Introducing the first hepcidin mimetic for the treatment of erythrocytosis in adults with polycythemia vera (PV)[1,2]

A new era in PV starts now

INDICATION

MIMRYLO is indicated for the treatment of erythrocytosis in adults with polycythemia vera (PV).

SELECT IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

- **New or Worsening Thrombocytosis:** MIMRYLO may increase platelet counts in patients with PV. Platelet counts generally plateaued on treatment by Week 8. After initiating MIMRYLO and during dose modifications, monitor CBC every 2 to 4 weeks or as clinically indicated. Platelet elevations associated with MIMRYLO may require cytoreductive therapy initiation, modification, or MIMRYLO dose modifications or discontinuation.

Please see additional Important Safety Information throughout, and MIMRYLO (rusfertide) full Prescribing Information.

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More patients taking MIMRYLO maintained HCT levels without requiring phlebotomies vs the control arm

VERIFY was a multicenter, randomized, double-blind, placebo-controlled phase 3 trial of 293 adult patients with PV, in which MIMRYLO was studied both alone and as a combination therapy[1]

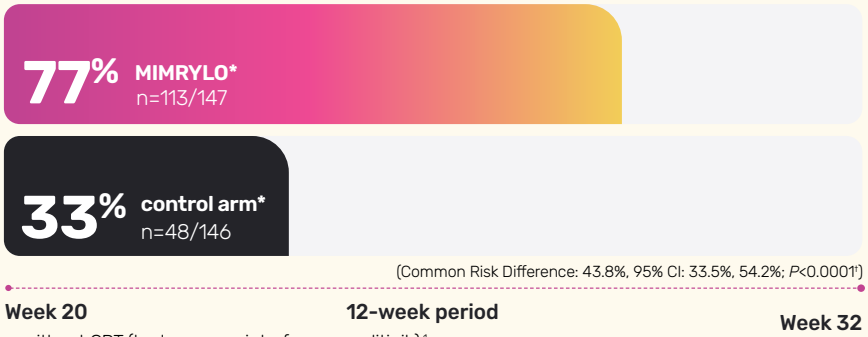
VERIFY PRIMARY ENDPOINT

77% of patients taking MIMRYLO did not require phlebotomies to maintain HCT control compared with 33% in the control arm[1]

A response was defined as absence of phlebotomy eligibility, meaning either a confirmed:

HCT ≥45% that is at least 3 percentage (absolute) points higher than the HCT obtained at baseline OR **HCT ≥48%**[1]

Proportion of patients achieving phlebotomy ineligibility response from Weeks 20-32[1]



*Both arms of the trial were studied with phlebotomy rescue, with or without CRT (hydroxyurea, interferon, ruxolitinib).[1]
†P-value is obtained from the Cochran-Mantel-Haenszel test stratifying by ongoing therapy.[1]

CI=confidence interval; CRT=cytoreductive therapy; HCT=hematocrit; PV=polycythemia vera.

SELECT IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont'd)

- **Injection-Site Reactions:** Injection site reactions (including Grade 3 reactions) have been reported in patients treated with MIMRYLO. The most common injection site reactions reported were erythema, pruritus, pain, and swelling. Use ice, topical corticosteroid creams, antihistamines or analgesics, as needed, to treat injection site pain and swelling.
- **Embryo-Fetal Toxicity:** Based on findings from animal reproduction studies, MIMRYLO may cause fetal harm when administered to a pregnant woman. Advise patients to stop taking MIMRYLO if they become pregnant.

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IN VERIFY

MIMRYLO was able to achieve key secondary endpoints

Through Week 32, patients saw:

- **A reduction in phlebotomies**
  (**Average of 0.5 in MIMRYLO*** vs 1.8 in the control arm* per patient)[1]
- **Consistent HCT control below 45%**
  (**63% in MIMRYLO*** vs 14% in the control arm*)[1]
- **Reduction of fatigue**
  (**Statistically significant reduction in fatigue measured by LSM difference: -1.8 in MIMRYLO*** vs 0.2 in the control arm*, as measured by PROMIS Fatigue Short Form 8a)[1]

Fatigue was measured by PROMIS Fatigue Short Form 8a T-score.[1]

*Both arms of the trial were studied with phlebotomy rescue, with or without CRT (hydroxyurea, interferon, ruxolitinib).[1]

A favorable safety profile

The safety of MIMRYLO was assessed in the largest pivotal trial in PV. MIMRYLO was studied both alone and as a combination therapy.[1,4,5]

In VERIFY, the most common adverse reactions (>15%) from Weeks 0-32 were injection site reactions (56%) and anemia (16%). The reporting of injection site reactions decreased over time.[1,3]

A low discontinuation rate of 5.5% was seen in the MIMRYLO arm vs 2.7% in the control arm between Weeks 0-32 in the VERIFY trial.[3]

In the safety population of 285 patients, a serious adverse reaction of anemia occurred in one (0.4%) patient who received MIMRYLO. Five patients discontinued MIMRYLO due to adverse reactions: two (0.7%) due to injection site reactions, two (0.7%) due to thrombocytosis, and one (0.4%) due to anemia.[1]

94%of patients (n=274/293) who completed the double-blind period continued into the long-term open-label portion of the phase 3 study[1,3]

Visit **MIMRYLOhcp.com/efficacy** to see more details about the trial and explore open-label extension data for MIMRYLO

CRT=cytoreductive therapy; HCT=hematocrit; PROMIS=Patient Reported Outcomes Measurement Information System; PV=polycythemia vera.

SELECT IMPORTANT SAFETY INFORMATION

ADVERSE REACTIONS

The most common (>15%) adverse reactions were injection site reactions (56%) and anemia (16%).

USE IN SPECIFIC POPULATIONS

- **Lactation:** Because of the potential for serious adverse reactions in the breastfed child, including impaired iron absorption, advise patients not to breastfeed during treatment with MIMRYLO and for 30 days after the final treatment.

Please see additional Important Safety Information throughout, and MIMRYLO (rusfertide) full Prescribing Information.

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See what MIMRYLO could do for your patients with PV

In the VERIFY trial, MIMRYLO[1]:

- **Maintained HCT control**
- **Reduced phlebotomies**
- **Reduced fatigue**
- **Demonstrated a favorable safety profile**
- **Was studied both alone and as a combination therapy**

Please see supporting data within the inner pages of this piece.

HCT=hematocrit; PV=polycythemia vera.

MIMRYLO is a once-weekly*, subcutaneous self-injection that can fit into your patients' lives and is individualized to their needs[1]

MIMRYLO is available as a lyophilized powder for reconstitution in single-dose vials. After initial training by a healthcare provider, MIMRYLO can be self-administered at home by the patient.[1]

Visit **MIMRYLOhcp.com/resources** to find useful guides, videos, and downloadable resources that can help you start your patients on MIMRYLO with confidence

*Dosing is one injection weekly from dosage increments of 9.5 mg up to 54 mg. Weekly dosages of 69 mg or 82 mg must be administered in two injections on the same day. Weekly dosages of 95 mg or 108 mg must be administered in two injections on separate days. Please see additional details on Dosing and Administration within the full Prescribing Information.[1]

SELECT IMPORTANT SAFETY INFORMATION

USE IN SPECIFIC POPULATIONS (cont'd)

- **Females and Males of Reproductive Potential**
  - **Pregnancy Testing:** Prior to initiating MIMRYLO, pregnancy testing is recommended for females of reproductive potential.
  - **Contraception:** Advise female patients of reproductive potential to use effective contraception during treatment with MIMRYLO and for at least 30 days after the final dose of MIMRYLO.

To report SUSPECTED ADVERSE REACTIONS, contact Takeda Pharmaceuticals at 1-844-662-8532 or the FDA at 1-800-FDA-1088 or **www.fda.gov/medwatch**.

Please see additional Important Safety Information throughout, and MIMRYLO (rusfertide) full Prescribing Information.

References: 1. MIMRYLO. Prescribing Information. Takeda Pharmaceuticals America, Inc; 2026. **2.** Handa S, Ginzburg Y, Hoffman R, et al. Hepcidin mimetics in polycythemia vera: resolving the irony of iron deficiency and erythrocytosis. *Curr Opin Hematol*. 2023;30(2):45-52. doi:10.1097/MOH.0000000000000747. **3.** Data on file. Takeda Pharmaceuticals U.S.A., Inc. **4.** BESREMi. Prescribing Information. PharmaEssentia Corporation; 2026. **5.** Jakafi. Prescribing Information. Incyte Corporation; 2026.

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