow-up of the STOPAGO study, a prospective multicenter study

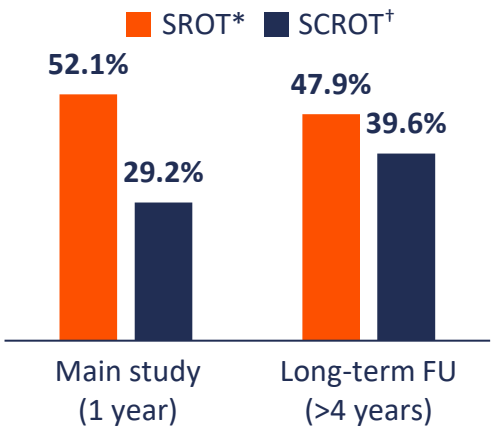
Cottu A, et al.

## Baseline characteristics (N=48)

| | |
|---|---|
| Chronic ITP at TPO-RA initiation | 63% |
| Median duration of ITP at TPO-RA discontinuation | 6 years |
| >2 lines of treatment | 47% |
| Most common TPO-RA | Eltrombopag 83% |

## Clinical outcomes (extended FU)

**Clinical response after TPO-RA discontinuation**




**Median duration of FU 5 years** (4–6.3)

**Two patients relapsed‡ >1 year** after TPO-RA discontinuation

**Chronic ITP** at TPO-RA initiation was a **risk factor for relapse‡** OR 5.4 (95% CI 1.27–22.62); p=0.022

~50% of patients maintained SROT for >4 years after TPO-RA discontinuation. Only two cases of relapse reported during long-term FU, confirming most cases occurred in the first weeks after discontinuation.

*SROT: platelet count ≥30 x $10^9$/L and no bleeding. †SCROT: platelet count ≥100 x $10^9$/L and no bleeding without ITP-specific medications. ‡Relapse defined as bleeding event and/or platelet count <30 x $10^9$/L. CI, confidence interval; FU, follow-up; ITP, immune thrombocytopenia; OR, odds ratio; SCROT, sustained complete response off treatment; SROT, sustained response off treatment; TPO-RA, thrombopoietin receptor agonist. Cottu A, et al. Presented at: EHA2024 Hybrid Congress, Madrid, Spain. 13–16 June 2024. Poster presentation P1628.

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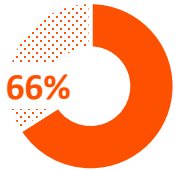
# P2232: Italian real-world experience with fostamatinib in adult patients with chronic ITP

Zaja F, et al.

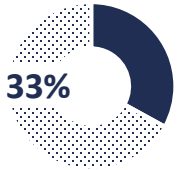
## Baseline characteristics (N=91)

- Previously received >1 TPO-RA: 57%
- Previous splenectomy: 23%
- ≥3 lines of prior treatment: 83%
- Median time from ITP diagnosis to fostamatinib Tx: 7 years

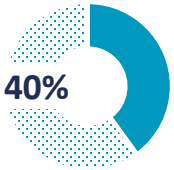
## Clinical outcomes



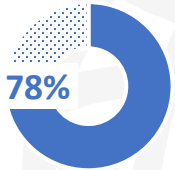

Overall response within 3 months




Complete response*




Still receiving Tx at 6 months




↑ fostamatinib dose

**59 side effects reported in 38 patients (31 were treatment-related); most common:** diarrhoea (n=13), hypertension (n=8), transaminitis (n=8), neutropenia (n=4)

**Tx discontinuation due to side effects:** neutropenia, transaminitis, hypertension (all n=1), diarrhoea (n=2)

**DVT: n=1** (grade 3) 5 months after cessation of fostamatinib

40% of patients with refractory, chronic ITP received fostamatinib for 6 months, suggesting fostamatinib is an effective therapeutic option in real-world practice with an acceptable safety profile.

*According to International Working Group criteria. DVT, deep vein thrombosis; ITP, immune thrombocytopenia; TPO-RA, thrombopoietin receptor agonist; Tx, treatment.

Zaja F, et al. Presented at: EHA2024 Hybrid Congress, Madrid, Spain. 13–16 June 2024. Poster presentation P2232.

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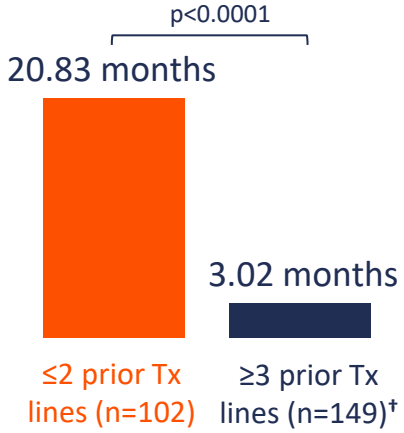
# P1626: The outcome of splenectomy in refractory ITP is poor: An analysis of real world UK ITP registry data

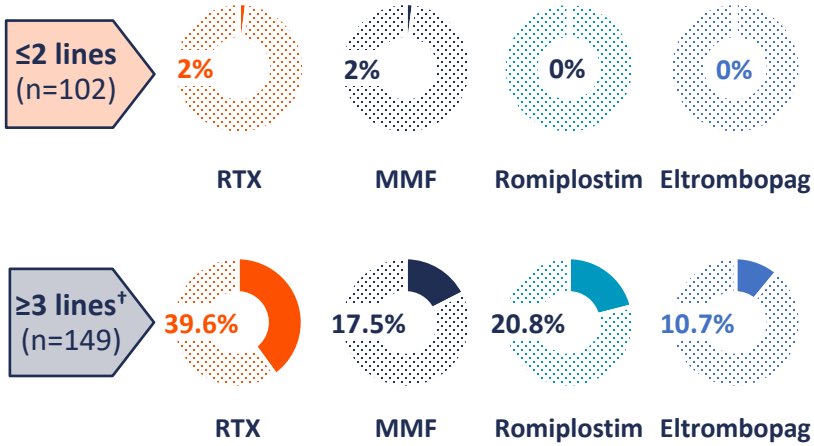
Chen F, et al.

Outcomes associated with splenectomy in patients with refractory ITP from the UK ITP registry after the year 2000

**Median time to first treatment post-splenectomy***




**Treatment prior to splenectomy**




**Time to splenectomy failure* was significantly shorter in patients >65 years vs patients ≤65 years (p=0.001)**

The probability of splenectomy inducing sustained remission in refractory patients with ITP is considerably lower vs non-refractory patients.

*Median time to first treatment post-splenectomy was a surrogate marker of splenectomy failure. †Refractory ITP defined as having received ≥3 lines of therapy.
ITP, immune thrombocytopenia MMF, mycophenolate mofetil; RTX, rituximab; Tx, treatment.

Chen F, et al. Presented at: EHA2024 Hybrid Congress, Madrid, Spain. 13–16 June 2024. Poster presentation P1626.

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# What data are there for emerging chronic ITP treatments and what do they tell us?

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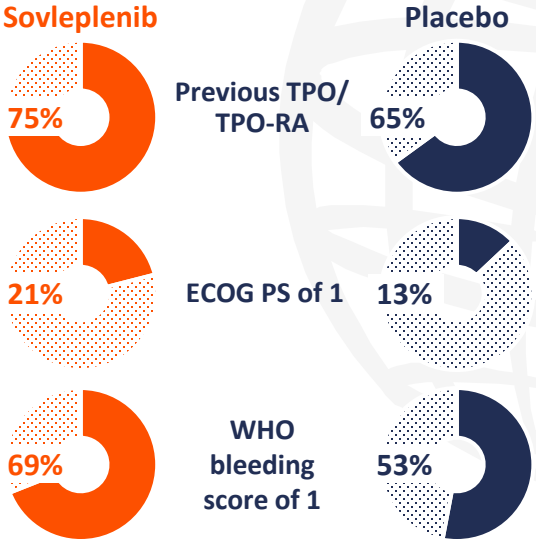
Recorded following EHA2024 Hybrid Congress, Madrid, Spain, 13–16 June, and ISTH 2024, Bangkok, Thailand, 22–26 June

# S316: Efficacy and safety of the SYK inhibitor sovleplenib (HMPL-523) in adult patients with chronic primary ITP in China (ESLIM-01): A randomized, double-blind, placebo-controlled phase 3 study Yang R, et al.

## Baseline demographics and characteristics*

| Randomized 2:1 | N=188 | |
|---|---|---|
| | Sovleplenib 300 mg QD (n=126) | Placebo 300 mg QD (n=62) |
| Median age, years (range) | 43.5 (18–72) | 42.0 (18–69) |
| Median time since first reduction in platelet count to randomization, years (range) | 7.6 (1.1–36.1) | 7.8 (1.1–41.2) |
| ≥3 years, % | 75 | 82 |
| BL platelet count <15 x $10^9$/L, % | 60 | 60 |
| Prior splenectomy, % | 4 | 5 |
| Concomitant anti-ITP treatment at BL, % | 33 | 32 |

### Imbalance with some BL characteristics




*Intention-to-treat set. Enrolment: Sep 2021–Dec 2022; data cut-off: 14 July 2023.
BL, baseline; ECOG PS, Eastern Cooperative Oncology Group Performance Status; ITP, immune thrombocytopenia; QD, once daily; TPO, thrombopoietin; TPO-RA, TPO-receptor agonist; WHO, World Health Organization.
Yang R, et al. Presented at: EHA 2024 Hybrid Congress, Madrid, Spain. 13–16 June 2024. Oral presentation S316.

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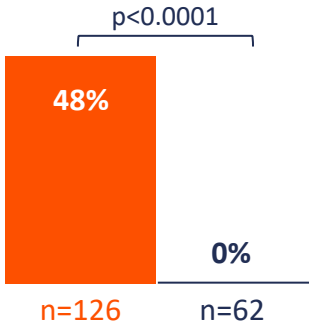
## Primary endpoint

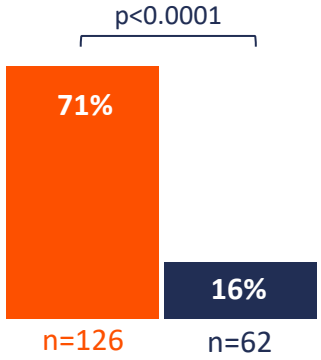
### DRR (assessed from 14–24 weeks)*



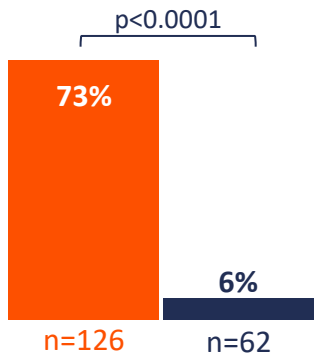

## Platelet-related secondary endpoints

### ORR (assessed from 0–24 weeks)

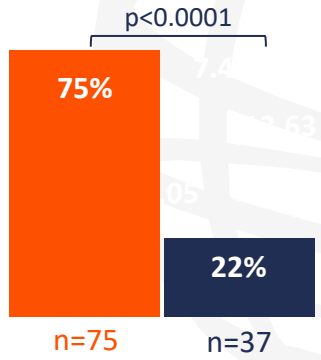
**≥1 PC ≥50 x $10^9$/L†**




**Two consecutive PCs ≥30 x $10^9$/L and double from BL**




**PC ≥30 x $10^9$/L and increased ≥20 x $10^9$/L from BL‡**




▪ Sovleplenib ▪ Placebo

**Sovleplenib significantly improved DRR and ORR vs placebo in the ITT population.**

P values based on Cochran–Mantel–Haenszel test adjusted for randomization stratification factors. *Platelet counts ≥50 x $10^9$/L at 4–6 visits during 14–24 weeks, not impacted by rescue treatment. †Not impacted by rescue treatment. ‡For patients with a platelet count of <15 x $10^9$/L at BL.

BL, baseline; DRR, durable response rate; ITP, immune thrombocytopenia; ITT, intention to treat; ORR, overall response rate; PC, platelet count.

Yang R, et al. Presented at: EHA 2024 Hybrid Congress, Madrid, Spain. 13–16 June 2024. Oral presentation S316.

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# S316: Efficacy and safety of the SYK inhibitor sovleplenib (HMPL-523) in adult patients with chronic primary ITP in China (ESLIM-01): A randomized, double-blind, placebo-controlled phase 3 study Yang R, et al.

## Drug exposure and safety analyses

**Median duration of exposure, weeks**

**Sovleplenib**


**Placebo**


| TEAEs, % | Sovleplenib (n=126) | Placebo (n=62) |
|---|---|---|
| ≥1 TEAE | 99 | 85 |
| Grade 3/4 | 25 | 24 |
| GI toxicities | | |
| Nausea | 1.6 | 3.2 |
| Vomiting | 1.6 | 1.6 |
| Diarrhoea | 1.6 | 0 |
| Hypertension | 12.7 | 6.5 |

| Most common TEAEs (≥15%), % | All grade | Grade 3 or 4 | All grade | Grade 3 or 4 |
|---|---|---|---|---|
| URTI | 29 | 2 | 10 | 0 |
| COVID-19 | 24 | 1 | 13 | 0 |
| ↑ blood LDH | 24 | 0 | 6 | 0 |

No thromboembolic events reported

There was a similar incidence of TEAEs with sovleplenib vs placebo.
No thromboembolic events or deaths were reported.

GI, gastrointestinal; ITP, immune thrombocytopenia; LDH, lactate dehydrogenase; TEAE, treatment-emergent adverse event; URTI, upper respiratory tract infection.

Yang R, et al. Presented at: EHA2024 Hybrid Congress, Madrid, Spain. 13–16 June 2024. Oral presentation S316.

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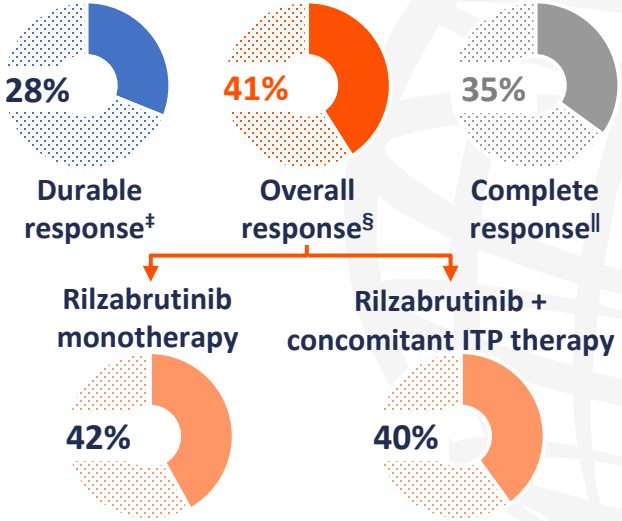
# OC 13.3: Pooled analysis of the efficacy and safety of oral bruton tyrosine kinase inhibitor rilzabrutinib in patients with previously treated ITP: Phase 2 Study

Kuter D, et al.

## Baseline characteristics

| Oral rilzabrutinib 400 mg BID for 24 weeks (N=71) | Part A* Dose finding (n=45) | Part B* Single-dose (n=26) |
|---|---|---|
| Median age, years (range) | 52 (19–75) | |
| Median duration of ITP, years (range) | 7.3 (0.4–53) | |
| Median platelet count, x $10^9$/L (range) | 14 (2–33) | |
| Median unique prior ITP therapies, n (range) | 6 (1–21) | |
| Median unique failed ITP therapies†, n (range) | 2 (1–19) | |
| Rilzabrutinib monotherapy / concomitant ITP therapy, % | 34 / 66 | |

## Pooled efficacy outcomes (N=71)




Pooled analyses showed a rapid and durable platelet response in adult patients with ITP receiving rilzabrutinib monotherapy or with concomitant ITP therapy.

*Data cut-off for part A, 9 Apr 2021; part B, 31 Jan 2023. †Defined as failing to reach platelet counts of >50 x $10^9$/L for a given treatment. ‡≥8 of the last 12 platelet counts ≥50 x $10^9$/L.
§≥2 consecutive platelet counts ≥50 x $10^9$/L and increased ≥20 x $10^9$/L from BL. ‖Platelet counts ≥100 x $10^9$/L.
BID, twice daily; BL, baseline; ITP, immune thrombocytopenia.
Kuter D, et al. Presented at: ISTH 2024, Bangkok, Thailand. 22–26 June 2024. Oral presentation OC 13.3.

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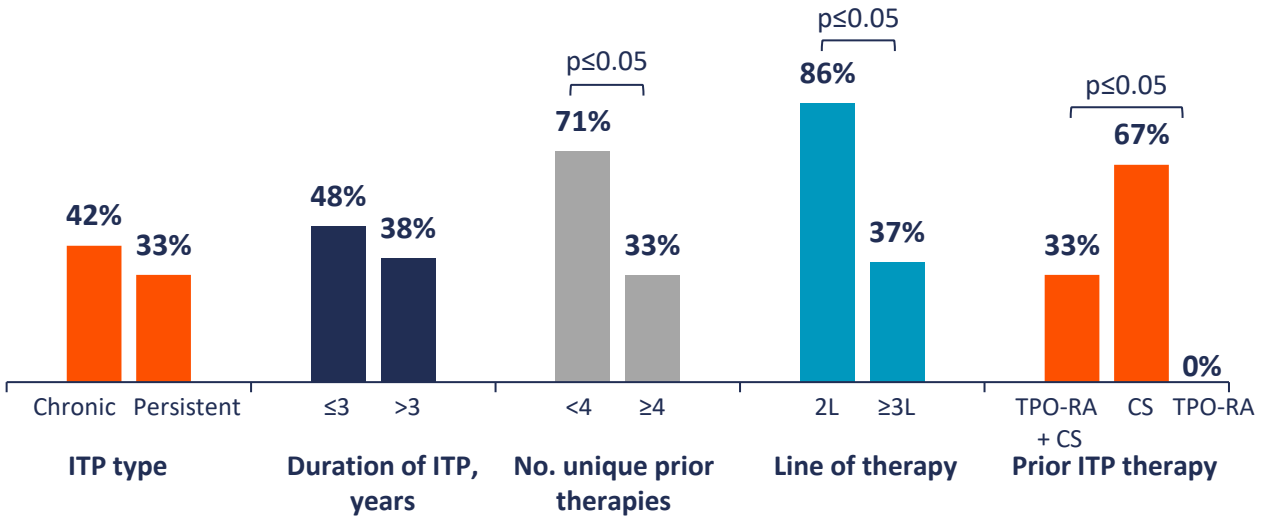
# OC 13.3: Pooled analysis of the efficacy and safety of oral bruton tyrosine kinase inhibitor rilzabrutinib in patients with previously treated ITP: Phase 2 Study

Kuter D, et al.

## Overall platelet response* by baseline variables




**Median time to first PC ≥50 x $10^9$/L for responders*** **12 days**

**Platelet response consistent irrespective of response to prior ITP therapies**

Patients with fewer prior and earlier lines of therapy had higher platelet responses vs patients with more and later lines of therapy.

Data cut-off: part A 9 Apr 2021; part B 31 Jan 2023. *Response defined as ≥2 consecutive platelet counts of ≥50 × $10^9$/L and increased ≥20 × $10^9$/L from BL without rescue medication.
BL, baseline; CS, corticosteroid; ITP, immune thrombocytopenia; PC, platelet count; TPO-RA, thrombopoietin-receptor agonist.

Kuter D, et al. Presented at: ISTH 2024, Bangkok, Thailand. 22–26 June 2024. Oral presentation OC 13.3.

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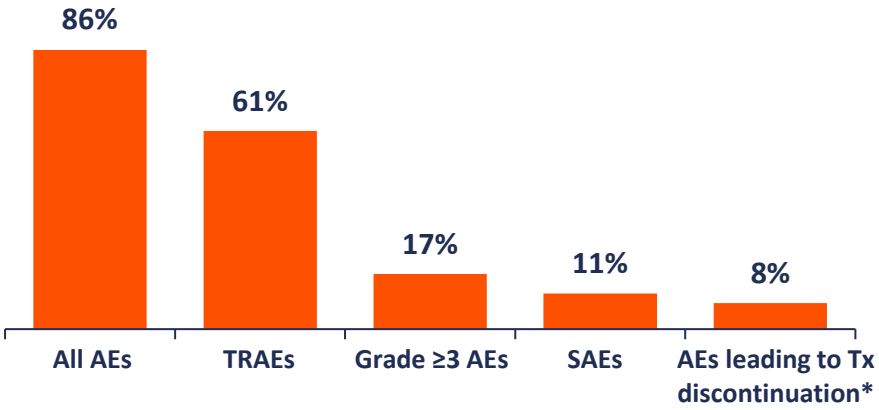
# OC 13.3: Pooled analysis of the efficacy and safety of oral bruton tyrosine kinase inhibitor rilzabrutinib in patients with previously treated ITP: Phase 2 Study

## Kuter D, et al.

### Safety data

**Proportion of patients with AEs**




One death occurred that was unrelated to treatment

| TRAEs (>2 patients), % | Patients (N=71) | |
|---|---|---|
| | Grade 1 | Grade 2 |
| **All TRAEs** | 54 | 27 |
| Diarrhoea | 28 | 7 |
| Nausea | 23 | 3 |
| Headache | 10 | 1 |
| Fatigue | 4 | 1 |
| Vomiting | 3 | 3 |

All TRAEs were transient, grade 1 or 2 events.
There were no treatment-related thrombotic events, SAEs or deaths.

Data cut-off: part A 9 Apr 2021; part B 31 Jan 2023. *Due to treatment-related hypokalaemia, grade 2 diarrhoea and grade 2 frequent bowel movements, and unrelated grade 2 gastritis, grade 3 subcutaneous abscess and grade 4 Evans syndrome. AE, adverse event; SAE, serious adverse event; TRAE, treatment-related AE; Tx, treatment.

Kuter D, et al. Presented at: ISTH 2024, Bangkok, Thailand. 22–26 June 2024. Oral presentation OC 13.3.

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# P1635: Long-term safety and efficacy of rilzabrutinib, an oral bruton tyrosine kinase inhibitor, in patients with ITP: Integrated phase 2 part A and part B

Cooper N, et al.

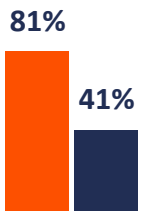
## Long-term efficacy and safety outcomes (N=27)*

**Of 17 patients receiving concomitant ITP therapy:**

- n=6 Discontinued ≥1 concomitant therapy
- n=2 ↓ concomitant therapy


Switched to rilzabrutinib monotherapy

**Proportion of patients with AEs**




▪ Any cause ▪ TRAEs

**All TRAEs were transient and grade 1 or 2†**

**No treatment-related bleeding or thrombotic events, SAEs, irreversible BTK class effects or deaths**

**Percent of visits reaching defined median PC in LTE**

- ≥50 x $10^9$/L — 90%
- ≥30 x $10^9$/L — 100%
- ≥20 x $10^9$/L above BL — 97%

Patients in the LTE showed high and durable PCs with rilzabrutinib ± ITP medication. Long-term use of rilzabrutinib 400 mg BID is well tolerated.

*Data cut-off for part A was 9 Apr 2021; part B was 2 Jan 2024. †Except non-serious, grade 3 influenza and lower respiratory tract infection in one patient.

AE, adverse event; BID, twice daily; BL, baseline; BTK, Bruton tyrosine kinase; ITP, immune thrombocytopenia; LTE, long-term extension; PC, platelet count; SAE, serious AE; TRAE, treatment-related AE. Cooper N, et al. Presented at: EHA2024 Hybrid Congress, Madrid, Spain. 13–16 June 2024. Poster presentation P1635.

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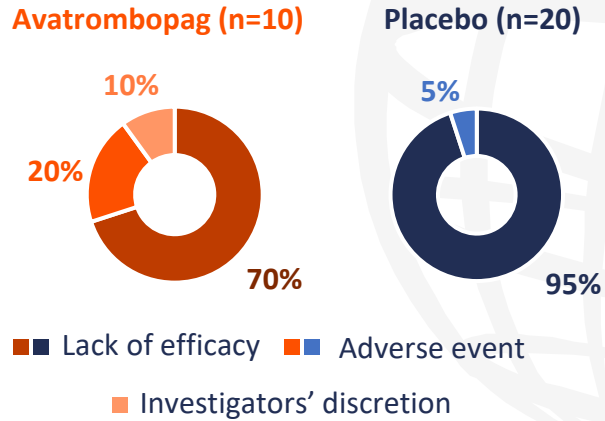
# S318: A phase 3, randomised, double-blind, placebo-controlled trial to evaluate the efficacy and safety of avatrombopag for the treatment of children with chronic ITP (AVA-PED-301) Grace RF, et al.

## Baseline demographics and clinical characteristics

| | Avatrombopag (n=54) | Placebo (n=21) |
|---|---|---|
| Mean ± SD age, years | 8.9 ± 4.4 | 9.9 ± 4.1 |
| PC ≤15 x $10^9$/L, % | 83.3 | 81.0 |
| Mean ± SD PC | 12.0 ± 6.8 | 11.2 ± 6.6 |
| Mean ± SD time from ITP Dx to first dose, weeks | 202 ± 164 | 225 ± 181 |
| ≥3 previous ITP Tx, % | 68.5 | 66.7 |
| Prior TPO-RA, % | 74.1 | 71.4 |
| Prior TPO-RA response, % | 42.5 | 20.0 |
| Completed core phase Tx, n (%) | 44 (81.5) | 1 (4.8) |

### Reason for discontinuation of core phase Tx




Time from diagnosis to treatment was >3 years for all patients. Most patients had ≥3 previous treatments, with 71–74% receiving prior TPO-RAs.

Dx, diagnosis; ITP, immune thrombocytopenia; PC, platelet count; SD, standard deviation; TPO-RA, thrombopoietin receptor agonist; Tx, treatment.

Grace RF, et al. Presented at: EHA2024 Hybrid Congress, Madrid, Spain. 13–16 June 2024. Oral presentation S318.

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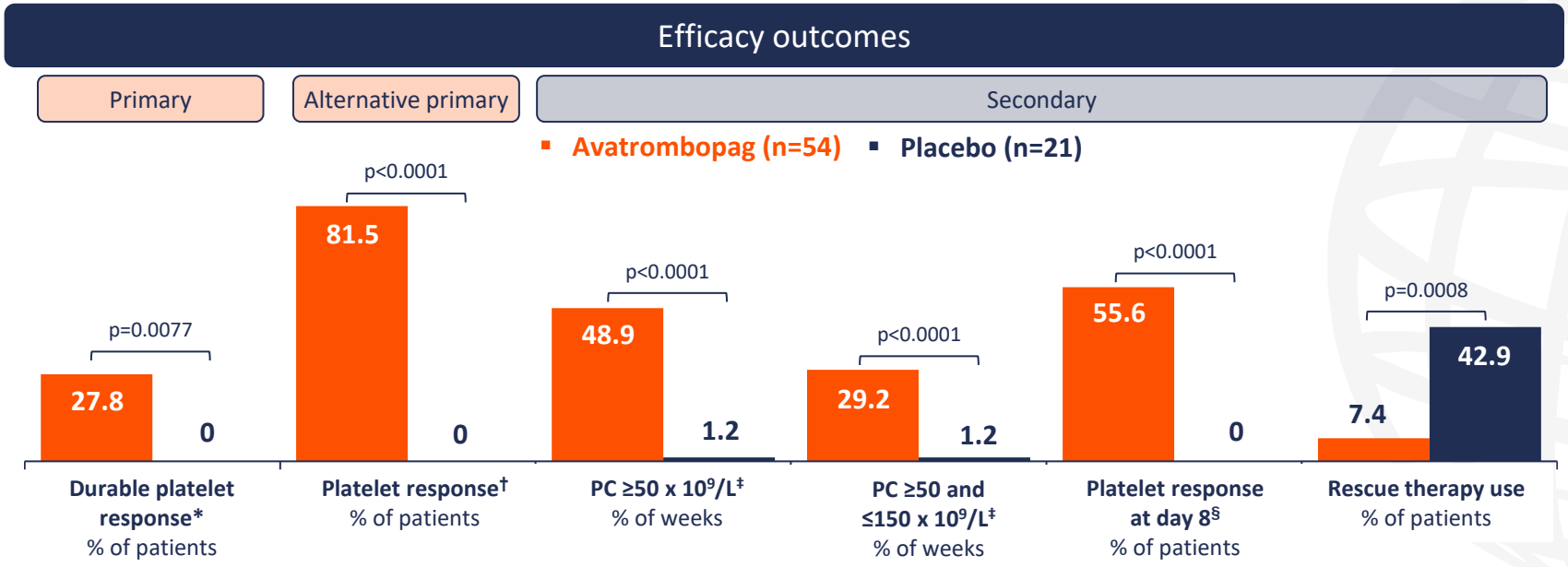
# S318: A phase 3, randomised, double-blind, placebo-controlled trial to evaluate the efficacy and safety of avatrombopag for the treatment of children with chronic ITP (AVA-PED-301) Grace RF, et al.




Avatrombopag was an effective oral TPO-RA for children and adolescents with persistent or chronic ITP with insufficient response to prior therapies.

*PC ≥50 x $10^9$/L in ≥6 of the last 8 weeks of the core phase in absence of rescue therapy. †≥2 consecutive PC ≥50 × $10^9$/L in 12-week core phase in the absence of rescue therapy. ‡During 12-week core phase in absence of rescue therapy. §PC ≥50 x $10^9$/L at day 8 in absence of rescue therapy. ITP, immune thrombocytopenia; PC, platelet count; TPO-RA, thrombopoietin receptor agonist. Grace RF, et al. Presented at: EHA2024 Hybrid Congress, Madrid, Spain. 13–16 June 2024. Oral presentation S318.

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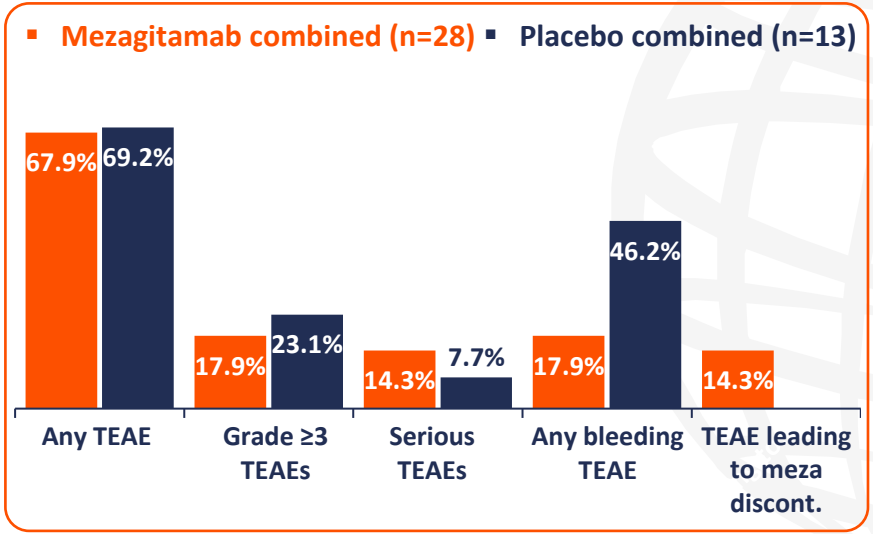
# LB 01.1: Safety, tolerability, and efficacy of mezagitamab (TAK-079) in chronic or persistent primary ITP: Interim results from a phase 2, randomized, double-blind, placebo-controlled study Kuter D, et al.

## Baseline characteristics

| | Mezagitamab combined (n=28) | | | Placebo combined (n=13) |
|---|---|---|---|---|
| | 100 mg (n=9) | 300 mg (n=8) | 600 mg (n=11) | |
| Mean ± SD age, years | 49.7 ± 16.7 | | | 38.8 ± 15.9 |
| Mean ± SD PC at screening, x $10^9$/L | 19.1 ± 12.8 | | | 17.3 ± 10.4 |
| Mean ± SD time since diagnosis, years | 10.8 ± 10.8 | | | 11.3 ± 10.9 |
| Mean ± SD number of prior Tx | 3.8 ± 2.4 | | | 4.2 ± 3.4 |

## Primary safety outcomes




Mezagitamab had a favorable safety and tolerability profile in adult patients with chronic/persistent ITP.

ITP, immune thrombocytopenia; PC, platelet count; SD, standard deviation; TEAE, treatment-emergent adverse event; Tx, treatment.

Kuter D, et al. Presented at: ISTH 2024, Bangkok, Thailand. 22–26 June 2024. Oral presentation LB 01.1.

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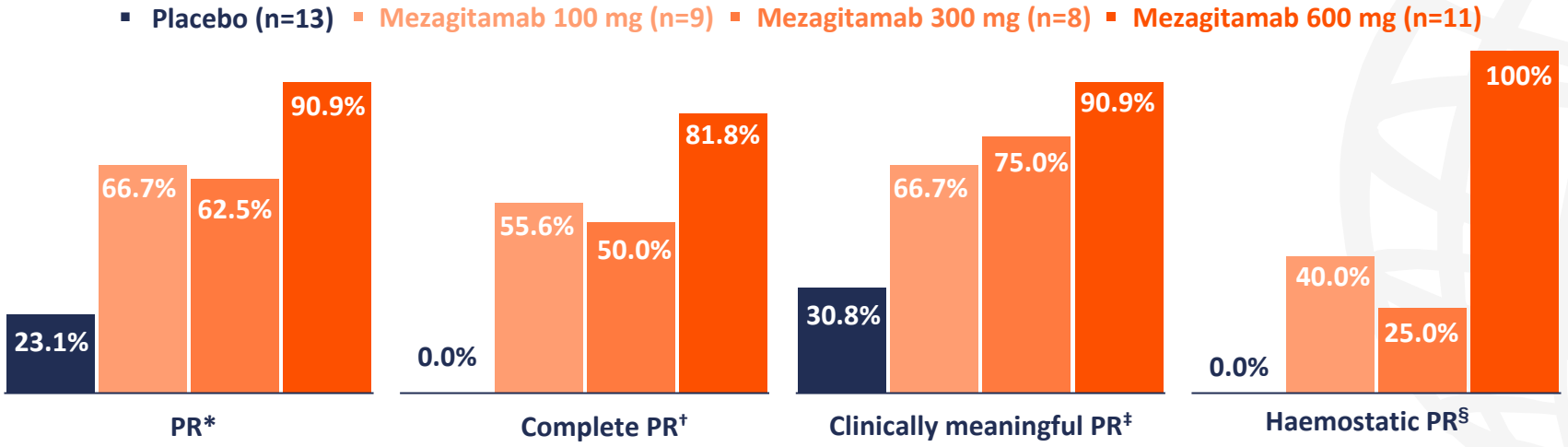
# LB 01.1: Safety, tolerability, and efficacy of mezagitamab (TAK-079) in chronic or persistent primary ITP: Interim results from a phase 2, randomized, double-blind, placebo-controlled study Kuter D, et al.

## Secondary efficacy outcomes (N=41)




All efficacy measures of platelet response were the highest for the mezagitamab 600 mg dose, with significant improvement vs placebo in all responses up to week 16.

*PC ≥50 x $10^9$/L and ≥20 x $10^9$/L above baseline on ≥2 visits. †PC ≥100 x $10^9$/L on ≥2 visits. ‡PC ≥20 x $10^9$/L above baseline on ≥2 visits. §PC ≥30 x $10^9$/L and ≥20 x $10^9$/L above baseline on ≥2 visits. ITP, immune thrombocytopenia; PC, platelet count; PR, platelet response.

Kuter D, et al. Presented at: ISTH 2024, Bangkok, Thailand. 22–26 June 2024. Oral presentation LB 01.1.

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