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# US FDA Approval of MIMRYLO™ (rusfertide) for Treatment of Erythrocytosis in Adults with Polycythemia Vera (PV)

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Conference Call
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# Now FDA Approved: MIMRYLO™

## First and Only Hepcidin Mimetic

Mimrylo™
rusfertide for injection

### Indication

- Indicated for treatment of erythrocytosis in adults with polycythemia vera (PV)

### Polycythemia Vera

- Blood cancer characterized by excessive production of red blood cells[1]
  - Elevated hematocrit (Hct)[2]
  - Primary treatment goal: maintain Hct <45%[3,4]

1. NORD Rare Disease Database, Polycythemia Vera. https://rarediseases.org/rare-diseases/polycythemia-vera/; 2. Spivak JL. *Curr Treat Options Oncol.* 2018;19(2):12; 3. Marchioli R, et al. *N Engl J Med.* 2013; 368(1):22-33; 4. Barbui, T, et al. *Leukemia.* 2018;32(5):1057-69.



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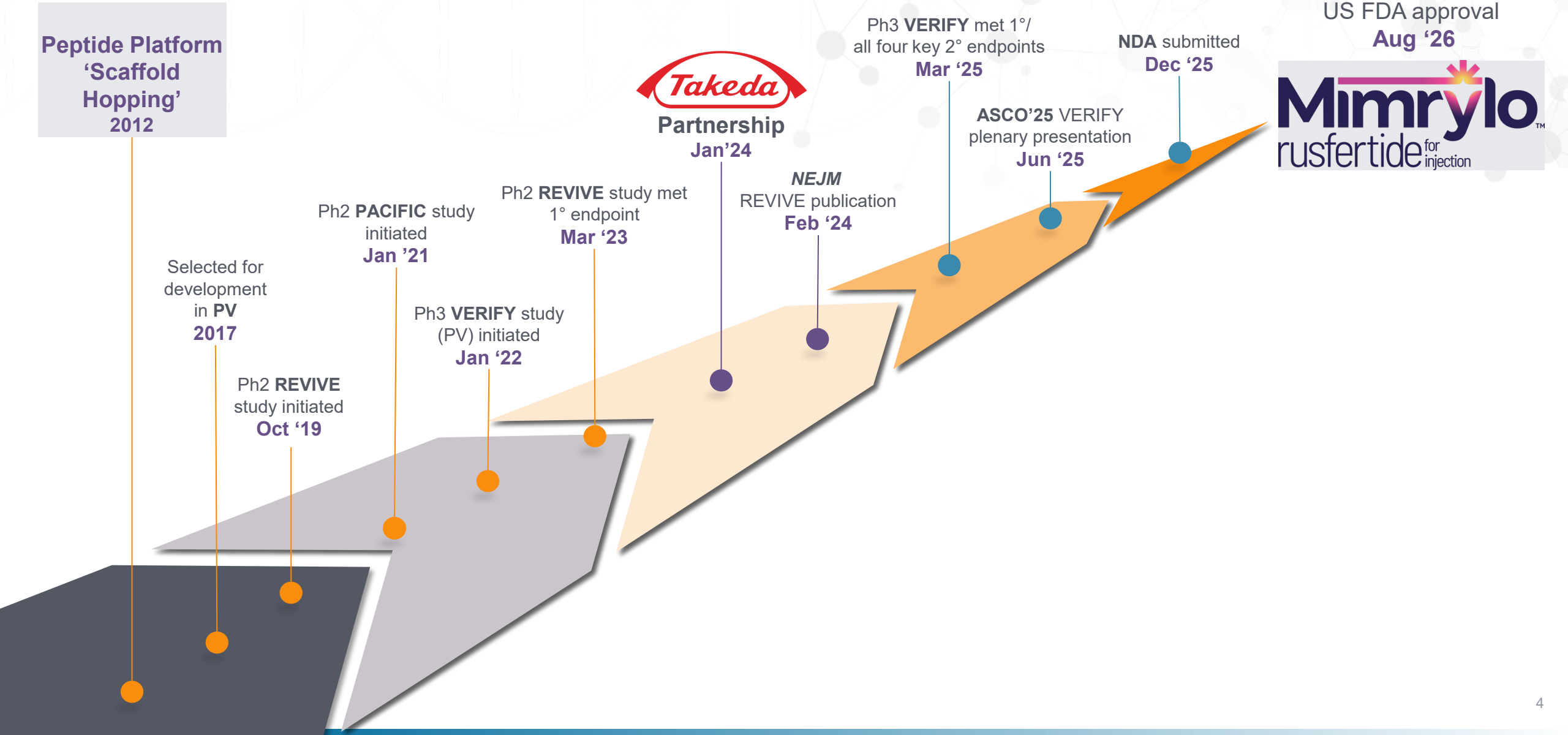
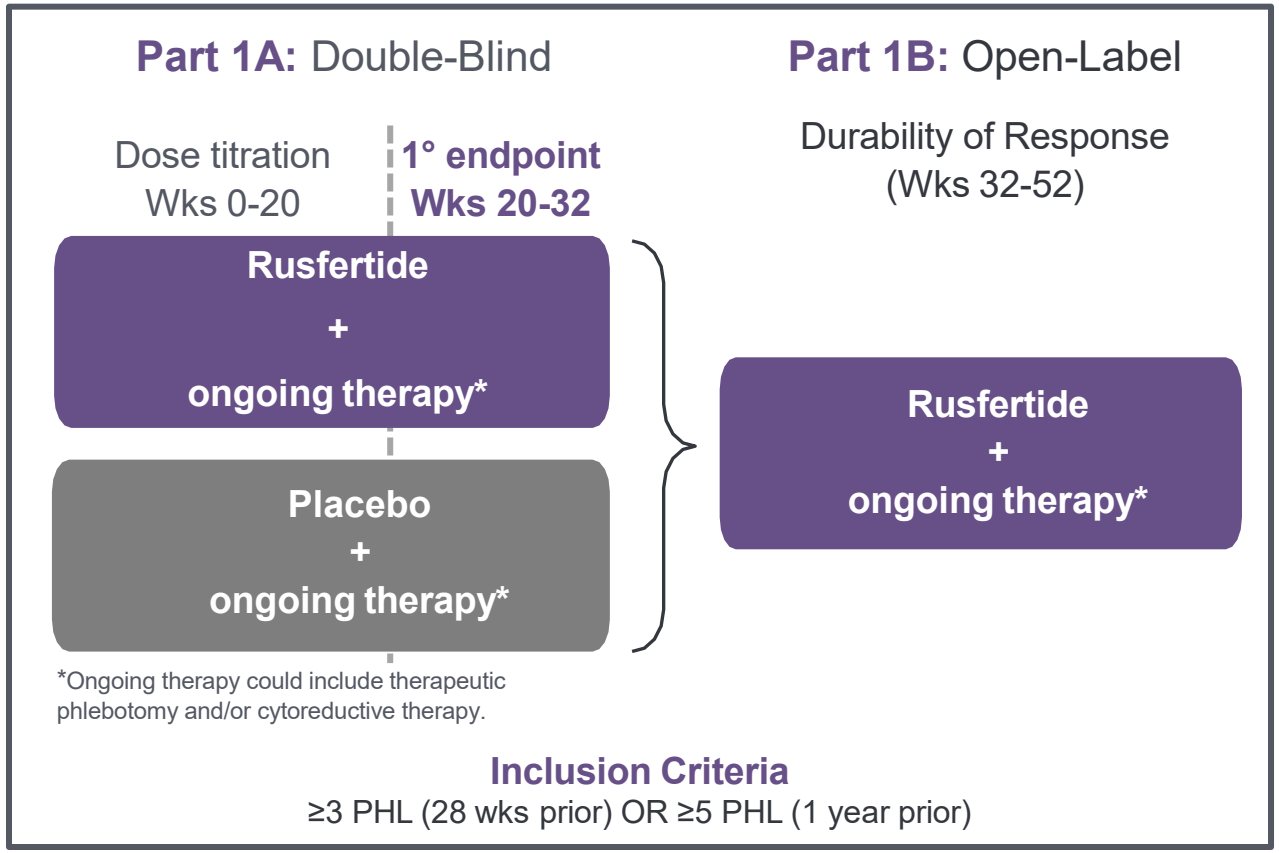
# MIMRYLO™ (Rusfertide, PTG-300): A Hepcidin Mimetic

## Journey from 'Concept to Commercial'



# Ongoing Phase 3 VERIFY Study: PV[1,2]

## Sustained Hct Control With Fewer PHLs vs. Placebo; Addresses Major Unmet Need in PV




- **Primary endpoint:** Wks 20-32
  1. Response: rusfertide vs placebo (p<0.0001) ✓
- **Key 2° endpoints:** Wks 0-32
  1. Average number of PHLs (p<0.0001) ✓
  2. Proportion of patients with Hct <45% (p<0.0001) ✓
  3. **PROMIS Fatigue SF-8a Score** ✓
  4. MFSAF Total Symptom Score ✓

**VERIFY** featured in **Plenary Presentation** at ASCO'25

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Hct, hematocrit; PHL, phlebotomy; PV, polycythemia vera.

1. Kuykendall AT, et al. *J Clin Oncol.* 2025;43(17_suppl):LBA3; 2. Kuykendall AT, et al. *Blood.* 2025;146(Suppl 1):81.

# MIMRYLO™: Highlights of Prescribing Information (Link)[1]

- **Efficacy:** 76.9% of patients achieved response between Weeks 20-32
  - MIMRYLO maintains hematocrit control and reduces phlebotomy burden

- **Patient reported outcomes (PRO):** MIMRYLO improves fatigue in adults with PV
  - Improvement in fatigue measured by the PROMIS Fatigue Short Form 8a

- **Safety:** no black box warning
  - **Carcinogenicity:** Rusfertide was not carcinogenic in a 6-month transgenic mouse study at subcutaneous doses up to 25 mg/kg/week or in a 2-year rat carcinogenicity study at doses up to 3 mg/kg/week.
  - **Warnings and Precautions:** New or worsening thrombocytosis, injection-site reactions, and embryo-fetal toxicity.
  - **Adverse reactions:** The most common (>15%) adverse reactions were injection site reactions (56%) and anemia (16%).
  - **Discontinuations:** Adverse reactions which resulted in permanent discontinuation of MIMRYLO included injection site reactions in 2 (0.7%) patients, thrombocytosis in 2 (0.7%) patients, and anemia in 1 (0.4%) patient.

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1. MIMRYLO™ (rusfertide). Prescribing information. Takeda Pharmaceuticals America, Inc.; 2026. Accessed on 28 August 2026. https://assets-dam.takeda.com/image/upload/v1787954309/Oncology/News/approval-mimrylo/MIMRYLO_NDA_Approved_Labels.pdf

# MIMRYLO™: Erythrocytosis-Specific Treatment Option for Adults With PV

## Peak Revenue Potential of $1-2 Billion[4]

**~155k**
**prevalence[1]**
**~78k**
**treated patients with PV in US[2]**

### Treatment Paradigm

Patients will cycle through various treatments[2]

**~41k** Phlebotomy (PHL) — And/Or — **~26k** Hydroxyurea (HU) — And/Or — **~6k** Ruxolitinib — And/Or — **~3k** Ropeg-interferon

- Unmet need exists at each step of the treatment landscape
  - **~78% with uncontrolled Hct>45% despite current treatments[3]**
    - **MIMRYLO expected to be used at each step[4]**

**MIMRYLO maintains hematocrit control, reduces phlebotomy burden and improves fatigue**


1. Mehta J, et al. *Leuk Lymphoma*. 2014;55(3):595-600.
2. Komodo Health closed claims dataset (2016-2023).
3. Verstovsek S, et al. *Ann Hematol*. 2023;102(3):571-81.
4. Takeda 44th Annual J.P. Morgan Healthcare Conference corporate presentation 2026.


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# Takeda and J&J Partnership Economics

## **MIMRYLO™ (rusfertide)**; SC Hepcidin Mimetic; Partner: Takeda

| $800M | $875M | 14–29%[1] | $1–2B[2] |
|---|---|---|---|
| Payments earned | Potential future milestones | Tiered worldwide royalties | Takeda-guided peak sales |

FDA Approved Aug ‘26 (PV) · Ph3 VERIFY PV study met primary + all 4 key secondary endpoints
**21% weighted-avg royalty at $1.5B; 29% for annual sales ≥$1.5B**

## **ICOTYDE™ (icotrokinra);** Oral IL-23R Antagonist; Partner: J&J

| $387.5M | $580M | 6–10% | >$10B[3] |
|---|---|---|---|
| Payments earned | Potential future milestones | Tiered worldwide royalties | ICOTYDE peak sales potential |

FDA Approved Mar ’26 (Mod to Sev Plaque PsO) · PsA Ph3 · UC Ph3 · CD Ph2/3 · EMA (CHMP) positive opinion: Jul ’26 · China (NMPA) Approved Aug ‘26
**7.25% weighted-avg royalty at $4B; 10% for annual sales ≥$4B**

**~$1.2B in upfront, milestone, and opt-out payments earned through August 2026**

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1. 1% royalty payable to Zealand Pharma; 2. Takeda 44th Annual J.P. Morgan Healthcare Conference corporate presentation 2026; 3. HSBC Dec 2025 Consensus Forecast (across all indications).
ICOTYDE is a trademark of Johnson & Johnson and its affiliates.

# Strong Financial Position and Anticipated Future Cash Flows

## Supports Aggressive Development of our R&D Portfolio and Potential Capital Return

**CASH, CASH EQUIVALENTS & MARKETABLE SECURITIES**

**$849.5M**

as of June 30, 2026

**ADDITIONAL PAYMENTS TRIGGERED UPON MIMRYLO APPROVAL**

**$275M**

$200M remaining opt-out payment and $75M FDA approval milestone

**POTENTIAL FUTURE CASH INFLOWS FROM PARTNERSHIPS**

**~$1.5B**

**Future milestones**
**+**
**6-10% royalties on ICOTYDE**
**+**
**14-29% royalties on MIMRYLO**

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# Revenue Engine Drives Pipeline Development

## Targeting Combined Addressable Markets >$100 Billion

## Revenue Engine

### Commercial & Partnered

**ICOTYDE™ (icotrokinra)**
Oral IL-23R Antagonist • Partner: J&J

**FDA Approved: Mar ’26**
EMA (CHMP) Positive Opinion: Jul ’26
**China (NMPA) Approved: Aug ‘26**
Moderate-to-Severe Plaque Psoriasis

6–10% royalties + milestone payments
>$10B peak potential[1]

**MIMRYLO™ (rusfertide)**
SC Hepcidin Mimetic • Partner: Takeda

**FDA Approved: Aug ’26**
Polycythemia Vera

14–29% royalties + milestone payments
$1-2B peak sales[2]

## Wholly-Owned Pipeline

### Inflammation & Immunology

**Oral PN-881 · IL-17A/F**
Ph1 completed
Ph2b initiation in psoriasis: Q1 ’27
Potential Indications: PsO, PsA, HS, SpA

**Oral IL-4Rα Antagonist**
Lead optimization
Potential Indications: AD, Asthma

### Metabolic

**Oral & SC PN-477 · GLP/GIP/GCG**
SC Ph1 ongoing; Oral Ph1: 1H ’27

**Oral PN-458 · GLP/GIP**
IND enabling studies

**Amylin Mono/Poly-Agonists**
Lead optimization

### Hematology

**Oral PN-8047 · Hepcidin Mimetic**
Ph1: Q1 ’27
Potential Indication: Polycythemia Vera

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1. HSBC Dec 2025 Consensus Forecast (across all indications); 2. Takeda 44th Annual J.P. Morgan Healthcare Conference corporate presentation 2026.

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# Thank you