The FIRST and ONLY Therapy for Adults With Indolent Systemic Mastocytosis (ISM)¹

AYVAKIT for your ISM patient

AYVAKIT 25 mg + BSC showed improvements vs placebo + BSC in key endpoints: ISM-SAF total symptom score, KIT D816V VAF, serum tryptase, and bone marrow mast cells¹*

The most common adverse reactions (≥10%) were eye edema, dizziness, peripheral edema, and flushing¹*

A once-daily oral therapy designed to target the driver of disease in ~95% of ISM cases1,6-8

Patients can experience a high symptom burden that may impact work and daily life2,3

*In a phase 2, randomized, placebo-controlled, double-blind clinical trial.

IMPORTANT SAFETY INFORMATION

Important Safety Information (Cont'd from Page 15)


BSC=best supportive care; ISM=indolent systemic mastocytosis; VAF=variant allele fraction.

Please see Important Safety Information on pages 15-16 and the full Prescribing Information for AYVAKIT.

INDICATION

AYVAKIT® (avapritinib) is indicated for the treatment of adult patients with indolent systemic mastocytosis (ISM).

Limitations of Use: AYVAKIT is not recommended for patients with platelet counts of <50 x 10⁹/L.

IMPORTANT SAFETY INFORMATION

There are no contraindications for AYVAKIT.

Intracranial Hemorrhage (ICH)—Serious ICH may occur with AYVAKIT treatment; fatal events occurred in <1% of patients. No events of ICH occurred in the 246 patients with ISM who received any dose of AYVAKIT in the PIONEER study. Monitor patients closely for risk factors of ICH which may include history of vascular aneurysm, ICH or cerebrovascular accident within the prior year, concomitant use of anticoagulant drugs, or thrombocytopenia. Symptoms of ICH may include headache, nausea, vomiting, vision changes, or altered mental status. Advise patients to seek immediate medical attention for signs or symptoms of ICH. Permanently discontinue AYVAKIT if ICH of any grade occurs.

Cognitive Effects—Cognitive adverse reactions can occur in patients receiving AYVAKIT and occurred in 7.8% of patients with ISM who received AYVAKIT + best supportive care (BSC) versus 7.0% of patients who received placebo + BSC; <1% were Grade 3. Depending on the severity, withhold AYVAKIT and then resume at the same dose, or permanently discontinue AYVAKIT.

Photosensitivity—AYVAKIT may cause photosensitivity reactions. In all patients treated with AYVAKIT in clinical trials (n=1049), photosensitivity reactions occurred in 2.5% of patients. Advise patients to limit direct ultraviolet exposure during treatment with AYVAKIT and for one week after discontinuation of treatment.

Please see Important Safety Information continued on back cover and Prescribing Information for AYVAKIT.
Patients with ISM can experience a high symptom burden that may impact work and daily life\(^2,3\)

Symptoms (including skin, neurocognitive, and GI) can be heterogeneous, chronic, and potentially debilitating\(^2,4,5\).

Patients report impact to their work and personal life due to living with ISM\(^3\).

Of 32 patients with moderate to severe ISM in the Blueprint Medicines-sponsored patient survey\(^1\):

- 56% reported reducing work hours due to their ISM
- 28% reported going on medical disability due to their ISM
- 72% reported avoiding leaving home due to their ISM symptoms

Medications Taken for ISM (n=37)\(^4\)

86% reported moderate to severe symptom burden despite taking a median of 3 OTC and 2 prescription medications for their ISM symptoms\(^5\).

Historically, there have been no approved therapies for ISM\(^2\).

In the Blueprint Medicines-sponsored TouchStone SM Patient Survey, US adults with a self-reported SM diagnosis (N=56) completed an online survey of 100 items. An analysis was conducted in patients with ISM (n=37), including 32 patients with moderate to severe ISM defined as an ISM-SAF TSS ≥20. Analyses were made from the TouchStone Patient SM Survey but have not been published.\(^6\)

HCP=healthcare provider; OTC=over the counter; SM=systemic mastocytosis.

\(^1\)Data based on ongoing medical history events in the PIONEER study (N=212). Events: skin disorders; headache, dizziness, migraine, memory impairment, disturbance in attention for nervous system disorders; and diarrhea, abdominal pain, nausea, gastroesophageal reflux disease, abdominal distension, constipation for gastrointestinal disorders.\(^2\)

GI=gastrointestinal.
The FIRST FDA-approved treatment for adults with ISM to target the underlying driver of disease in ~95% of patients.\textsuperscript{1,6-8}

**Avapritinib is a TKI designed for potent and selective inhibition of KIT D816\textsuperscript{V}\textsuperscript{1}**

Demonstrated greater inhibitory potency for KIT D816\textsuperscript{V} vs wild type KIT in cellular assays.\textsuperscript{3}

**INDICATION**

AYVAKIT\textsuperscript{\textregistered} (avapritinib) is indicated for the treatment of adult patients with indolent systemic mastocytosis (ISM).\textsuperscript{2}

**SELECT SAFETY INFORMATION**

**Intercranial Hemorrhage (ICH)—**Serious ICH may occur with AYVAKIT treatment; fatal events occurred in <1% of patients. No events of ICH occurred in the 246 patients with ISM who received any dose of AYVAKIT in the PIONEER study.\textsuperscript{5}

Monitor patients closely for risk factors of ICH which may include history of vascular aneurysm, ICH or cerebrovascular accident within the prior year, concomitant use of anticoagulant drugs, or thrombocytopenia.

Please see Important Safety Information on pages 15-16 and the full Prescribing Information for AYVAKIT.

**EXPLORATORY ENDPOINT**

(Anti)bone erosion (Bone X-ray)

- Significant improvements in (anti)bone erosion vs BSC alone (p<0.001, 2-tailed t-test).\textsuperscript{28}

**LIMITATIONS**

- Mean change in TSS at all time points except Week 24 were prespecified, nonranked endpoints and were not adjusted for multiplicity. Therefore, treatment differences at these time points cannot be regarded as statistically significant and results should be interpreted with caution and conclusions cannot be drawn.

**AYVAKIT should be taken:**

- Once a day
- In the morning
- With a meal

- AYVAKIT is being sold in tablet form
- AYVAKIT tablets are available in the following strengths:
  - 150 mg
  - 25 mg

**Important Safety Information (Cont’d from Page 15)**

**STUDY DESIGN**\textsuperscript{1,9}

<table>
<thead>
<tr>
<th>Randomization (R) Double-blind treatment period (26 weeks)*</th>
<th>Open-label extension (5 years)\textsuperscript{1}</th>
</tr>
</thead>
<tbody>
<tr>
<td>[N=212]</td>
<td></td>
</tr>
<tr>
<td>AYVAKIT 25 mg QD + BSC N=141 AYVAKIT 25 mg QD + BSC (ongoing)</td>
<td></td>
</tr>
<tr>
<td>Placebo QD + BSC N=71</td>
<td></td>
</tr>
<tr>
<td>Both groups continued BSC as needed</td>
<td></td>
</tr>
</tbody>
</table>

- **Primary endpoint:** Absolute mean change in ISM-SAFTSS compared with placebo + BSC from baseline to Week 24\textsuperscript{1}
- **Select key secondary endpoints:** Proportion of patients achieving ≥50% reduction in serum tryptase levels; ≥50% reduction in KIT D816\textsuperscript{V} VAF or undetectable; ≥50% reduction in bone marrow mast cells or no aggregates, all compared with placebo + BSC at Week 24\textsuperscript{1,9}
- **Exploratory endpoints:** Mean change in ISM-SAFTSS individual symptom scores; mean change in most severe symptom score at Week 24\textsuperscript{1,9}

- **Key eligibility criteria:** ≥18 years of age; centrally confirmed ISM diagnosis per WHO criteria; uncontrolled moderate to severe ISM symptoms (defined as ISM-SAFTSS ≥28) despite ≥2 symptom-directed therapies\textsuperscript{2}

- **The recommended dose of AYVAKIT for the double-blind treatment period was identified in Part 1 of PIONEER**\textsuperscript{9}

\*Data cutoff was June 23, 2022.

\textsuperscript{1}OLE: The open-label study is evaluating the long-term efficacy and safety of AYVAKIT 25 mg + BSC for up to 5 years. All eligible patients either continued AYVAKIT 25 mg + BSC daily or switched from placebo + BSC to AYVAKIT 25 mg + BSC daily.

\textsuperscript{9}In peripheral blood.

ISM-SAF=Indolent Systemic Mastocytosis-Symptom Assessment Form; OLE=open-label extension; QD=every day; TSS=total symptom score; VAF=variant allele fraction; WHO=World Health Organization.
**The Indolent Systemic Mastocytosis-Symptom Assessment Form (ISM-SAF) is a validated symptom assessment tool**

The ISM-SAF is a patient-reported outcome measure assessing ISM signs and symptoms. The ISM-SAF is a 12-item questionnaire. Individual symptom scores are evaluated, and the 11 symptom severity scores are combined to calculate the TSS (0-110), with higher scores representing greater symptom severity.

### Scoring

- Individual symptoms scored 0-10 daily
- 0=no symptom, 10=worst imaginable symptom

A biweekly average ISM-SAF TSS was used to evaluate efficacy endpoints in PIONEER.

**SELECT SAFETY INFORMATION**

**Intracranial Hemorrhage (ICH) (cont’d)—**Symptoms of ICH may include headache, nausea, vomiting, vision changes, or altered mental status. Advise patients to seek immediate medical attention for signs or symptoms of ICH.

Permanently discontinue AYVAKIT if ICH of any grade occurs.

**Patient demographics in PIONEER were similar between both arms**

**SELECT BASELINE DEMOGRAPHIC AND DISEASE CHARACTERISTICS (N=212)**

<table>
<thead>
<tr>
<th>Patient Demographic</th>
<th>AYVAKIT + BSC (n=141)</th>
<th>Placebo + BSC (n=71)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median age [range]</td>
<td>50 years (18-77)</td>
<td>54 years (26-79)</td>
</tr>
<tr>
<td>Female</td>
<td>71%</td>
<td>76%</td>
</tr>
<tr>
<td>Mean ISM-SAF TSS (SD)</td>
<td>50.2 (19.1)</td>
<td>52.4 (19.8)</td>
</tr>
<tr>
<td>Median no. of BSC treatments [range]</td>
<td>3 (0-11)</td>
<td>4 (1-8)</td>
</tr>
<tr>
<td>Median serum tryptase, ng/mL [range]</td>
<td>38.4 (3.6-256.0)</td>
<td>43.7 (5.7-501.6)</td>
</tr>
<tr>
<td>Mast cell aggregates present</td>
<td>75%</td>
<td>80%</td>
</tr>
</tbody>
</table>

- **93% of patients in the AYVAKIT + BSC arm had a KIT D816V mutation**
- **BSC medications allowed in the PIONEER study included anti-immunoglobulin E antibody (omalizumab), glucocorticoids, cromolyn sodium, H1 antihistamines, H2 antihistamines, leukotriene inhibitors, and proton pump inhibitors**

BSC=best supportive care.

**SELECT SAFETY INFORMATION**

**Cognitive Effects—**Cognitive adverse reactions can occur in patients receiving AYVAKIT and occurred in 7.8% of patients with ISM who received AYVAKIT + best supportive care (BSC) versus 7.0% of patients who received placebo + BSC; <1% were Grade 3. Depending on the severity, withhold AYVAKIT and then resume at the same dose, or permanently discontinue AYVAKIT.

Please see Important Safety Information on pages 15-16 and the full Prescribing Information for AYVAKIT.
AYVAKIT demonstrated a statistically significant improvement in ISM-SAF TSS at 24 weeks\(^1\)

<table>
<thead>
<tr>
<th>Week 24</th>
<th>AYVAKIT + BSC (N=141)</th>
<th>Placebo + BSC (N=71)</th>
<th>2-sided P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Absolute mean change in the ISM-SAF TSS (95% CI)</td>
<td>-15.33 [-18.36, -12.31]</td>
<td>-9.64 [-13.61, -5.68]</td>
<td>0.012</td>
</tr>
</tbody>
</table>

\(\text{ITT analysis: Markov chain Monte Carlo simulation was used to impute the missing values at Baseline or Week 24.}\)

### ISM-SAF TSS OVER TIME*\(^1\)

**Study week**
- Baseline
- 4
- 8
- 12
- 16
- 20
- 24

**Number of patients**
- **AYVAKIT + BSC**
  - 141
- **Placebo + BSC**
  - 71

*\(\text{ITT analysis: Markov chain Monte Carlo simulation was used to impute the missing values.}\)

**LIMITATIONS:** Mean change in TSS at all time points except Week 24 were prespecified, nonranked endpoints and were not adjusted for multiplicity. Therefore, treatment differences at these time points cannot be regarded as statistically significant and results should be interpreted with caution.

**ITT=Intention to treat.**

——

**AYVAKIT demonstrated a statistically significant improvement in ISM-SAF TSS at 24 weeks**

**Week 24**
- AYVAKIT + BSC (N=141)
- Placebo + BSC (N=71)
- 2-sided P value

**Absolute mean change in the ISM-SAF TSS (95% CI)**
- AYVAKIT + BSC: -15.33 [-18.36, -12.31]
- Placebo + BSC: -9.64 [-13.61, -5.68]
- 2-sided P value: 0.012

**ITT analysis: Markov chain Monte Carlo simulation was used to impute the missing values at Baseline or Week 24.**

**ISM-SAF TSS OVER TIME**

**Study week**
- Baseline
- 4
- 8
- 12
- 16
- 20
- 24

**Number of patients**
- AYVAKIT + BSC: 141
- Placebo + BSC: 71

**LIMITATIONS:**
- Mean change in TSS at all time points except Week 24 were prespecified, nonranked endpoints and were not adjusted for multiplicity. Therefore, treatment differences at these time points cannot be regarded as statistically significant and results should be interpreted with caution.
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**ITT=Intention to treat.**

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**AYVAKIT demonstrated a statistically significant improvement in ISM-SAF TSS at 24 weeks**

**Week 24**
- AYVAKIT + BSC (N=141)
- Placebo + BSC (N=71)
- 2-sided P value

**Absolute mean change in the ISM-SAF TSS (95% CI)**
- AYVAKIT + BSC: -15.33 [-18.36, -12.31]
- Placebo + BSC: -9.64 [-13.61, -5.68]
- 2-sided P value: 0.012

**ITT analysis: Markov chain Monte Carlo simulation was used to impute the missing values at Baseline or Week 24.**

**ISM-SAF TSS OVER TIME**

**Study week**
- Baseline
- 4
- 8
- 12
- 16
- 20
- 24

**Number of patients**
- AYVAKIT + BSC: 141
- Placebo + BSC: 71

**LIMITATIONS:**
- Mean change in TSS at all time points except Week 24 were prespecified, nonranked endpoints and were not adjusted for multiplicity. Therefore, treatment differences at these time points cannot be regarded as statistically significant and results should be interpreted with caution.
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**ITT=Intention to treat.**

——

**Exploratory endpoint: Mean change in ISM-SAF TSS through 48 weeks**

**ISM-SAF TSS THROUGH 48 WEEKS**

**Study week**
- Baseline
- 4
- 8
- 12
- 16
- 20
- 24
- 32
- 36
- 44
- 48

**Number of patients**
- AYVAKIT + BSC
- Placebo + BSC
- Placebo to AYVAKIT + BSC
- AYVAKIT + BSC to Placebo

**LIMITATIONS:**
- Mean change in TSS at all time points except Week 24 were prespecified, nonranked endpoints and were not adjusted for multiplicity. Therefore, treatment differences at these time points cannot be regarded as statistically significant and results should be interpreted with caution and conclusions cannot be drawn. In an open-label extension, there is a potential for enrichment of the long-term data in the remaining patient populations since patients who are unable to tolerate or do not respond to the drug often drop out.

**ISM-SAF=Indolent Systemic Mastocytosis-Symptom Assessment Form; TSS=total symptom score.**

**SELECT SAFETY INFORMATION**

**Photosensitivity**—AYVAKIT may cause photosensitivity reactions. In all patients treated with AYVAKIT in clinical trials \(n=1049\), photosensitivity reactions occurred in 2.5% of patients. Advise patients to limit direct ultraviolet exposure during treatment with AYVAKIT and for one week after discontinuation of treatment.

Please see Important Safety Information on pages 15-16 and the full Prescribing Information for AYVAKIT.
**Exploratory endpoint: Individual symptom scores at 24 weeks**

Reductions across all individual symptom scores were observed at 24 weeks.

**MEAN CHANGE FROM BASELINE AT 24 WEEKS BY ISM-SAF INDIVIDUAL SYMPTOM SCORE**

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Mean change from baseline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flushing</td>
<td>-1.89</td>
</tr>
<tr>
<td>Itching</td>
<td>-2.21</td>
</tr>
<tr>
<td>Spots</td>
<td>-1.86</td>
</tr>
<tr>
<td>Abdominal Pain</td>
<td>-2.00</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>-1.08</td>
</tr>
<tr>
<td>Nausea</td>
<td>-2.00</td>
</tr>
<tr>
<td>Bone Pain</td>
<td>-2.10</td>
</tr>
<tr>
<td>Fatigue</td>
<td>-2.10</td>
</tr>
<tr>
<td>Skin</td>
<td>-2.10</td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td>-2.10</td>
</tr>
<tr>
<td>Neurocognitive</td>
<td>-2.10</td>
</tr>
<tr>
<td>Other</td>
<td>-2.10</td>
</tr>
</tbody>
</table>

**LIMITATIONS:** Individual components in a descriptive exploratory analysis were prespecified, nonranked endpoints, not adjusted for multiplicity, and not powered. Therefore, data should be interpreted with caution, conclusions cannot be drawn.

**SELECT SAFETY INFORMATION**

**Embryofetal Toxicity**—AYVAKIT can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise females and males of reproductive potential to use an effective method of contraception during treatment with AYVAKIT and for 6 weeks after the final dose of AYVAKIT. Advise women not to breastfeed during treatment with AYVAKIT and for 2 weeks after the final dose.

Please see Important Safety Information on pages 15-16 and the full Prescribing Information for AYVAKIT.

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**Key secondary endpoints**

Significantly more patients treated with AYVAKIT had reductions in objective measures of mast cell burden at 24 weeks.

**Proportion of patients achieving ≥50% reduction in objective measures of mast cell burden at 24 weeks**

More than half of the evaluated AYVAKIT + BSC patients experienced ≥50% reductions in serum tryptase, KIT D816V VAF, and BM MC levels.

- **Serum tryptase:**
  - AYVAKIT + BSC: 53.9% (n=141)
  - Placebo + BSC: 0% (n=71)

- **KIT D816V VAF:**
  - AYVAKIT + BSC: 67.8% (n=118)
  - Placebo + BSC: 6.3% (n=63)

- **Additional information:**
  - 52.8% of 106 patients receiving AYVAKIT + BSC achieved ≥50% reduction in BM MCs vs 22.8% of 57 patients receiving placebo + BSC (2-sided P<0.0001).

1. Percent of patients with ≥50% reduction in peripheral blood KIT D816V VAF or undetectable.
2. Percent of patients with ≥50% reduction in BM MCs or no aggregates.

**ITT analysis:** For patients with high-dose steroid use within 7 days before Week 24, or greater than 14 consecutive days at any point from baseline to Week 24, the Week 24 score was set to missing.

BM = bone marrow; MC = mast cell.
AYVAKIT was generally well tolerated in PIONEER1

ADVERSE REACTIONS OCCURRING IN PATIENTS WITH ISM DURING PIONEER TRIAL1

<table>
<thead>
<tr>
<th>Adverse Reactiona,b</th>
<th>AYVAKIT (25 mg once daily) + BSC n=141, %</th>
<th>Placebo + BSC n=71, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye edema1</td>
<td>13</td>
<td>7</td>
</tr>
<tr>
<td>Dizziness1</td>
<td>13</td>
<td>10</td>
</tr>
<tr>
<td>Peripheral edema2</td>
<td>12</td>
<td>6</td>
</tr>
<tr>
<td>Flushing1</td>
<td>11</td>
<td>4</td>
</tr>
<tr>
<td>Respiratory tract infection4</td>
<td>8</td>
<td>1</td>
</tr>
<tr>
<td>Face edema1</td>
<td>7</td>
<td>1</td>
</tr>
<tr>
<td>Rash1</td>
<td>6</td>
<td>4</td>
</tr>
<tr>
<td>Liver transaminase increased4</td>
<td>6</td>
<td>3</td>
</tr>
<tr>
<td>Insomnia</td>
<td>6</td>
<td>3</td>
</tr>
<tr>
<td>Hematoma1</td>
<td>6</td>
<td>1</td>
</tr>
<tr>
<td>Blood alkaline phosphatase increased</td>
<td>6</td>
<td>1</td>
</tr>
<tr>
<td>Hemorrhage1</td>
<td>5</td>
<td>3</td>
</tr>
</tbody>
</table>

*Adverse reactions that occurred in ≥25% of AYVAKIT-treated patients and ≥22% more than placebo-treated patients.
*For National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE) version 5.0.
*Eye edema includes periocular edema, eye edema, swelling of eyelid, orbital edema, eye swelling, eyelid edema and eyelid ptosis.
*Term includes several similar terms.

- Serious adverse reactions occurred in 1 patient (0.7%) who received AYVAKIT due to pelvic hematoma.
- Permanent discontinuation of AYVAKIT due to an adverse reaction occurred in 1 patient (0.7%) due to dyspnea and dizziness1

- Dosage interruptions of AYVAKIT due to an adverse reaction occurred in 5% of patients1
- Of all adverse reactions, 55% were Grade 1, 38% were Grade 2, and 7% were Grade 31
- Among patients with edema adverse reactions, 95% were Grade 1 and 5% were Grade 2. Among patients with hemorrhage adverse reactions, 86% were Grade 1 and 14% were Grade 21

The recommended dosage for patients with ISM is 25 mg, orally, once daily1

AYVAKIT should be taken1:

- On an empty stomach, at least 1 hour before or at least 2 hours after a meal

A modified starting dosage of AYVAKIT is recommended for patients with severe hepatic impairment (Child-Pugh Class C): 25 mg orally every other day.1

Avoid concomitant use of AYVAKIT with strong or moderate CYP3A inhibitors or inducers.1

SELECT SAFETY INFORMATION

Adverse Reactions—The most common adverse reactions (≥10%) in patients with ISM were eye edema, dizziness, peripheral edema, and flushing.

Drug Interactions—Avoid coadministration of AYVAKIT with strong or moderate CYP3A inhibitors or inducers.

Please see Important Safety Information on pages 15-16 and the full Prescribing Information for AYVAKIT.
YourBlueprint® provides dedicated, personalized support to help your patients from Day 1.

Blueprint Medicines offers a series of programs to support patient access, including:

- Co-pay Support
- Patient Assistance Program
- Prior Authorization Support
- Coverage Interruption
- Quick Start

To see how we can help:

Call: 1-888-BLUPRINT (1-888-258-7768) Monday-Friday, 8 am-8 pm Eastern Time [ET]
Email: info@yourblueprint.com
Fax: 1-866-370-3082
Visit: www.YourBlueprint.com/HCP

Enroll your patients at time of prescription to support the patient experience and access to programs

Important Safety Information

INFORMATION

INDICATION
AYVAKIT® (avapritinib) is indicated for the treatment of adult patients with indolent systemic mastocytosis (ISM).

Limitations of Use: AYVAKIT is not recommended for patients with platelet counts of <50 x 10^9/L.

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Please see Important Safety Information continued on back cover and Prescribing Information for AYVAKIT.

References:

Consider AYVAKIT for your ISM patient

Patients can experience a high symptom burden that may impact work and daily life\(^2,3\)  
AYVAKIT 25 mg + BSC showed improvements vs placebo + BSC in key endpoints: ISM-SAF total symptom score, KIT D816V VAF, serum tryptase, and bone marrow mast cells\(^1\)*

A once-daily oral therapy designed to target the driver of disease in ~95% of ISM cases\(^1,6-8\)

The most common adverse reactions (≥10%) were eye edema, dizziness, peripheral edema, and flushing\(^1\)*

*In a phase 2, randomized, placebo-controlled, double-blind clinical trial.

BSC=best supportive care; ISM=indolent systemic mastocytosis; VAF=variant allele fraction.

For more information, visit AYVAKITHCP.com.

Important Safety Information (Cont’d from Page 15)

Embryo-Fetal Toxicity—AYVAKIT can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise females and males of reproductive potential to use an effective method of contraception during treatment with AYVAKIT and for 6 weeks after the final dose of AYVAKIT. Advise women not to breastfeed during treatment with AYVAKIT and for 2 weeks after the final dose.

Adverse Reactions—The most common adverse reactions (≥10%) in patients with ISM were eye edema, dizziness, peripheral edema, and flushing.

Drug Interactions—Avoid coadministration of AYVAKIT with strong or moderate CYP3A inhibitors or inducers.

To report suspected adverse reactions, contact Blueprint Medicines Corporation at 1-888-258-7768 or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please click here to see the full Prescribing Information for AYVAKIT.