CHALLENGING CASES

Systemic Mastocytosis

Prepared by: Cornerstone Specialty Network

Challenging Cases conducted: April 1, April 8, April 16, May 27, October 2, and November 4, 2025

Participating Practices

Challenging Cases in…

Systemic Mastocytosis

Program conducted:
April–November 2025

Note: Aggregated results and high-level summary based on 6 practices (≤34 HCPs) and do not necessarily reflect the views and opinions of the moderator or Cornerstone Specialty Network unless otherwise stated. Clinical data, NCCN Guidelines, and FDA approvals current at time of presentation.

- **New Mexico Cancer Center (n=7)** — **April 1, 2025**
- **Fort Wayne Medical Oncology & Hematology (n=6)** — **April 8, 2025**
- **Center for Cancer and Blood Disorders (n=4)** — **April 16, 2025**
- **Cancer Center of Kansas (n=4)** — **May 27, 2025**
- **Maryland Oncology & Hematology (n=5)** — **October 2, 2025**
- **Atlantic Health System (n=8)** — **November 4, 2025**

Overall Program Impact and Future Considerations

Limited experience with treating systemic mastocytosis (SM) in community oncology; most evaluate systemic mastocytosis using serum tryptase, KIT mutation analysis, and bone marrow biopsy. Avapritinib is the preferred therapy, while clinical trials, observation, or short-term treatment trial periods are considered for indolent or smoldering disease. Assessment is complicated by nonspecific symptoms such as fatigue, GI issues, rash, and anaphylaxis and by limited familiarity with WHO diagnostic criteria

- **Diagnosis & risk assessment:** Evaluation typically includes serum tryptase, KIT mutation analysis, and bone marrow biopsy; and collaboration with pathologists, along with access to high-sensitivity testing, improves diagnostic accuracy
- **Front-line strategy:** Avapritinib is the preferred treatment for systemic mastocytosis (SM), with clinical trials or observation for select patients; limited trial period of therapy for 3-6 months can determine benefit in cases with fluctuating or nonspecific symptoms
- **Symptom management:** Fatigue, GI complaints, rash, and anaphylaxis are common but nonspecific; patients often underrecognize or underreport symptoms, complicating assessment of true disease burden and treatment initiation decisions
- **Emerging considerations:** Interest exists for future of KIT inhibitors for cutaneous disease and GLP-1 receptor agonists for cardiovascular or quality-of-life benefits; awareness and consistent application of WHO diagnostic criteria remain limited across community oncologists
- ***Recommended actions:*** *Increase educational initiatives emphasizing avapritinib efficacy and symptom management through Challenging Cases; engage community oncologists through advisory boards and real-world evidence trials through CSN to reinforce timely, appropriate patient identification (KIT testing), treatment initiation, and monitoring strategies*

Challenging Cases in… Hematologic disorders

Systemic Mastocytosis

Patient case: untreated disease

- Systemic Mastocytosis (SM) is classified as a Myeloid Neoplasm by WHO
- Prevalence of SM is estimated at ~1 in 10,000 adults
- 80% to 90% of cases are non-advanced SM (Indolent SM or Smoldering SM)

- *How can we reduce patient referral times?*
- *What is the optimal patient identification process?*
- *High sensitivity KIT D816V testing awareness ?*

SM, systemic mastocytosis; **WHO**, World Health Organization.

REFERENCES: **1**. Swerdlow SH et al, eds. *WHO Classification of Tumours of Haematopoietic and Lymphoid Tissues*. Revised 4th ed. Lyon, France: International Agency for Research on Cancer; 2017. **2**. Sperr WR et al. *Lancet Haematol*. 2019;6(12):e638-e649. **3**. Cohen SS et al. *Br J Haematol*. 2014;166(4):521-528. **4**. Brockow K. *Immunol Allergy Clin North Am*. 2014;34(2):283-295.

Patient History

71-year-old man

History of hypertension, dyslipidemia, cataract surgeries

Referred to hematology

Patient reported fatigue, headaches, intermittent episodes of diarrhea, and noticing macular spots x 6 months

No anaphylaxis

Diagnostics

Initial lab results:

December 10, 2022:

WBC 5, Hgb 13.4, Platelets 171

June 17, 2023:

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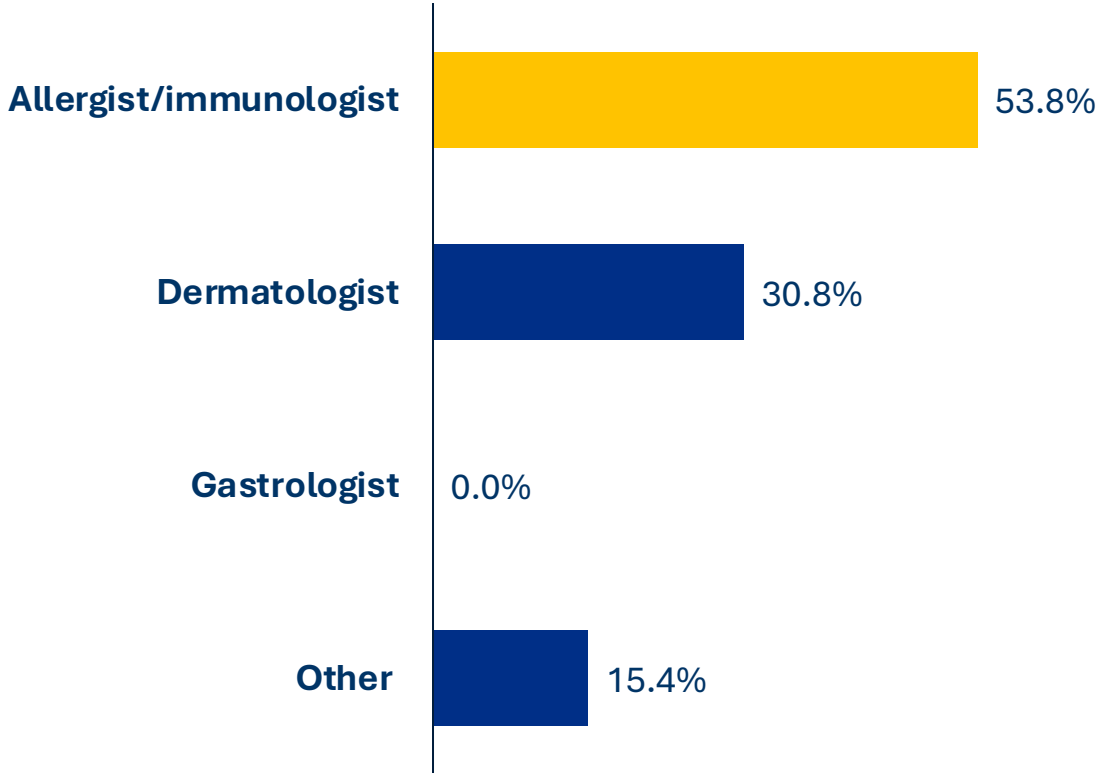
July 28, 2023:

ultrasound showed spleen 14 cm in length. Liver was normal.

How are patients most often referred to you for potential SM?

ARS Results from HCP Participants

How are patients most often referred to you for potential SM?



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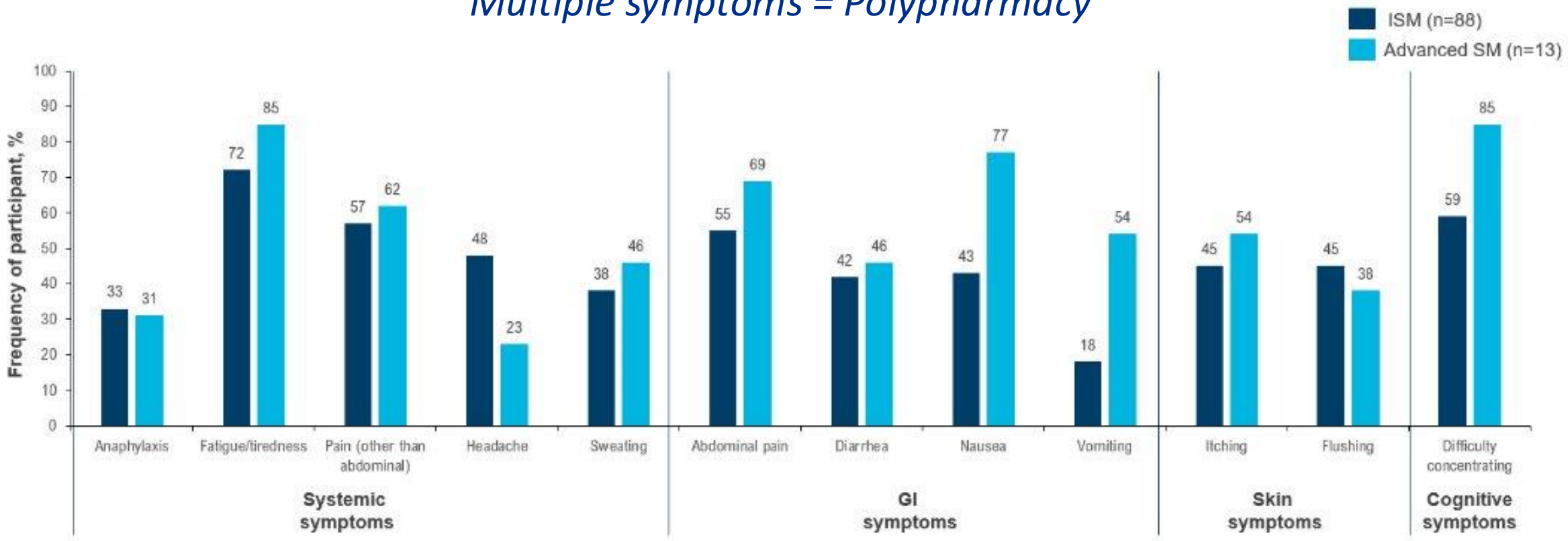
Spectrum of Symptom Burden for SM

Patients with ISM and advanced SM may experience severe symptoms

Multiple symptoms = Polypharmacy



Jennings SV et al. Immunol Allergy Clin North Am. 2018;38(3):505-525.

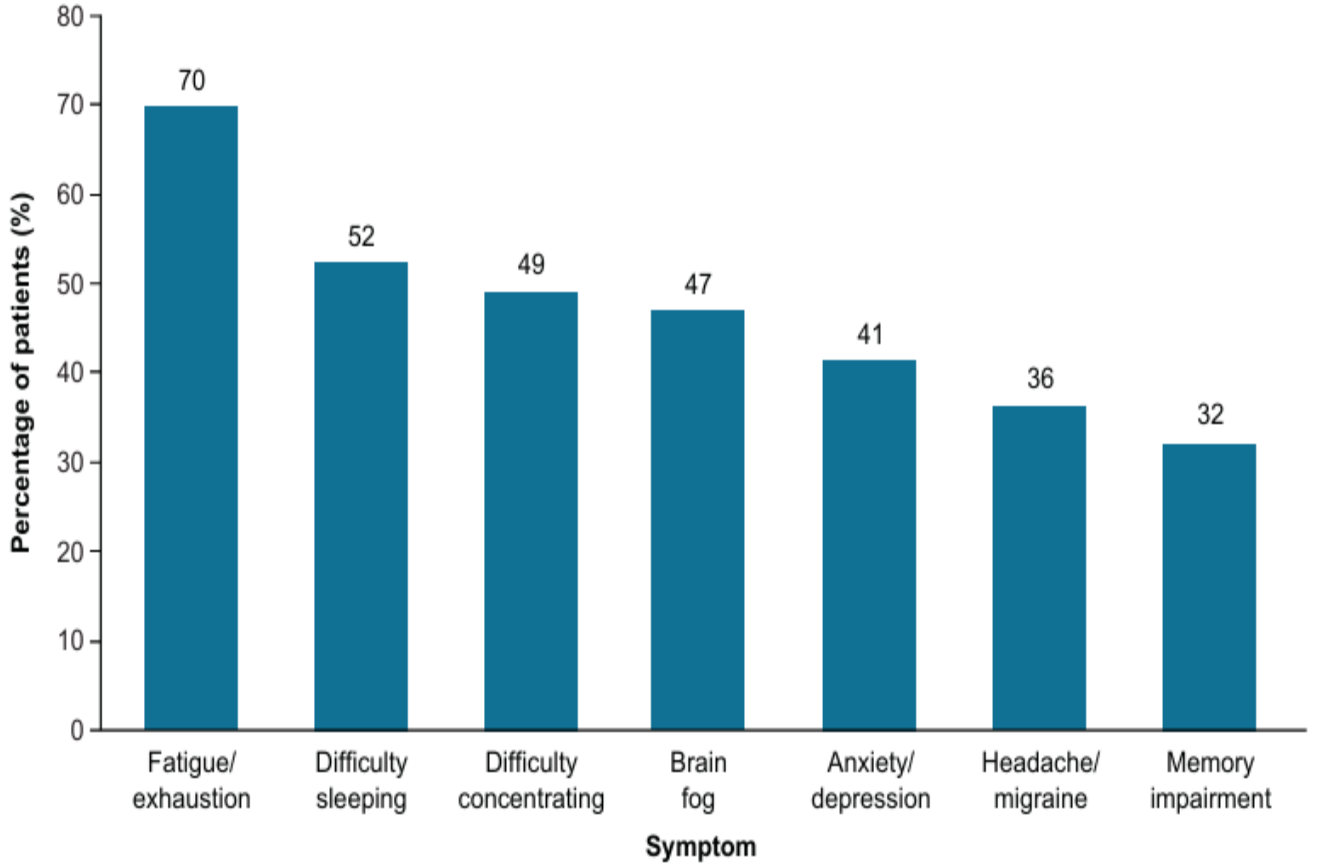
Does the spectrum of symptom burden for ISM surprise you?

Perceptions Realities and Insights on Systemic Mastocytosis (**PRISM**) survey, results from 237 patients with ISM:

- 67% reported a total symptom score (TSS) of ≥28, indicating moderate or severe symptoms
- 33% reported a TSS of <28, indicating mild symptoms

Patient demographic	Total (N=237)	TSS <28 mild symptoms (N=79)	TSS ≥28, moderate/ severe symptoms (N=158)
Age, years, mean (SD)	49.1 (12.7)	52.3 (13.7)	47.4 (12.0)
Sex, Female, n (%)	168 (71)	48 (61)	120 (76)
Time since SM diagnosis, mean (SD) (months)	114.7 (105.1)	160.9 (124.3)	91.7 (85.5)

Patients, regardless of TSS score, reported cognitive, psychological, and fatigue problems due to ISM



EAACI 2025 Congress, 13–16 June 2025, Poster Number 000488

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How do you currently assess patients for potential mast cell disease?

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ARS Results from HCP Participants

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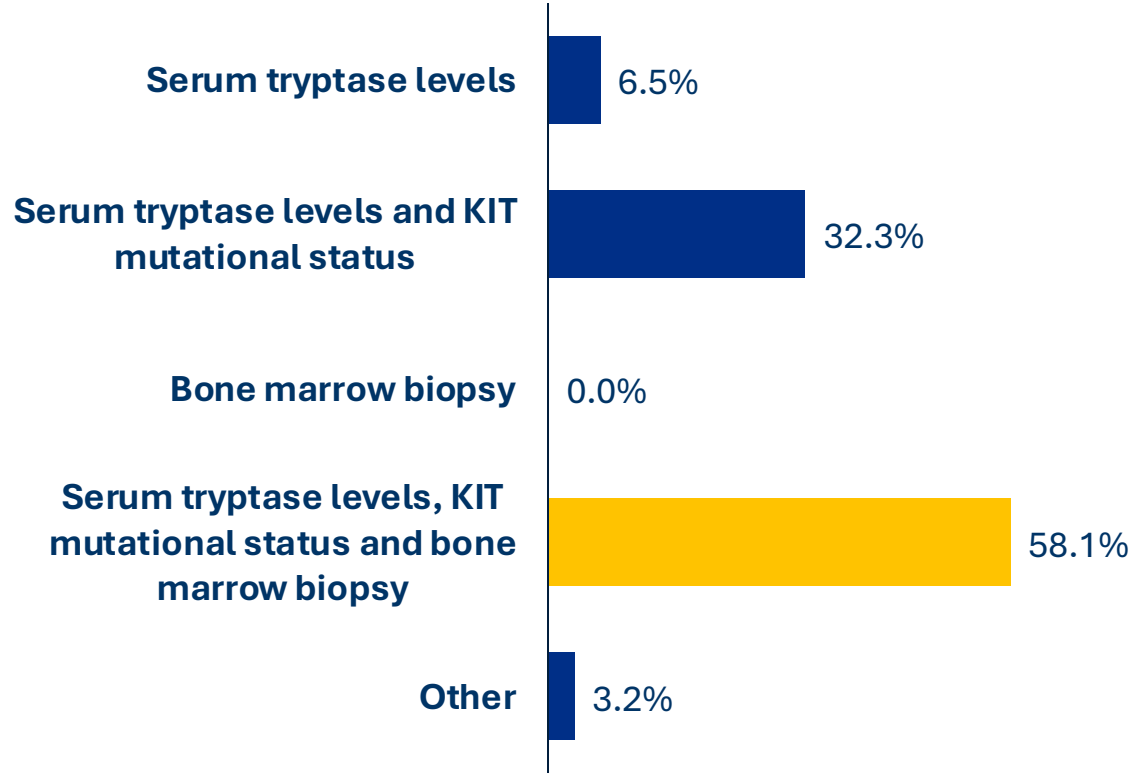

Answered: 31

National Comprehensive Cancer Network®

NCCN Guidelines Version 1.2025
Systemic Mastocytosis

NCCN Guidelines Index
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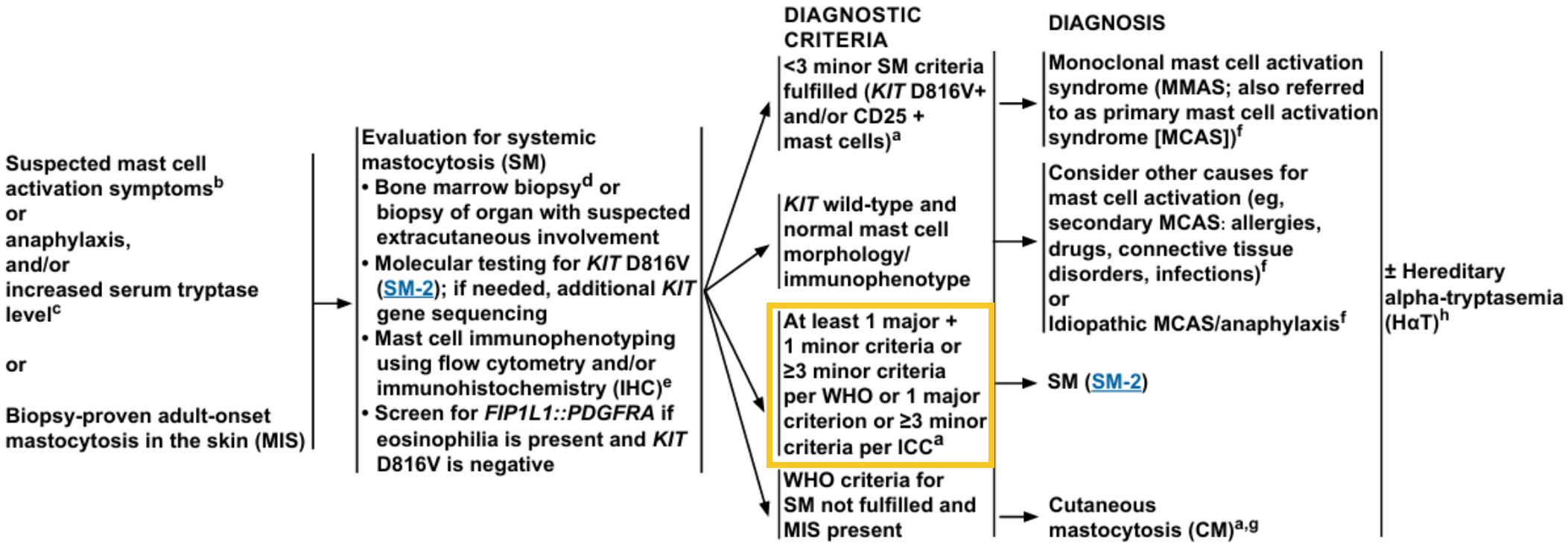
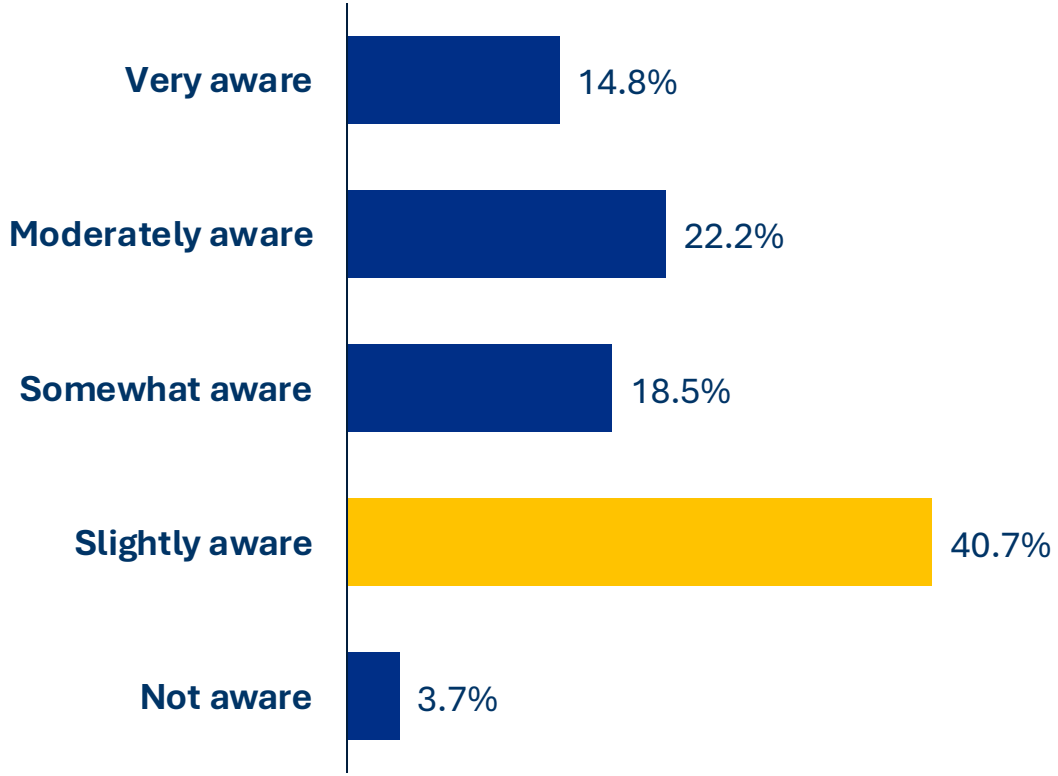
Discussion

DIAGNOSTIC ALGORITHM FOR THE PATIENT PRESENTING WITH SIGNS OR SYMPTOMS OF MASTOCYTOSIS[a]



ARS Results from HCP Participants

How aware are you of the WHO Criteria for SM?



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WHO Criteria

WHO Criteria for Diagnosis of SM:

1 Major criterion and **1 Minor** criterion **OR ≥ 3 Minor** criteria

Major criterion

- Multifocal dense infiltrates of mast cells (≥15 mast cells/aggregate) detected in bone marrow and/or extracutaneous organs

Minor criterion

- Detection of *KIT* 816V in bone marrow, blood or an extracutaneous organ
- Serum tryptase >20 ng/mL (unless associated myeloid neoplasm is present)
- >25% of infiltrating mast cells are spindle-shaped or atypical on biopsy of bone marrow or extracutaneous organ or >25% of all mast cells in bone marrow aspirate smears are immature or atypical
- Mast cells in bone marrow, blood or extracutaneous organ express CD25 with or without CD2

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SM subtypes

Non-advanced

Indolent SM: Meets the general criteria for systemic mastocytosis; <2 B-findings; No C-findings; Low mast cell burden; No evidence of an associated hematologic neoplasm; Skin lesions are frequently present

Smoldering SM: Meets the general criteria for systemic mastocytosis; ≥2 B-findings; No C-findings; No evidence of an associated hematologic neoplasm; Does not meet the criteria for mast cell leukemia

Advanced

Aggressive SM: Meets the general criteria for systemic mastocytosis; ≥1 C-finding; Does not meet the criteria for mast cell leukemia; Skin lesions are usually absent

SM with an associated hematologic neoplasm: Meets the general criteria for systemic mastocytosis; Meets the criteria for an associated neoplasm

Mast Cell Leukemia: Bone marrow aspirate smears show ≥20% mast cells; In classic cases, mast cells account for ≥10% of the peripheral blood white blood cells, but the aleukemic variant (in which mast cells account for <10%) is more common; Skin lesions are usually absent; Mast cell variants include:

- Acute MCL [≥1 C-finding(s)] vs. chronic MCL (no C-findings)
- MCL with an AHN vs. MCL without an AHN
- Primary (de novo) vs. secondary MCL (arising from another SM variant)

Evaluation of B- and C- findings and organ involvement

- **B-Findings: Indicate a high burden of MCs and expansion of the neoplastic process into multiple hematopoietic lineages, without evidence of organ damage**
  - High mast cell burden (shown on bone marrow biopsy): >30% infiltration of cellularity by MCs (focal, dense aggregates) AND serum total tryptase >200 ng/mL.
  - Signs of dysplasia or myeloproliferation in non-mast cell lineage(s), but criteria are not met for definitive diagnosis of an AHN, with normal or only slightly abnormal blood counts.
  - Hepatomegaly without impairment of liver function, palpable splenomegaly without hypersplenism, and/or lymphadenopathy on palpation or imaging

- **C-Findings: Are indicative of organ damage produced by MC infiltration (should be confirmed by biopsy if possible)**
  - Bone marrow dysfunction caused by neoplastic mast cell infiltration, manifested by ≥1 cytopenia; absolute neutrophil count <1.0 x 10^9/L, hemoglobin level <10 g/dL, and/or platelet count <100 x 10^9/L
  - Palpable hepatomegaly with impairment of liver function, and/or ascites, and/or portal hypertension
  - Skeletal involvement, with large osteolytic lesions (if the size of the lesion is ≥2 cm, it is considered large) with or without pathologic fractures (pathologic fractures caused by osteoporosis do not qualify as a C-finding). Small osteolytic and/or sclerotic lesions do not define advanced SM.
  - Palpable splenomegaly with hypersplenism
  - Malabsorption with weight loss due to gastrointestinal mast cell infiltrates

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ISM is Primarily Driven by the *KIT* D816V Mutation

- The ***KIT* D816V** mutation is present in **~95%** of patients with ISM and is an underlying driver of disease[1]
- The D816V mutation causes structural changes that result in constitutive activation of *KIT*[2]
- **Mast cells harboring the *KIT* D816V mutation have constitutive *KIT* activation/signaling resulting in uncontrolled mast cell proliferation and activation**[3,4]

Methods to detect KIT D816V include:

- ✓ ASO-qPCR
- ✓ ddPCR

ISM in PIONEER Trial	Local assessment n (%)[1]	TruSight NGS n (%)[1]	ddPCR n (%)[1]
KIT D816V detected	31 (80)	11 (28)	**37 (95)**
KIT D816V not detected	8 (20)	28 (72)	2 (5)
Patients analyzed	39	39	39

The high-sensitivity ddPCR assay method demonstrated:

- KIT D816V mutation detection in 95% of peripheral blood samples from patients with previously confirmed ISM
- 30-fold greater sensitivity over NGS for measuring MAF; median percentage MAF (range) was 0.36 (0.02–30.22) by ddPCR and 11 (1.9–32) by NGS
- Greater diagnostic sensitivity for ISM compared with serum tryptase >20 ng/mL (77%) and presence of bone marrow mast cell aggregates (90%)

1. Garcia-Montero AC et al. Blood. 2006;108(7):2366-2372.
2. Laine E et al. PLoS Comput Biol. 2011;6:e1002068.
3. Cruse G et al. Immunol Allergy Clin North Am. 2014;34(2):219-237.
4. Theoharides TC et al. N Engl J Med. 2015;373(2):163-172.

Data on file. Blueprint Medicines Corporation, Cambridge, MA. 2022.

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What treatment do you recommend?

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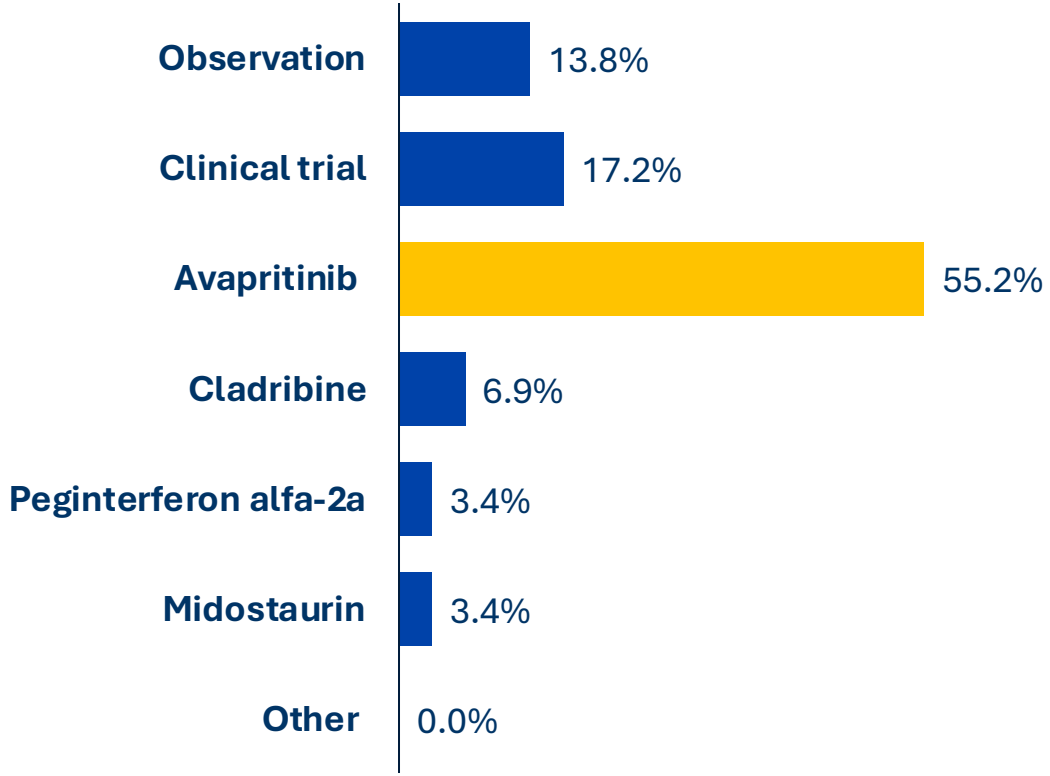
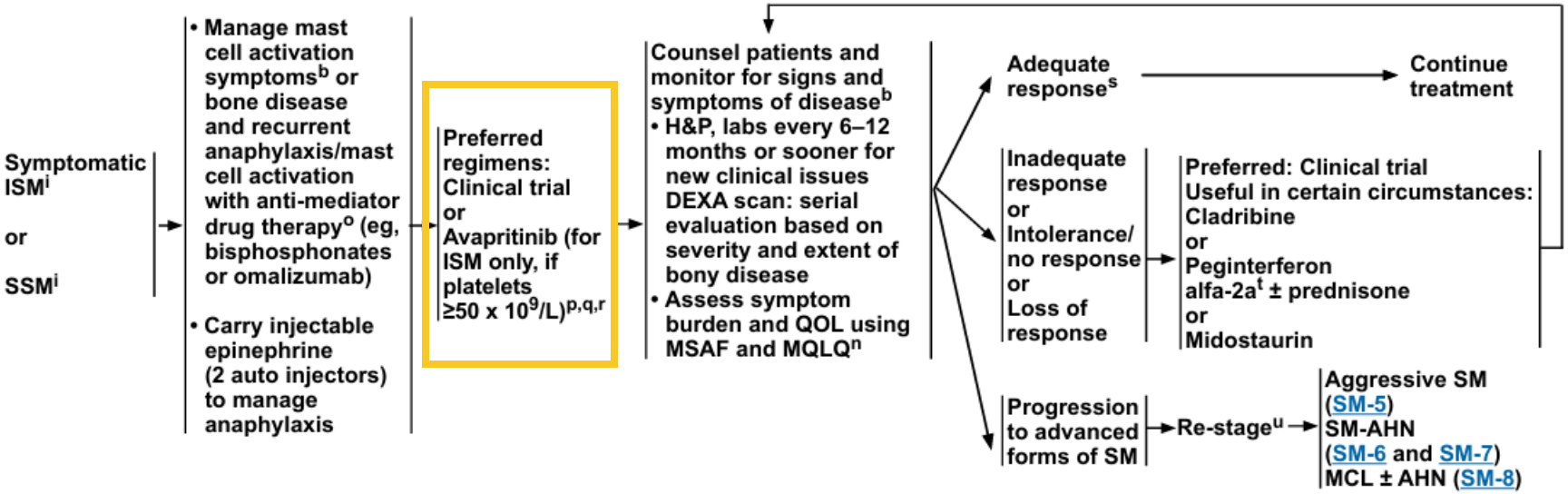
ARS Results from HCP Participants

What treatment do you recommend?



Answered: 29

TREATMENT FOR INDOLENT SYSTEMIC MASTOCYTOSIS AND SMOLDERING SYSTEMIC MASTOCYTOSIS[l]



[b] Patients should be counseled about the signs/symptoms and potential triggers of mast cell activation (SM-J). Multidisciplinary collaboration with subspecialists (eg, anesthesia for procedures/surgery; high-risk obstetrics for pregnancy) is recommended (SM-L).

[i] Diagnostic Criteria for the Variants of Systemic Mastocytosis (SM-D).

[l] Adverse Prognostic Variables and Risk Stratification in Systemic Mastocytosis (SM-I).

[n] van Anrooij D, et al. Allergy 2016;71:1585-1593. MSAF and MQLQ have been validated only in patients with ISM, not in patients with more advanced forms of mast cell disease. To access the questionnaires for MSAF and MQLQ, select "Supporting Information" and "See Appendix S1 and Appendix S2."

[o] See (SM-K) for anti-mediator drug therapy approaches for mast cell activation symptoms.

[p] Avapritinib is not recommended for the treatment of patients with platelet counts of less than 50 X 10^9/L.

[q] Refer to the package insert for the full prescribing information, dose modifications, and monitoring for adverse reactions: https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm.

[r] Gotlib J, et al. NEJM Evid 2023;2:EVIDoa2200339.

[s] Response assessment should be based on improvement of disease-related symptoms and/or improvement of B-findings in ISM or SSM.

[t] In the event that peginterferon alfa-2a is unavailable, the use of other available pegylated interferons (eg, ropeginterferon alfa-2b-njft) is appropriate.

[u] Bone marrow aspirate and biopsy, serum tryptase level, and additional staging studies should be performed as clinically indicated (if supported by increased symptoms and signs of progression). See Discussion.

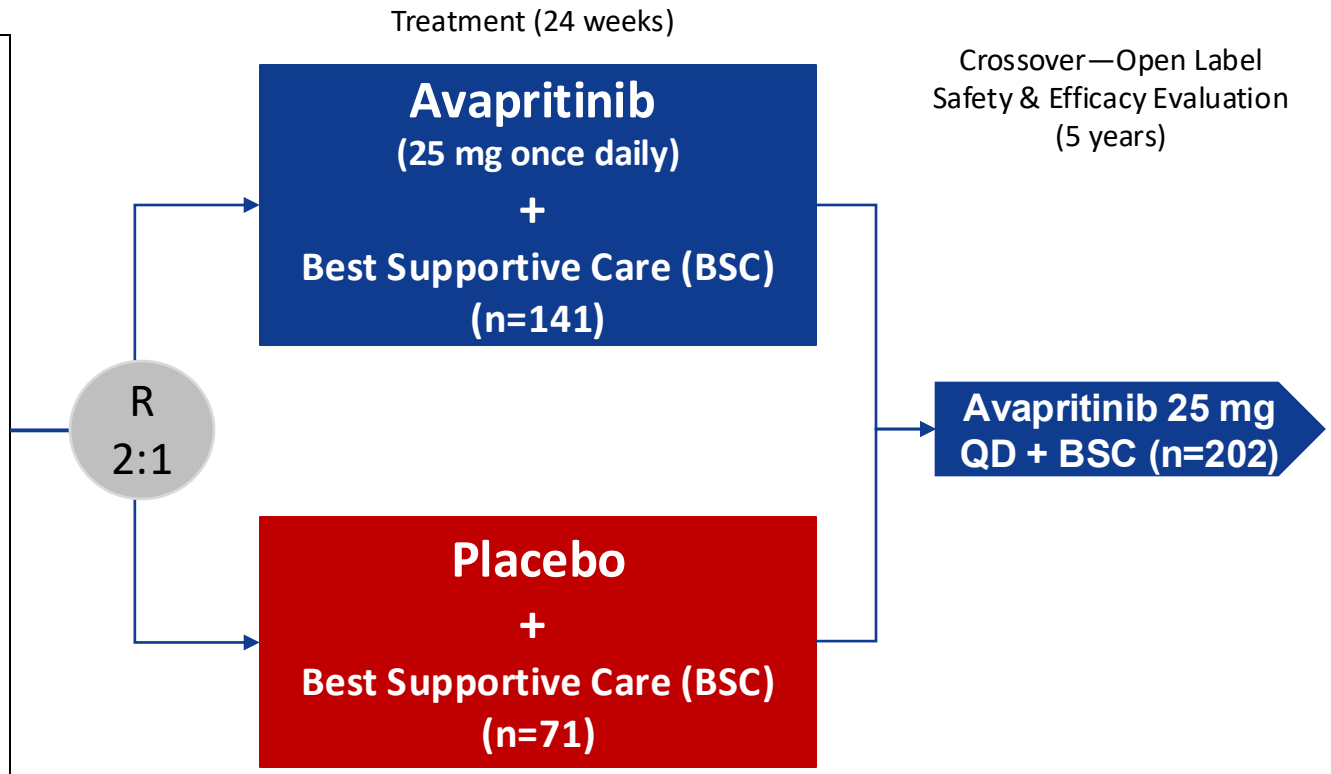
Note: All recommendations are category 2A unless otherwise indicated.

PIONEER

Study Design: randomized double-blind, placebo-controlled, multipart Phase 2 trial

- Patients with indolent systemic mastocytosis (SM) confirmed by Central Pathology Review of BM biopsy, and central review of B- and C-findings by WHO diagnostic criteria
- Patient must have moderate-to-severe symptoms based on minimum mean total symptom score (TSS of ≥28; scores range from 0 to 110, with higher numbers indicating more severe symptoms) of the ISM Symptom Assessment Form (ISM-SAF) over the 14-day eligibility screening period
- Patient must have failed to achieve adequate symptom control for 1 or more Baseline symptoms
- For patients receiving corticosteroids, the dose must be ≤ 20 mg/d prednisone or equivalent, and the dose must be stable for ≥ 14 days
- ECOG PS of 0 – 2

N =212



Primary endpoint: Mean change in total symptom score (TSS) based on the 14-day average of patient-reported severity of 11 symptoms at 24 weeks

Secondary endpoints: Reductions in serum tryptase and blood KIT D816V variant allele fraction (≥50%), reductions in TSS (≥50% and ≥30%), reduction in bone marrow mast cells (≥50%), and quality of life measures

ClinicalTrials.gov ID NCT03731260

PIONEER

Baseline Characteristics

Characteristic	Avapritinib (n=141)	Placebo (n=71)
Age – Years, Median (range)	50.0 (18–77)	54.0 (26–79)
Female — n (%)	100 (70.9)	54 (76.1)
Ethnicity — n (%)		
• Hispanic or Latino	6 (4.3)	1 (1.4)
• Not Hispanic or Latino	99 (70.2)	58 (81.7)
• Not reported	22 (15.6)	10 (14.1)
• Unknown	14 (9.9)	2 (2.8)
Tryptase (central) — ng/ml, mean (SD)	57.6 (54.4)	67.6 (74.2)
• Baseline — median (range)	38.4 (3.6–256.0)	43.7 (5.7–501.6)
• ≥20 — n (%)	113 (80.1)	56 (78.9)
• <20 — n (%)	28 (19.9)	15 (21.1)
TSS		
• Baseline — mean (SD)	50.2 (19.1)	52.4 (19.8)
• <28 — n (%)	14 (10.1)	4 (5.6)
• ≥28 to <42 — n (%)	38 (27.3)	22 (31.0)
• ≥42 — n (%)	87 (62.6)	45 (63.4)

A total of two patients in the avapritinib group had missing baseline TSS values; therefore, the denominator was on the basis of patients with available data at baseline (n=139).

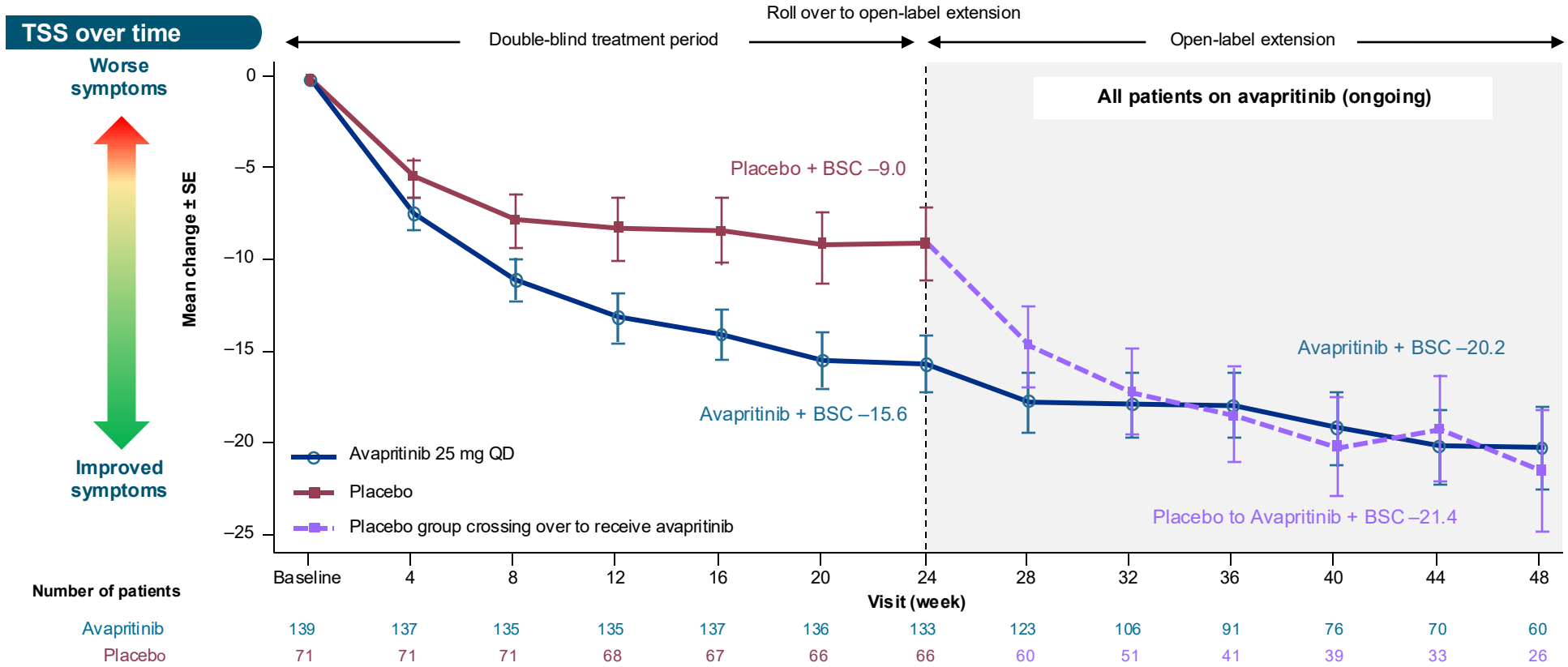
Characteristic	Avapritinib (n=141)	Placebo (n=71)
Bone marrow biopsy mast cells (central)		
• Mean (SD) — %	11.0 (11.1)	12.2 (12.6)
• Median (range) — %	7.0 (1.0–50.0) 106	7.0 (1.0–70.0)
• Mast-cell aggregates present — n (%)	(75.2)	57 (80.3)
KIT D816V VAF in peripheral blood		
• Below level of detection (<0.02%) — n (%)	23 (16.3)	8 (11.3)
• ≥0.02% to <1% — n (%)	78 (55.3)	37 (52.1)
• ≥1% — n (%)	40 (28.4)	26 (36.6)
• Median VAF (range)	0.4 (0.02–41.3)	0.3 (0.02–36.7)
Prior cytoreductive therapy — n (%)	19 (13.5)	7 (9.9)
Prior TKI therapy — n (%)	10 (7.1)	4 (5.6)
Number of BSC treatments — median (range)	3 (0–11)	4 (1–8)

All patients had at least two BSC prior to or at screening. A total of 10 (7.1%) patients treated with avapritinib and 5 (7.0%) patients treated with placebo had less than two BSC at the start of the trial.

ClinicalTrials.gov ID NCT03731260

PIONEER

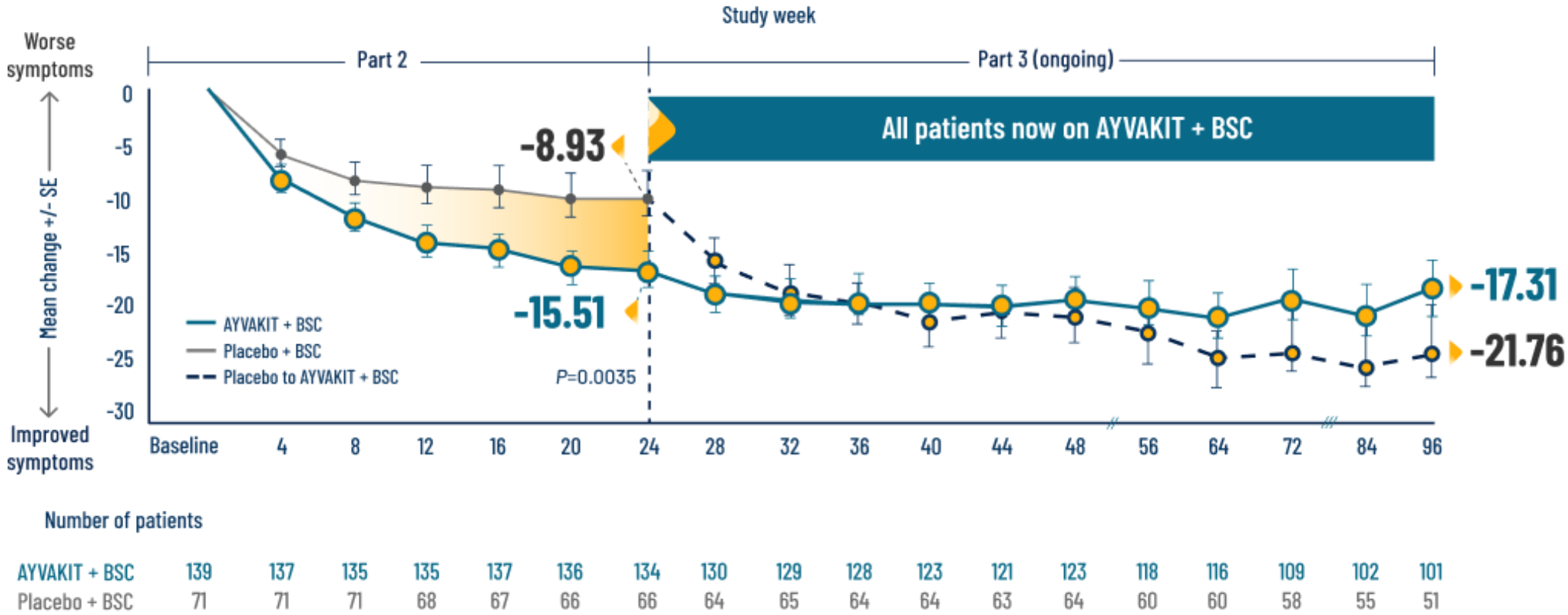
Primary Endpoint: Indolent Systemic Mastocytosis Symptom Assessment Form Total Symptom Score over Time with Avapritinib versus Placebo



	Avapritinib 25 mg (N=128)	Placebo (N=65)	P-value
Mean Change in TSS (95% CI)	-15.58 (-18.61, -12.55)	-9.15 (-13.12, -5.18)	0.003

ClinicalTrials.gov ID NCT03731260

Exploratory Endpoint: 96-week follow up



BSC: Best supportive care

https://www.ayvakithcp.com/ism/efficacy/

KEY DATA

PIONEER

Secondary Endpoints

≥50% Reduction in Serum Tryptase over Time
And ≥50% Reduction in KIT D816V Variant Allele Fraction over Time

	Avapritinib 25mg (n=128)	**Placebo** (n=65)	P-value
≥50% Reduction in Serum Tryptase (95% CI)	**53.9%** (45.3, 62.3)	**0.0%** (0.0, 5.1)	<0.0001
≥50% Reduction in *KIT* D816V VAF (95% CI)	**67.8%** (58.6, 76.1)	**6.3%** (1.8, 15.5)	<0.0001

≥30% and ≥50% Reductions in Indolent Systemic Mastocytosis Symptom Assessment Form Total Symptom Score (TSS) over Time with Avapritinib versus Placebo

	Avapritinib 25mg (n=128)	**Placebo** (n=65)	P-value
≥30% Reduction in TSS (95% CI)	**45.4%** (37.0, 54.0)	**29.6%** (19.3, 41.6)	0.009
≥50% Reduction in TSS (95% CI)	**24.8%** (17.9, 32.8)	**9.9%** (4.1, 19.3)	0.005

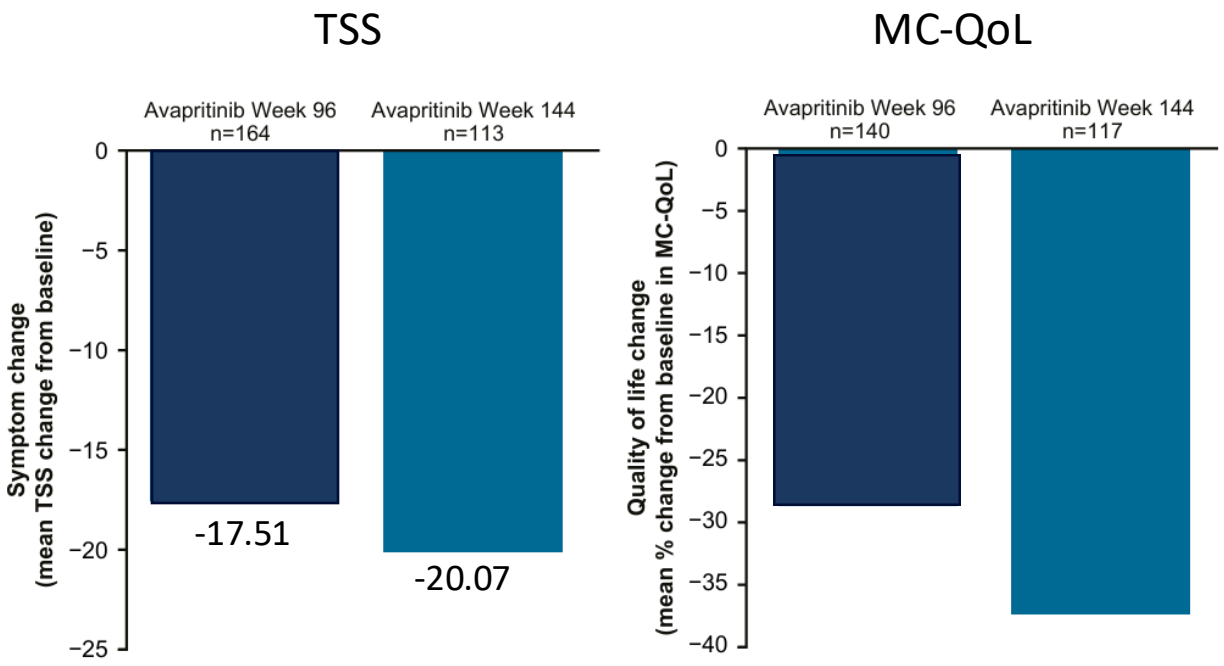
Gotlib et al., NEJM Evid 2023;2(6)

ClinicalTrials.gov ID NCT03731260

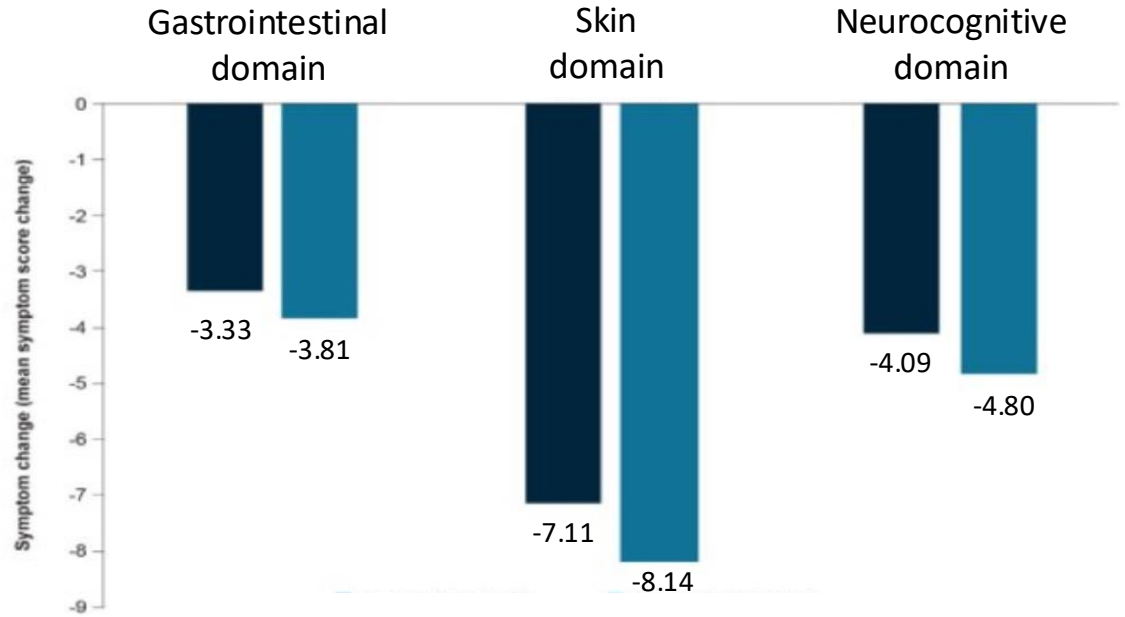
KEY DATA

PIONEER Longer term efficacy data

Durable improvements in TSS and Mastocytosis-QoL at week 96 and week 144 (25 mg avapritinib QD)



Mean change in individual domain symptom scores from baseline at week 96 and week 144 (25 mg avapritinib QD)



Avapritinib Week 96 Avapritinib Week 144

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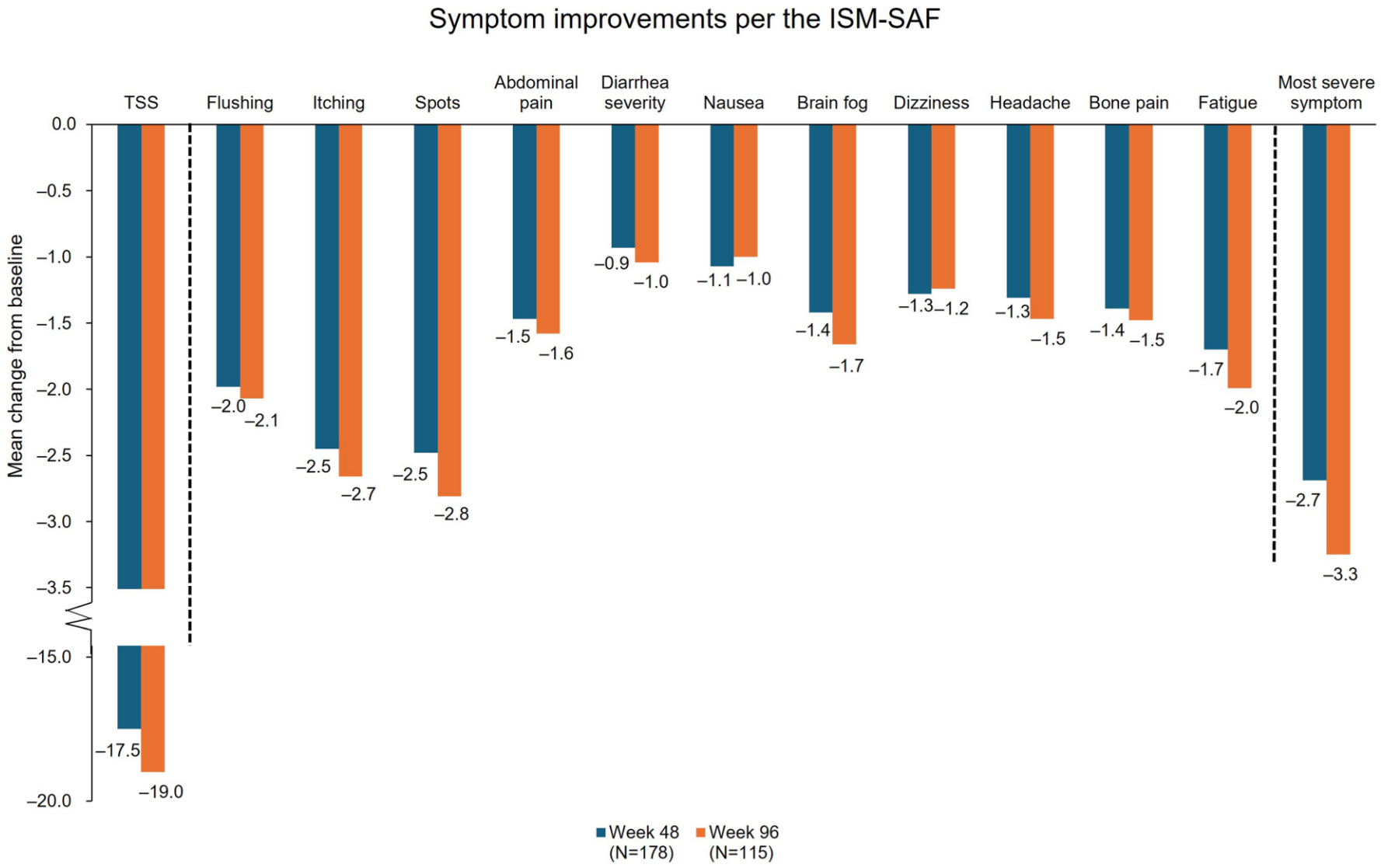
Castells M et al, 2025 AAAAI/WAO Joint Congress Poster #534
Elberink et al., EAACI-2025 Poster #000621

KEY DATA

Mean change from date of first avapritinib dose to weeks 48 and 96 in ISM-SAF individual symptom and most severe symptom scores.

ISM-SAF, Indolent Systemic Mastocytosis Symptom Assessment Form; TSS, Total Symptom Score.



JACI Volume 13, Issue 8p2194-2196.e1August 2025

PIONEER

Safety

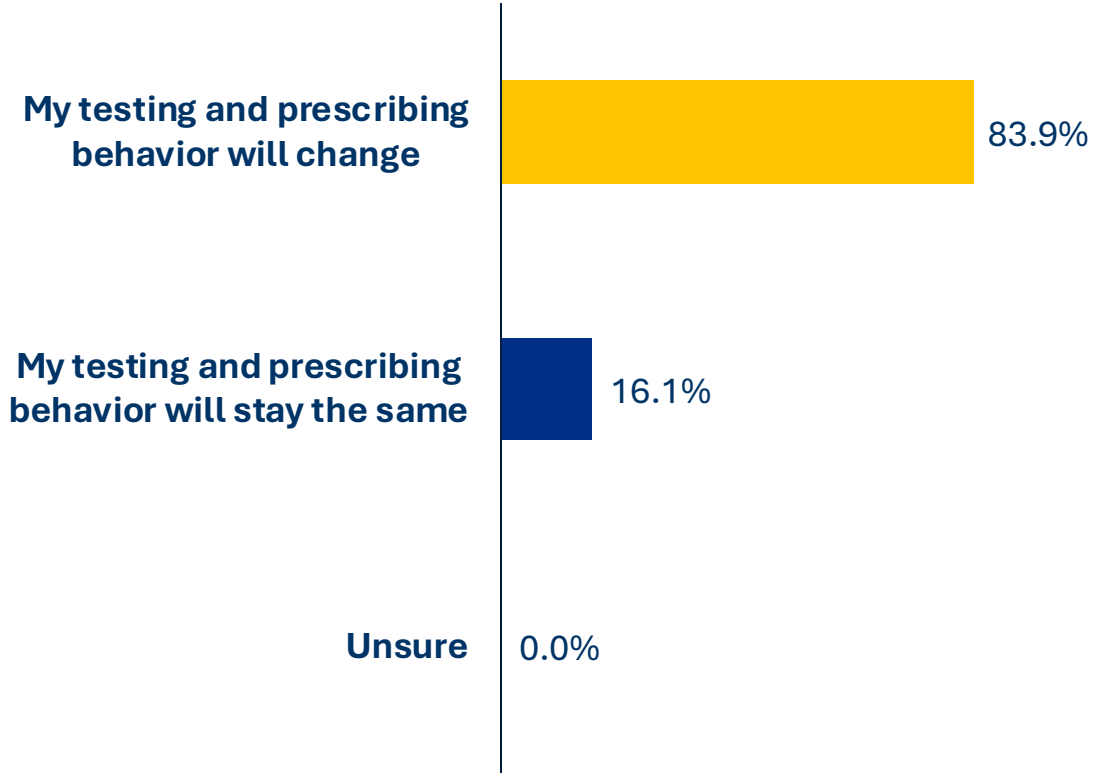
	Avapritinib 25 mg QD + BSC (N=141)	Placebo + BSC (N=71)
Any AEs[a,b], n (%)	128 (90.8)	66 (93.0)
• Grade 1–2 AEs	98 (69.5)	51 (71.8)
• Grade 1–2 related AEs	74 (52.5)	30 (42.3)
• Grade ≥3 AEs	30 (21.3)	15 (21.1)
• Grade ≥3 related AEs	3 (2.1)	2 (2.8)
Any grade TRAEs	77 (54.6)	32 (45.1)
Most frequently reported TRAEs (≥5% of patients)		
• Headache	1 (7.8)	7 (9.9)
• Nausea	9 (6.4)	6 (8.5)
• Peripheral edema	9 (6.4)	1 (1.4)
• Periorbital edema	9 (6.4)	2 (2.8)
• Dizziness	4 (2.8)	5 (7.0)
AEs leading to discontinuation	3 (2.1)	1 (1.4)
• TRAEs leading to discontinuation	2 (1.4)	1 (1.4)

- Majority of AEs were Grade 1 or 2 with a low rate of discontinuation
- SAEs were reported more frequently in the placebo arm (no treatment-related SAEs in either arm)
- Edema events were slightly higher in the avapritinib group (majority Grade 1 and did not result in discontinuation)
- Very few TRAEs on avapritinib vs placebo required dose interruption (3.5 vs 5.6% respectively) or reduction (0.7% vs 1.4%, respectively)

ClinicalTrials.gov ID NCT03731260

ARS Results from HCP Participants

How will the PIONEER trial data and avapritinib impact your assessment and treatment of patients with suspected ISM?



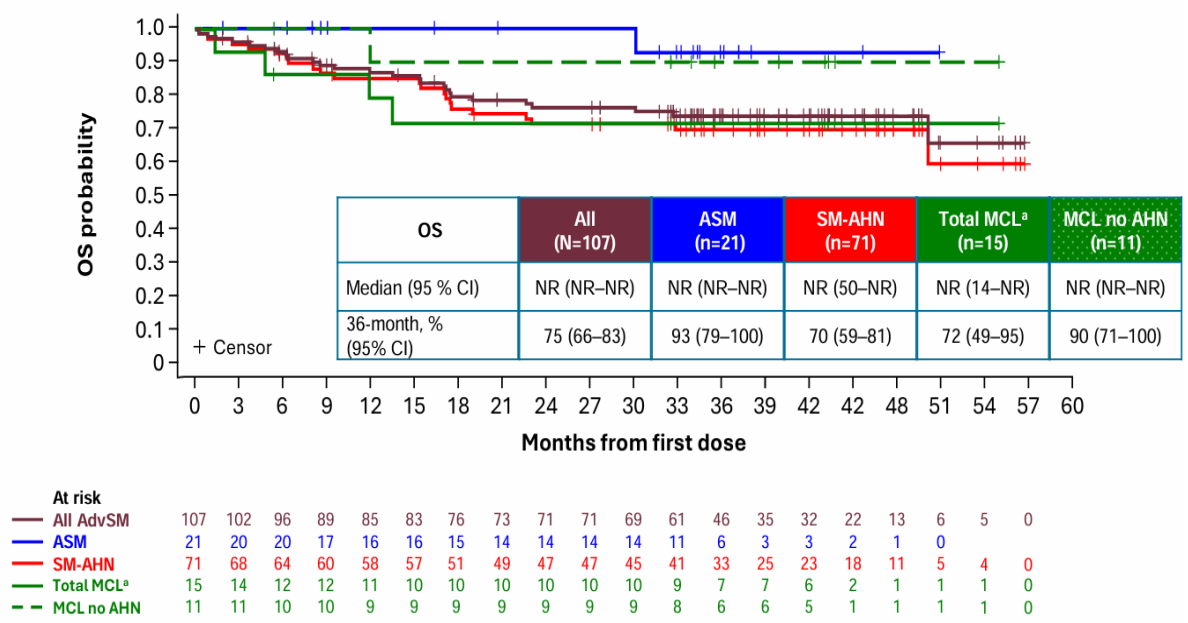
Answered: 31

KEY UPDATE

PATHFINDER Can avapritinib benefit patients with advanced systemic mastocytosis? 3-year follow-up

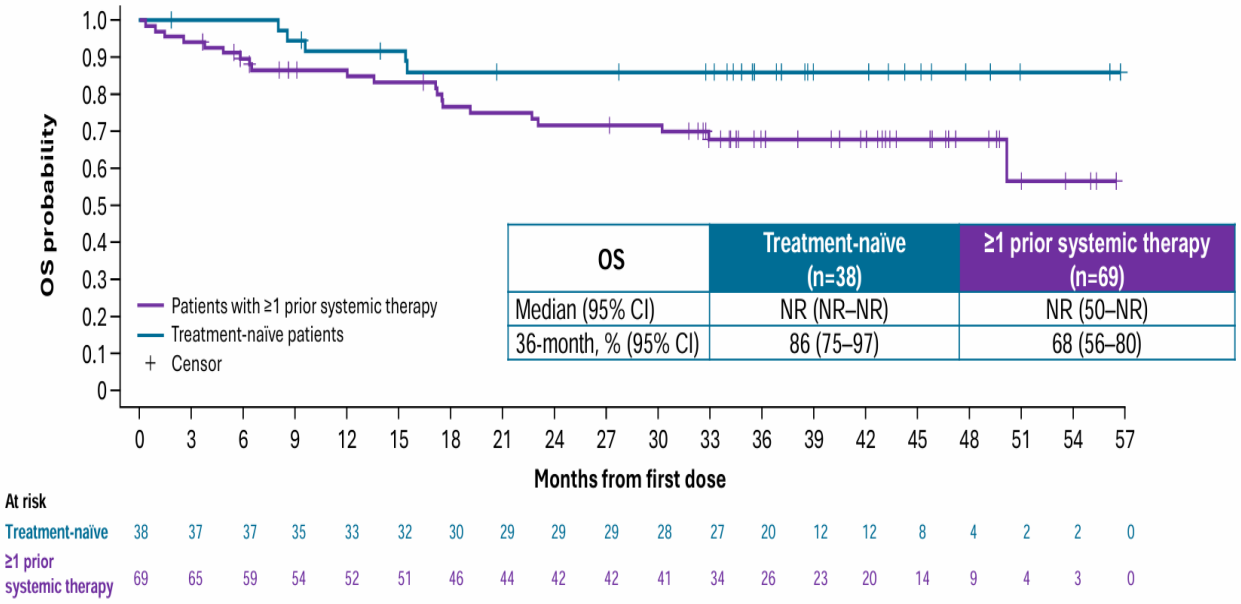
Study design/objective: patients with AdvSM treated with avapritinib 200mg QD starting dose in the international, multicenter, open-label, single-arm, phase 2 PATHFINDER study (Median follow-up was 38 months)

Median overall survival was not reached regardless of AdvSM subtype



OS	All (N=107)	ASM (n=21)	SM-AHN (n=71)	Total MCL[a] (n=15)	MCL no AHN (n=11)
Median (95 % CI)	NR (NR–NR)	NR (NR–NR)	NR (50–NR)	NR (14–NR)	NR (NR–NR)
36-month, % (95% CI)	75 (66–83)	93 (79–100)	70 (59–81)	72 (49–95)	90 (71–100)

Median overall survival was not reached regardless of treatment history



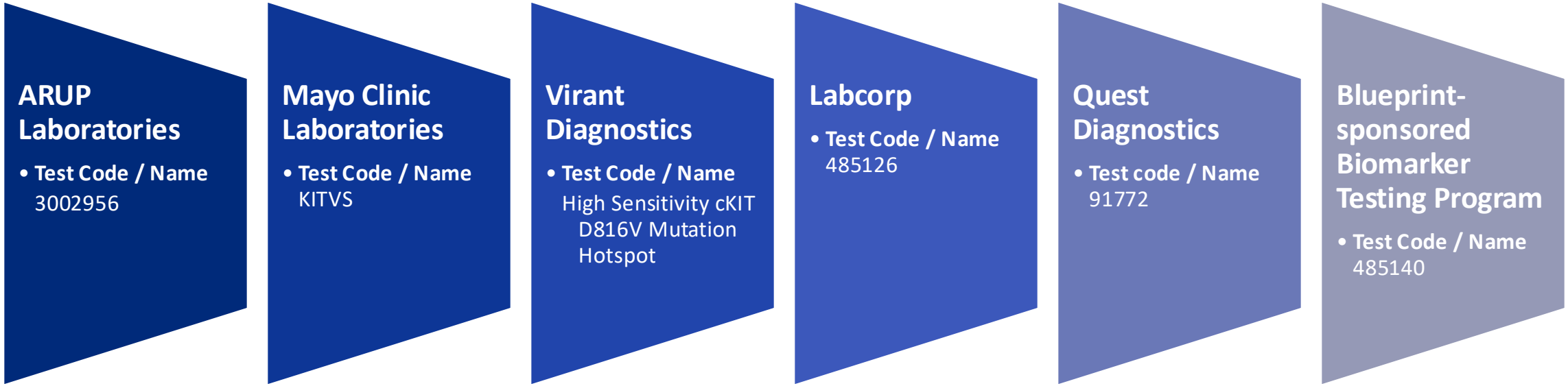
OS	Treatment-naïve (n=38)	≥1 prior systemic therapy (n=69)
Median (95% CI)	NR (NR–NR)	NR (50–NR)
36-month, % (95% CI)	86 (75–97)	68 (56–80)

Response Rates	All (n=83)	ASM (n=13)	SM-AHN (n=55)	MCL (n=15)	Treatment naïve (n=30)	≥1 prior systemic therapy (n=53)
ORR, n (%)	**61 (73%)**	**10 (77%)**	**41 (75%)**	**10 (67%)**	**26 (87%)**	**35 (66%)**
• CR or CRh	24 (29%)	3 (23%)	18 (33%)	3 (20%)	13 (43%)	11 (21%)
• PR	33 (40%)	7 (54%)	19 (35%)	7 (47%)	13 (43%)	20 (38%)
• SD	13 (16%)	3 (23%)	7 (13%)	3 (20%)	3 (10%)	10 (19%)
• PD	2 (2%)	0	1 (2%)	1 (7%)	0	2 (4%)

*Advanced SM includes aggressive SM, SM with an associated hematologic neoplasm and mast cell leukemia.

Molecular testing for KIT D816V

- NCCN Guidelines recommends a highly sensitive assay such as ASO-qPCR or digital droplet PCR on peripheral blood for initial screening
- A thorough analysis of KIT mutational status should include bone marrow evaluation



[Precision Medicine - Cornerstone Specialty Network (cornerstoneoncology.com)]

Key Takeaways

Systemic Mastocytosis

- *Identification of patients is key to reduce impact on patient quality of life and reduce the time to diagnosis*
  - *Patient education, self awareness and self advocacy can support earlier identification*
- *Coordination with other specialists from primary care physicians to allergist/immunologist, dermatologist and pathologists can reduce patient referral times*
- *Awareness of WHO criteria and high sensitivity KIT D816V testing (bone marrow) is critical to identify patients*
- *Avapritinib is the only approved treatment for indolent Systemic Mastocytosis*

cornerstone specialty network