

# Long-term Results From a Phase II Open-label Study of Ruxolitinib in Patients With Essential Thrombocythemia Refractory to or Intolerant of Hydroxyurea

Srdan Verstovsek,<sup>1</sup> Francesco Passamonti,<sup>2</sup> Alessandro Rambaldi,<sup>3</sup> Giovanni Barosi,<sup>4</sup> Elisa Rumi,<sup>4</sup> Elisabetta Gattoni,<sup>5</sup> Lisa Pieri,<sup>6</sup> Haifeng Zhang,<sup>7</sup> Mario Cazzola,<sup>4,8</sup> Hagop M. Kantarjian,<sup>9</sup> Tiziano Barbui,<sup>3</sup> Alessandro M. Vannucchi<sup>10</sup>

## Introduction

- Essential thrombocythemia (ET) is a Philadelphia chromosome–negative myeloproliferative neoplasm (MPN) characterized by persistent thrombocytosis, excessive proliferation of megakaryocytes in the bone marrow, and normal erythrocyte mass
- Complications of ET include progression to post-ET myelofibrosis (MF) or acute myeloid leukemia (AML) as well as an increased risk of arterial and venous thrombosis and hemorrhage
  - Age > 60 years and previous thrombosis are major predictors of vascular complications<sup>1</sup>
- Patients are treated with low-dose aspirin if microvascular disturbances are present, and those with high-risk disease receive hydroxyurea for cytoreduction<sup>1-3</sup>
- As with other Philadelphia-chromosome–negative MPNs, MF and polycythemia vera (PV), ET is associated with dysregulated Janus kinase (JAK)–signal transducer and activator of transcription (STAT) signaling<sup>4</sup>
- Ruxolitinib is an oral JAK1/JAK2 inhibitor that has shown clinical benefit in patients with MF and PV<sup>5-8</sup>

## Objective

- To report the long-term efficacy and safety of ruxolitinib in patients with ET refractory to or intolerant of hydroxyurea

## Methods

### Patients

- Age ≥ 18 years
- ET refractory to or intolerant of hydroxyurea as assessed by the investigator
- Eastern Cooperative Oncology Group performance status ≤ 2
- Platelet count > 650 × 10<sup>9</sup>/L unless receiving treatment
- Absolute neutrophil count ≥ 1.2 × 10<sup>9</sup>/L

### Study Design

- This was an open-label, phase II study (INCB18424-256; NCT00726232) that enrolled patients with ET or PV
  - Results in patients with PV have previously been reported<sup>6</sup>
- In the initial (dose-finding) phase of the study, patients with ET were randomly assigned to receive oral ruxolitinib at a dose of 10 mg twice daily (BID; n = 8), 25 mg BID (n = 9), or 50 mg once daily (QD; n = 9)
  - Patients were to remain on the initial treatment regimen for a minimum of 8 weeks; dose adjustments were allowed only for safety reasons during this time
  - After the first 8 weeks, investigators were permitted to adjust the dose regimen using their discretion to achieve an optimal balance of efficacy and safety
- Based on the dose-finding phase, the starting dose for the expansion phase was determined to be 25 mg BID and 13 additional patients were enrolled at this starting dose
- Ruxolitinib treatment occurred in an outpatient setting in continuous 4-week cycles until a patient met a withdrawal criterion, had an intolerable toxicity, experienced disease progression, or withdrew consent

### Study Assessments

- Efficacy assessments included achievement of:
  - Platelet count ≤ 400 × 10<sup>9</sup>/L in patients with baseline count > 400 × 10<sup>9</sup>/L
  - Platelet count ≤ 600 × 10<sup>9</sup>/L in patients with baseline count > 600 × 10<sup>9</sup>/L
  - White blood cell (WBC) count ≤ 10 × 10<sup>9</sup>/L in patients with baseline count > 10 × 10<sup>9</sup>/L
  - ≥ 50% reduction in palpable splenomegaly in patients with a palpable spleen at baseline
- Patients were asked to assess their ET-related symptoms (pruritus, bone pain, night sweats, asthenia, and paresthesia) on a scale from 0 (not present) to 10 (worst imaginable) at each study visit, reporting the worst level of symptoms experienced during the 7 days preceding the study visit
- Safety and tolerability were assessed by monitoring frequency, duration, and severity of adverse events regardless of causality, graded using the National Cancer Institute CTCAE v3.0, and the results of laboratory tests, electrocardiogram findings, vital sign measurements, and physical examinations

## Results

### Patients

- Baseline demographics and characteristics of the 39 patients with ET are presented in Table 1
- The majority of patients (64.1%) were receiving aspirin prior to enrolling in the study

**Table 1. Baseline Demographics and Clinical Characteristics**

	Patients With ET (N = 39)
Age, median (range), years	51 (25–87)
Male, n (%)	14 (35.9)
White, n (%)	39 (100)
BMI, median (range), kg/m <sup>2</sup>	24.3 (17.3–31.9)
Duration since diagnosis, median (range), months	87.6 (0.4–273.1)
Hematocrit, median (range), %	40.4 (31.1–49.0)
Hematocrit < 45%, n (%)	34 (87.2)
Platelet count, median (range), × 10 <sup>9</sup> /L	849 (325–2640)
Platelet count > 400 × 10 <sup>9</sup> /L, n (%)	38 (97.4)
Platelet count > 600 × 10 <sup>9</sup> /L, n (%)	35 (89.7)
WBC count, median (range), × 10 <sup>9</sup> /L	8.15 (3.47–34.7)
Palpable spleen measurement from costal margin, median (range), cm	5.0 (3–7) (n = 4)
History of thromboembolic events, n (%)	7 (17.9)
Prior therapies, n (%)	
Hydroxyurea	37 (94.9)
Anagrelide	9 (23.1)
Interferon	7 (17.9)
Pipobroman	4 (10.3)
JAK2V617F positive, n (%)	25 (64.1)
JAK2V617F allele burden, median (range), %	24 (5–84)

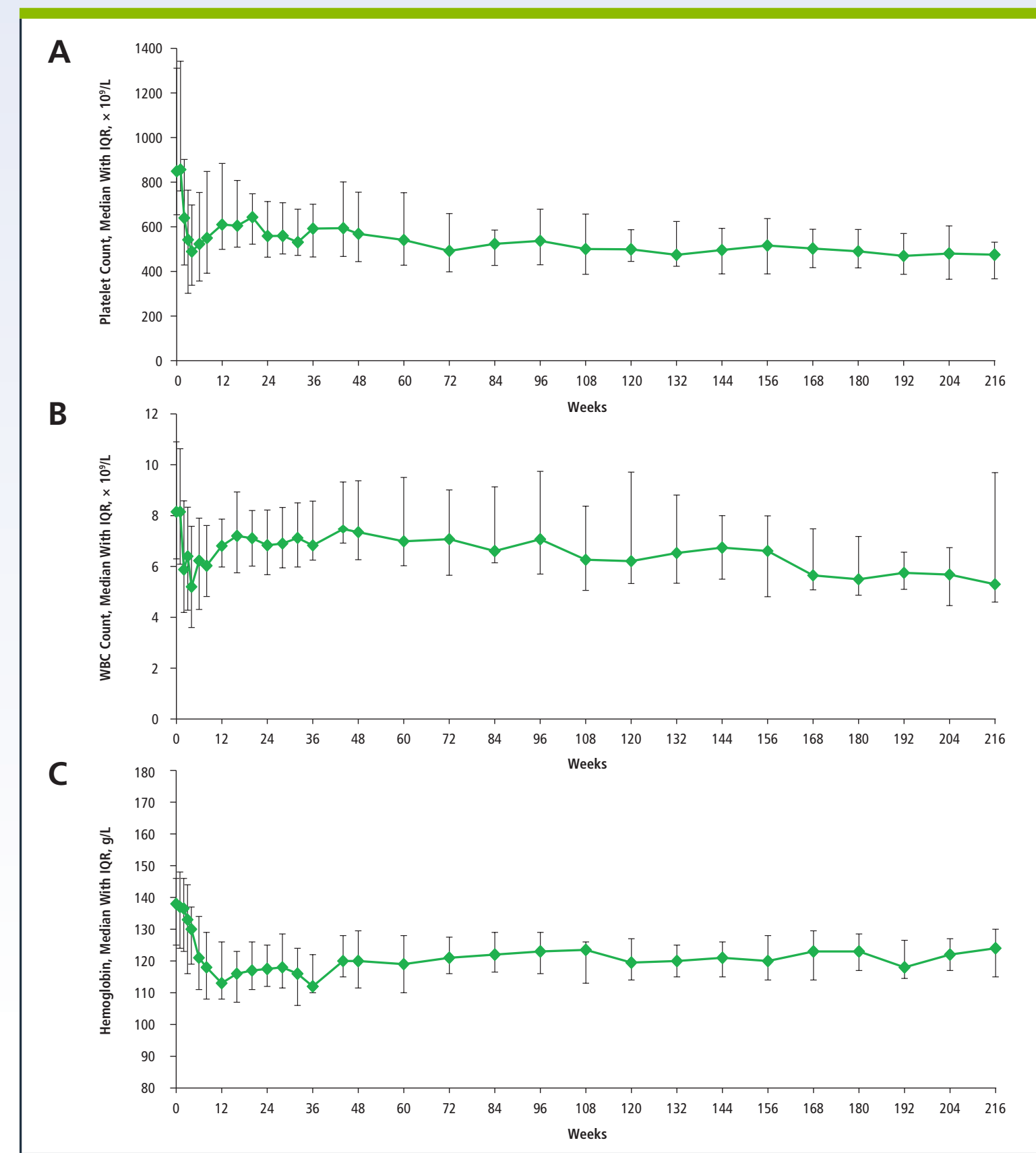
BMI, body mass index; ET, essential thrombocythemia; WBC, white blood cell.

- At the time of data cutoff, 61.5% of patients were still receiving treatment
- Reasons for discontinuation (38.5% of patients; n = 15) were: adverse event (n = 5), consent withdrawn (n = 2), death (n = 1), or other (n = 7)

### Efficacy

- Median platelet count decreased rapidly after initiation of therapy and remained relatively stable over time (Figure 1A)
- Median WBC count decreased rapidly during the first 4 weeks, followed by an increase and stabilization in the normal range (Figure 1B)
- Median hemoglobin decreased over the first 12 weeks of ruxolitinib administration, followed by stabilization throughout follow-up (Figure 1C)

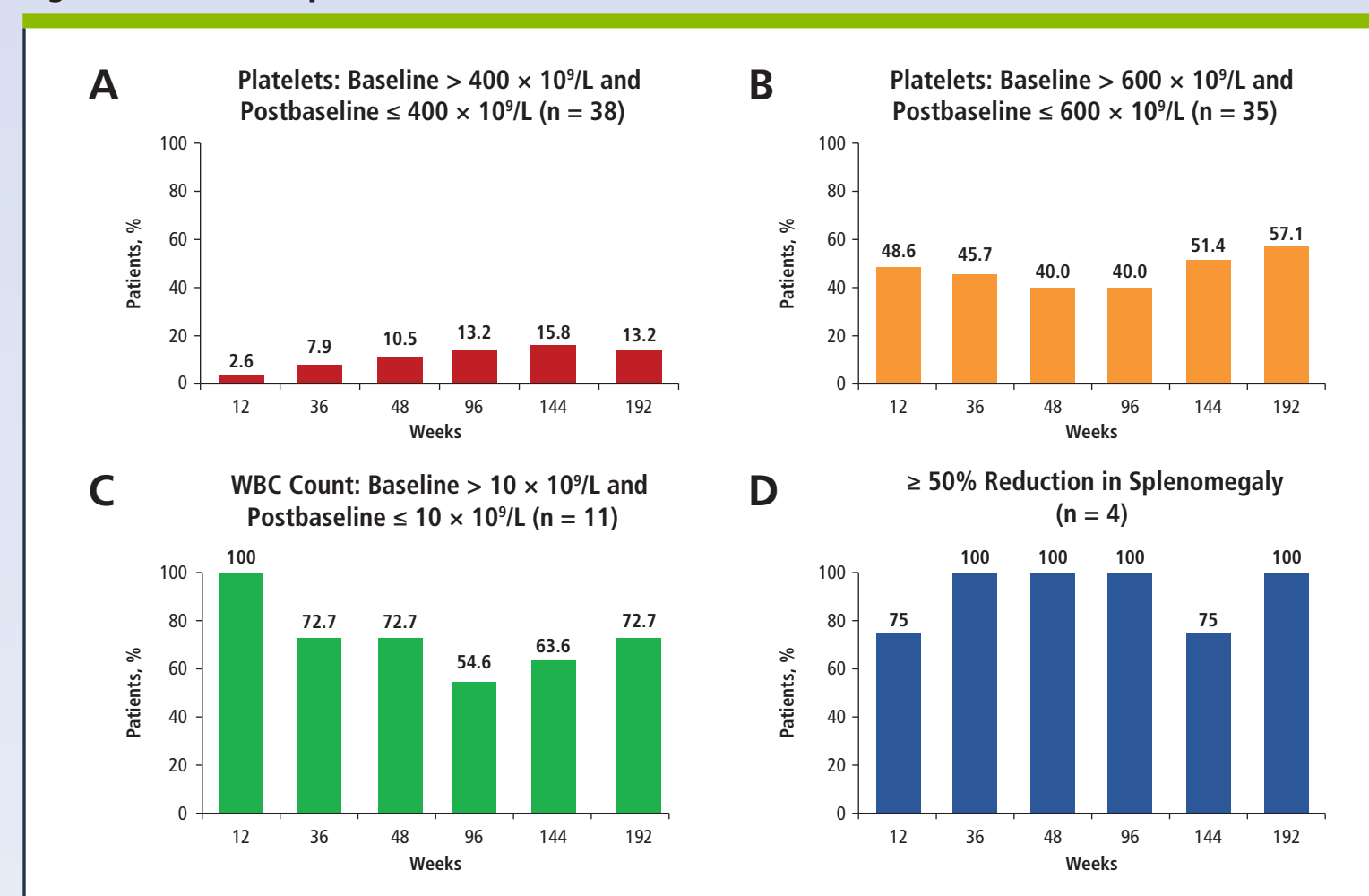
**Figure 1. Median With IQR Laboratory Values for (A) Platelet Count, (B) WBC Count, and (C) Hemoglobin**



IQR, interquartile range; WBC, white blood cell.

- Of the patients with baseline platelet count > 400 × 10<sup>9</sup>/L (n = 38), 2.6%, 10.5%, and 13.2% of patients had a platelet count ≤ 400 × 10<sup>9</sup>/L at week 12, 48, and 192, (month 3, 12, and 48) respectively (Figure 2A)
- Of the patients with baseline platelet count > 600 × 10<sup>9</sup>/L (n = 35), 48.6%, 40.0%, and 57.1% of patients had a platelet count ≤ 600 × 10<sup>9</sup>/L at week 12, 48, and 192, respectively (Figure 2B)
- Of the patients with baseline WBC count > 10 × 10<sup>9</sup>/L (n = 11), 100%, 72.7%, and 72.7% of patients had a WBC count ≤ 10 × 10<sup>9</sup>/L at week 12, 48, and 192, respectively (Figure 2C)
- Of the 4 patients with palpable spleen at baseline (median, 5.0 cm), all patients achieved ≥ 50% reduction and 3 patients achieved absence of palpable splenomegaly by the week 36 visit (Figure 2D)
  - Of the remaining 35 patients without palpable spleen at baseline, 1 patient developed intermittent palpable splenomegaly 1 cm below the costal margin, which was not palpable at the time of data cutoff

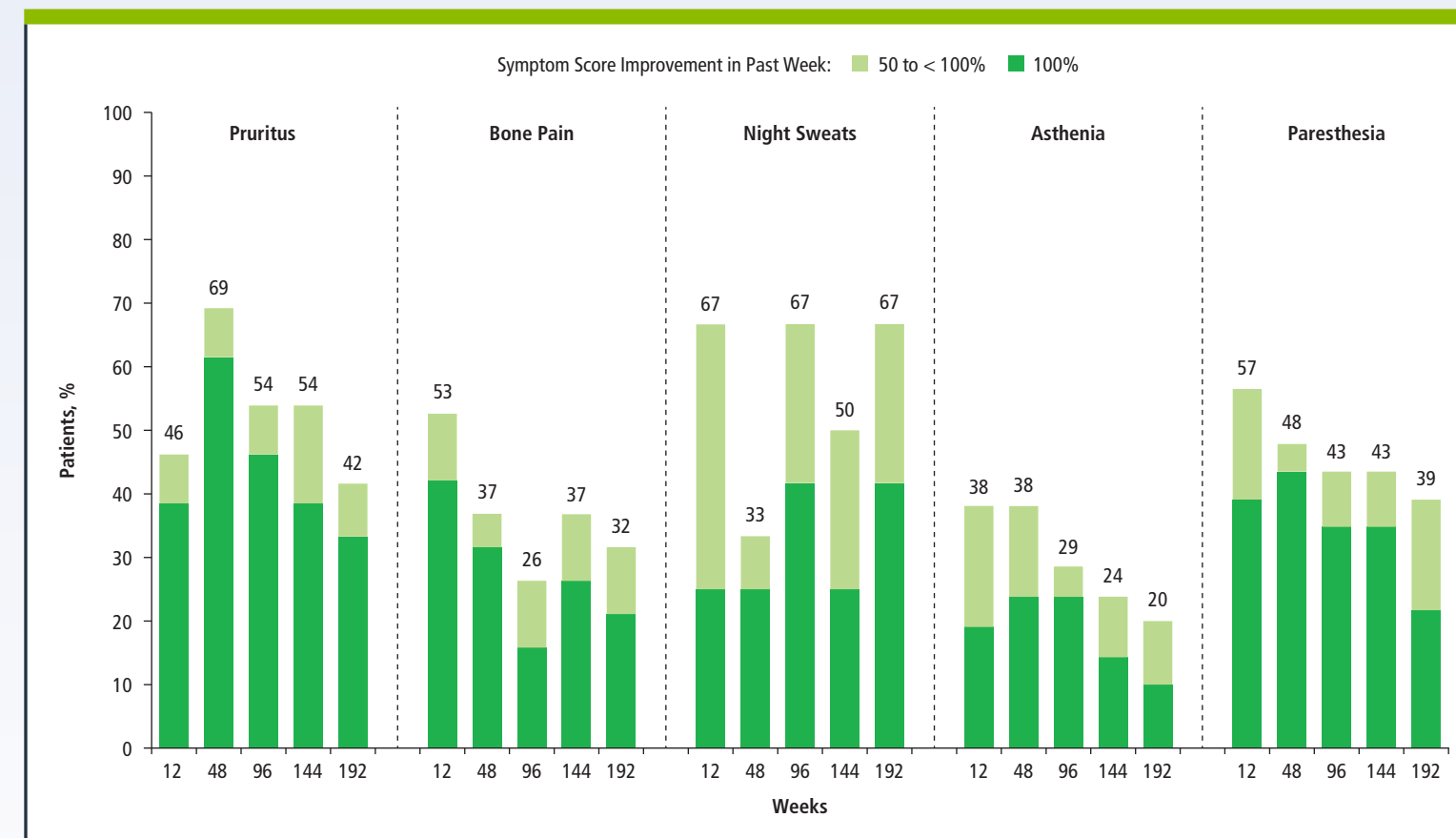
**Figure 2. Clinical Response to Ruxolitinib Treatment**



WBC, white blood cell.

- Clinically meaningful improvements in pruritus, bone pain, night sweats, asthenia, and paresthesia were reported by patients as early as week 12 and were largely sustained through week 192 (Figure 3)

**Figure 3. Proportion of Patients With ≥ 50% or 100% Improvement in ET-Related Symptoms With Ruxolitinib Therapy**



Includes patients with baseline symptom scores > 0 within each symptom. Data labels represent proportion of patients with ≥ 50% improvement in symptom score.

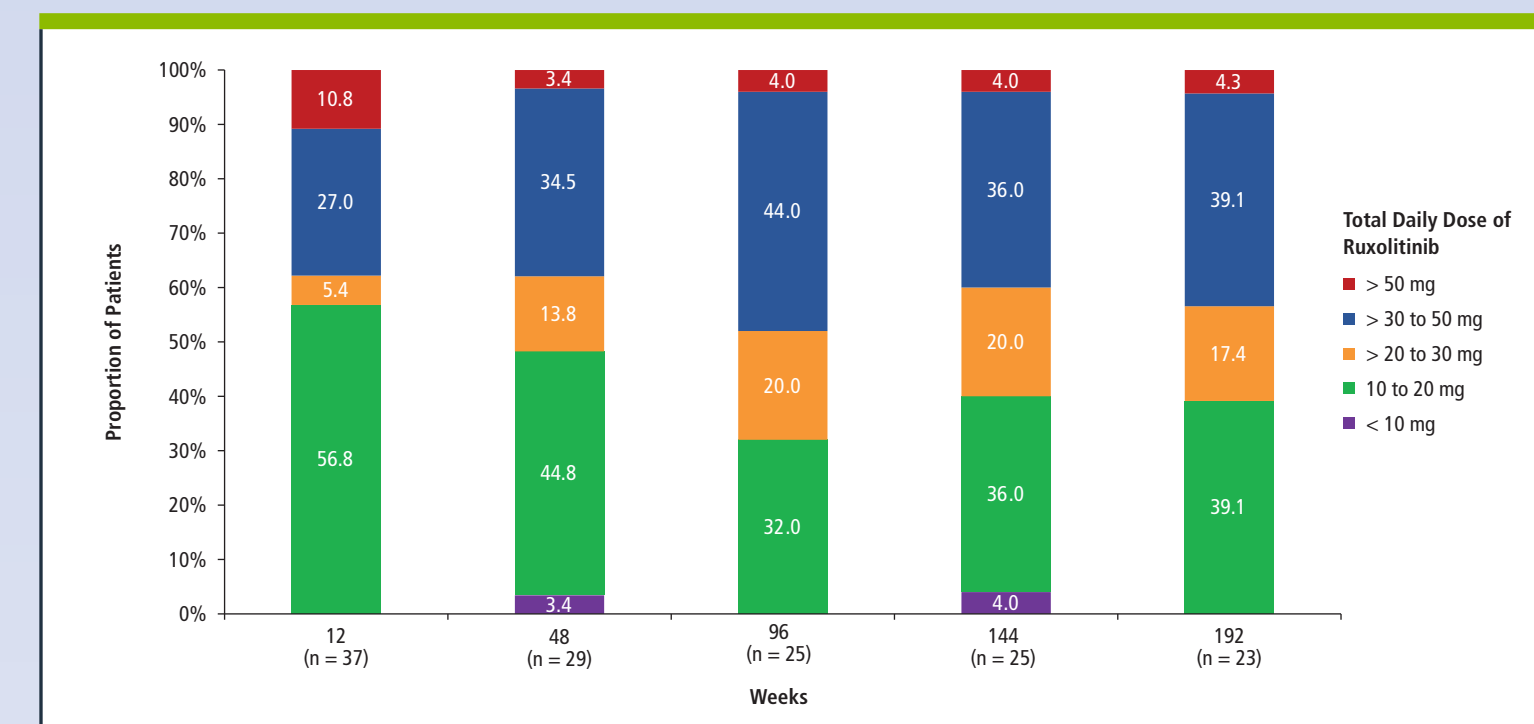
### JAK2V617F Allele Burden

- Median percent change from baseline in JAK2V617F allele burden was –2.8% at week 24 (n = 22), +1.9% at week 48 (n = 20), and –33.3% at week 192 (n = 15)

### Exposure and Safety

- At the time of data cutoff, the median exposure to ruxolitinib was 205.6 weeks (approximately 48 months; range, 13–226 weeks)
- The majority of patients (71.8%) received ruxolitinib for ≥ 96 weeks (24 months)
- The median daily dose was 30.1 mg (range, 10–74 mg)
- The majority of patients received ruxolitinib in total daily doses of 10 to 20 mg or > 30 to 50 mg (Figure 4)

**Figure 4. Ruxolitinib Dose Distribution Over Time**



- Long-term ruxolitinib treatment was generally well tolerated; the majority of adverse events were grade 1 or grade 2
- The most common any-grade nonhematologic adverse events regardless of causality (Table 2) were increased weight (35.9%), diarrhea (28.2%), cough, and headache (25.6% each)
- New or worsening grade 3 or 4 leukopenia, neutropenia, and lymphopenia occurred in 3 patients each (7.7%), and new or worsening grade 3 anemia occurred in 1 patient (2.6%)
- Two patients experienced thrombotic events on study
  - A 66-year-old woman with a history of vascular disease originally randomized to 50 mg QD experienced a grade 2 venous thrombosis of the limb on study day 333, which resolved with administration of antithrombotic agents; the patient discontinued from study approximately 3 months later for grade 2 extremity pain in the left foot (etiology not determined), which resolved within 1 week of study discontinuation
  - A 60-year-old woman originally randomized to 25 mg BID experienced a pulmonary embolism on study day 1091, which resolved with administration of antithrombotic agents; the patient remains on study as of the data cutoff for this analysis
- Infections of any grade were reported in 26 patients (66.7%); of these, grade ≥ 3 infections were reported in 2 patients (5.1%; n = 1, bronchitis and n = 1, pneumonia)
- There were no reports of AML or transformation to post-ET MF

**Table 2. Nonhematologic Adverse Events Occurring in ≥ 15% of Patients (Any Grade)**

Adverse Event, n (%)	Any Grade	Grade ≥ 3
Increased weight	14 (35.9)	0
Diarrhea	11 (28.2)	0
Cough	10 (25.6)	0
Headache	10 (25.6)	2 (5.1)
Hypercholesterolemia	9 (23.1)	1 (2.6)
Increased blood creatine phosphokinase	8 (20.5)	1 (2.6)
Bronchitis	8 (20.5)	1 (2.6)
Pain in extremity	8 (20.5)	0
Pyrexia	8 (20.5)	0
Arthralgia	7 (17.9)	0
Hypertension	7 (17.9)	0
Constipation	6 (15.4)	0
Hyperuricemia	6 (15.4)	1 (2.6)
Nausea	6 (15.4)	0

## Conclusions

- Ruxolitinib treatment resulted in rapid and sustained improvements in platelet count, WBC count, and splenomegaly in patients with ET who were refractory to or intolerant of hydroxyurea
- Rapid reductions in ET-related symptoms were noted during the study and were largely sustained through week 192
- Ruxolitinib was generally well tolerated, and most adverse events that occurred were grade 1 or 2
- No new safety concerns were observed during long-term treatment with ruxolitinib in this cohort of patients with ET who were resistant to or intolerant of hydroxyurea

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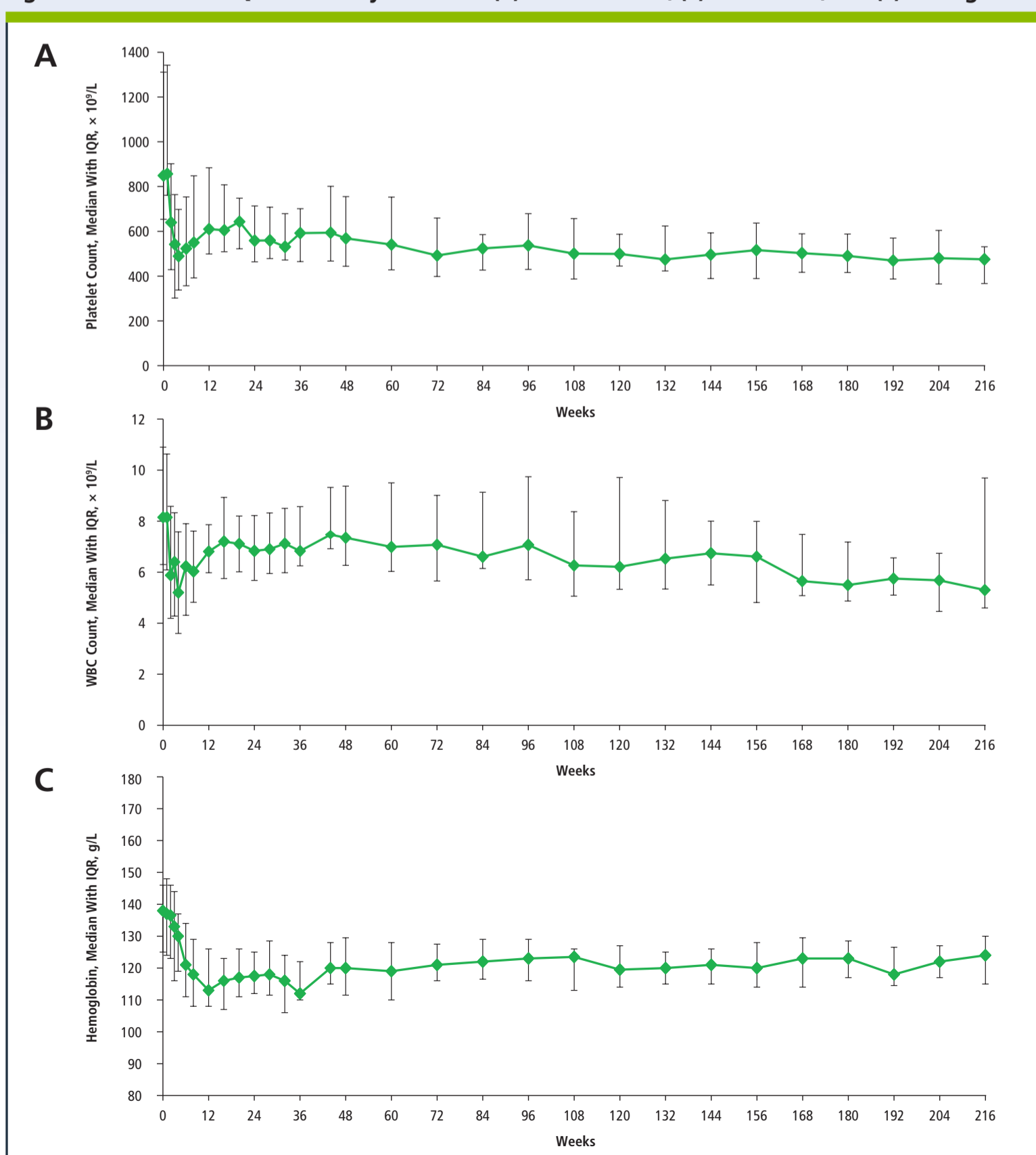
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### Efficacy

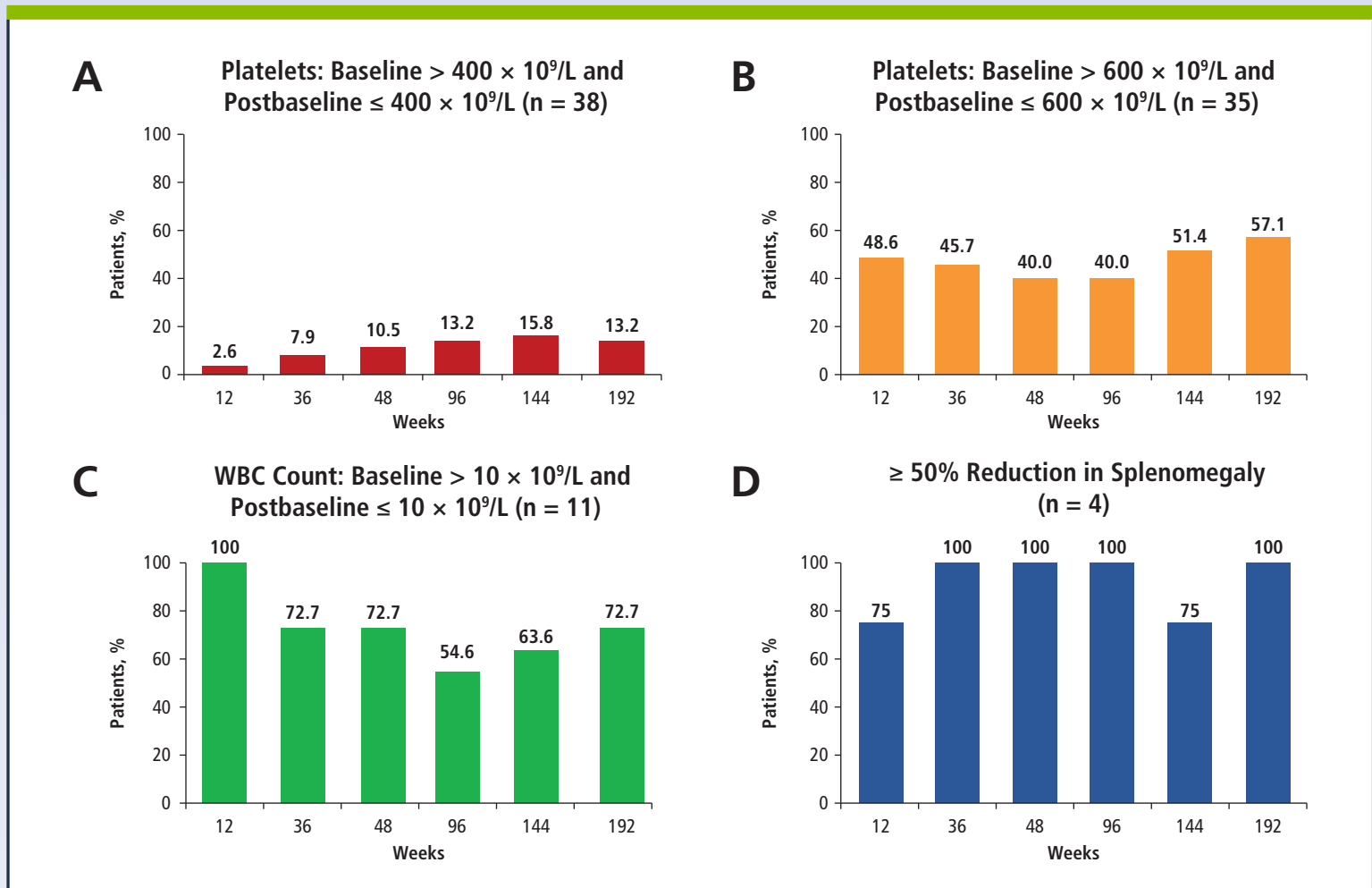
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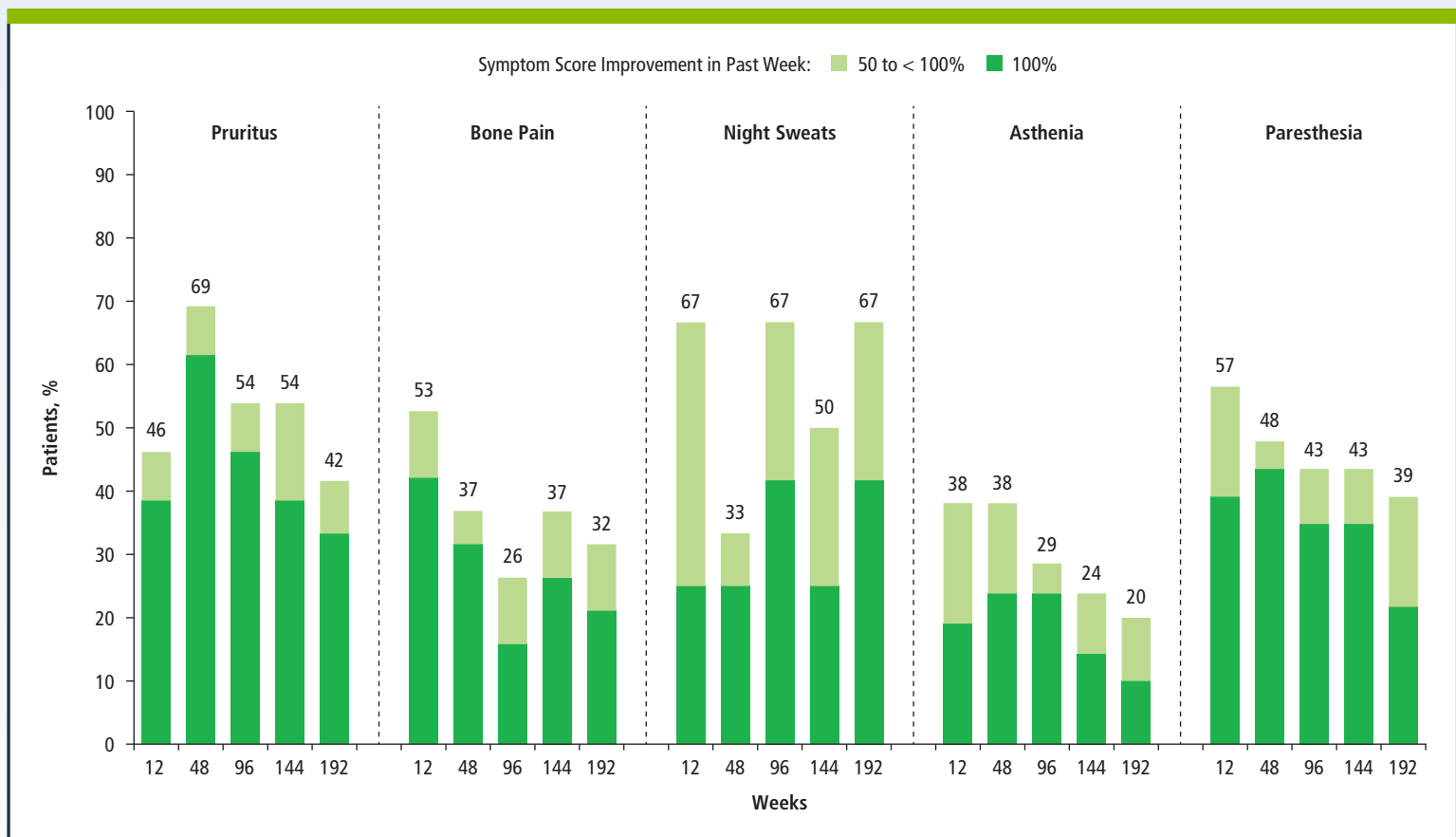
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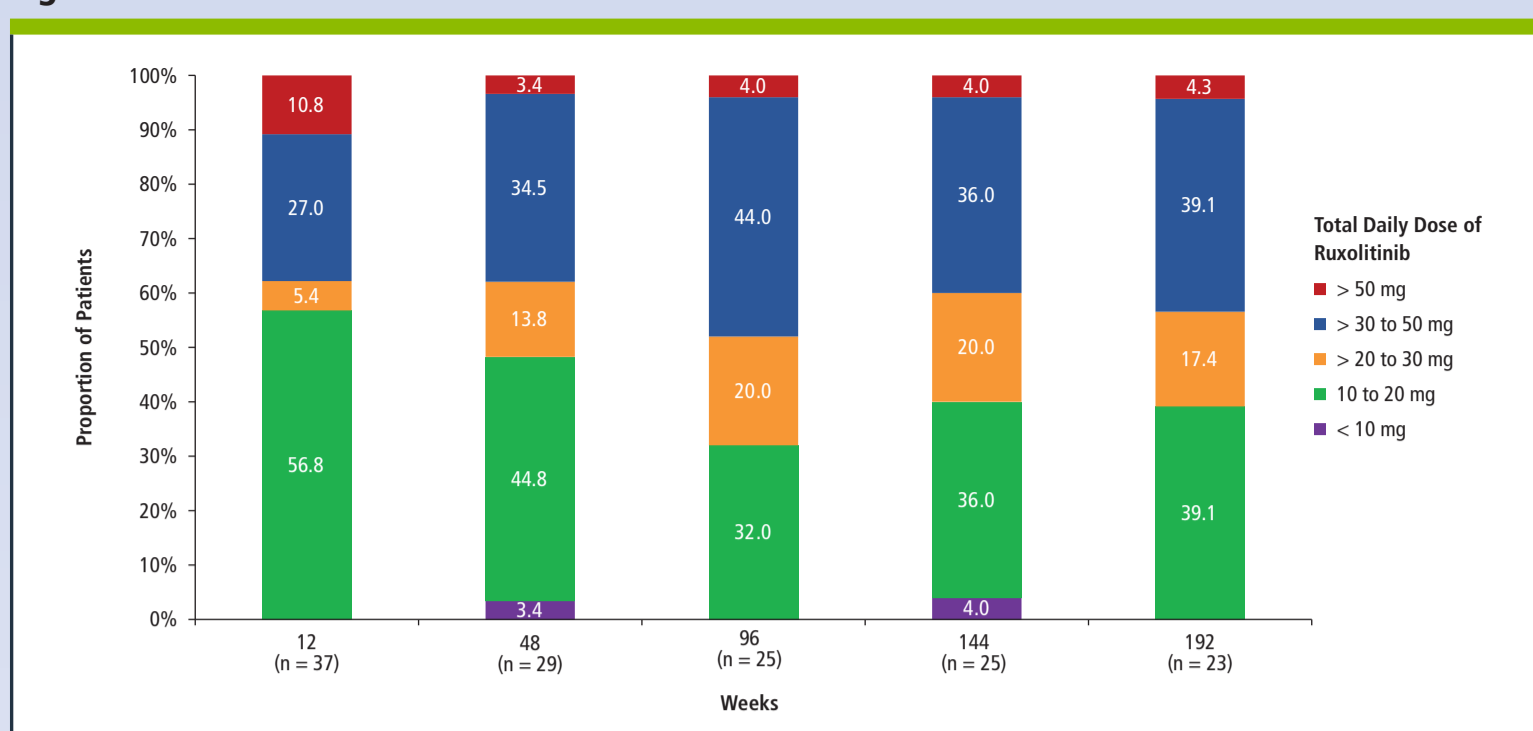
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**Figure 4. Ruxolitinib Dose Distribution Over Time**



- Long-term ruxolitinib treatment was generally well tolerated; the majority of adverse events were grade 1 or grade 2
- The most common any-grade nonhematologic adverse events regardless of causality (Table 2) were increased weight (35.9%), diarrhea (28.2%), cough, and headache (25.6% each)
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Increased blood creatine phosphokinase	8 (20.5)	1 (2.6)
Bronchitis	8 (20.5)	1 (2.6)
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Nausea	6 (15.4)	0

## Conclusions

- **Ruxolitinib treatment resulted in rapid and sustained improvements in platelet count, WBC count, and splenomegaly in patients with ET who were refractory to or intolerant of hydroxyurea**
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