EXPLORE KIM'S PNH JOURNEY WITH FABHALTA

Kim's treatment experience changed when she and her doctor found FABHALTA—the first and only oral monotherapy to help deliver comprehensive hemolysis control (IVH and EVH) in PNH[1]

Taking FABHALTA was part of the process of taking control of my health.

KIM, ACTUAL PATIENT TAKING FABHALTA

COMPENSATED FOR HER TIME BY NOVARTIS.
INDIVIDUAL RESULTS MAY VARY.

EVH, extravascular hemolysis;
IVH, intravascular hemolysis.

FABHALTA® (iptacopan) 200 mg capsules

INDICATION

FABHALTA is indicated for the treatment of adults with paroxysmal nocturnal hemoglobinuria (PNH).

IMPORTANT SAFETY INFORMATION

WARNING: SERIOUS INFECTIONS CAUSED BY ENCAPSULATED BACTERIA

FABHALTA, a complement inhibitor, increases the risk of serious infections, especially those caused by encapsulated bacteria, such as *Streptococcus pneumoniae, Neisseria meningitidis,* and *Haemophilus influenzae* type b. Life-threatening and fatal infections with encapsulated bacteria have occurred in patients treated with complement inhibitors. These infections may become rapidly life-threatening or fatal if not recognized and treated early.

- **Complete or update vaccinations for encapsulated bacteria at least 2 weeks prior to the first dose of FABHALTA, unless the risks of delaying therapy with FABHALTA outweigh the risk of developing a serious infection. Comply with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccinations against encapsulated bacteria in patients receiving a complement inhibitor.**
- **Patients receiving FABHALTA are at increased risk for invasive disease caused by encapsulated bacteria, even if they develop antibodies following vaccination. Monitor patients for early signs and symptoms of serious infections and evaluate immediately if infection is suspected.**

Because of the risk of serious infections caused by encapsulated bacteria, FABHALTA is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the FABHALTA REMS.

Please click here for Important Safety Information. Please click here for full Prescribing Information, including Boxed WARNING and Medication Guide.

Meet Kim: An active and adventurous mother of 3 from South Carolina

57 years old | Diagnosed with PNH in 2021

- Practices yoga, Pilates, and weightlifting
- Loves traveling with her friends and family
- Enjoys cooking and exploring new cuisines

> ***I made a conscious decision that PNH was not going to define me.***

Kim faced common challenges in her initial PNH treatment journey:

Low Hb levels, EVH, and managing her infusion schedule

- Prior to diagnosis, Kim was experiencing shortness of breath and noticed unusual swelling in her ankles, which prompted her to visit her doctor
- Follow-up bloodwork revealed that she had critically low Hb levels, leading to her hospitalization and diagnosis with PNH
- For the next few years, Kim tried several treatments (including different C5is) but she did not respond as expected due to her EVH and was also looking for an alternative to her infusions

> ***Blood tests revealed that I was experiencing extravascular hemolysis...my bloodwork wasn't very stable. My numbers were kind of jumping all over the place, and we became a little bit concerned.***

DETERMINED TO FIND HER PATH FORWARD, KIM CONSULTED WITH A PNH SPECIALIST TO **DISCOVER FABHALTA**

C5i, complement 5 inhibitor; EVH, extravascular hemolysis; Hb, hemoglobin; PNH, paroxysmal nocturnal hemoglobinuria; RBC, red blood cell.

CONTRAINDICATIONS

- Patients with serious hypersensitivity to FABHALTA or any of the excipients.
- For initiation in patients with unresolved serious infection caused by encapsulated bacteria, including *Streptococcus pneumoniae, Neisseria meningitidis,* or *Haemophilus influenzae* type b.

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WARNINGS AND PRECAUTIONS

Serious Infections Caused by Encapsulated Bacteria

- FABHALTA, a complement inhibitor, increases a patient's susceptibility to serious, life-threatening, or fatal infections caused by encapsulated bacteria, including *Streptococcus pneumoniae, Neisseria meningitidis* (caused by any serogroup, including nongroupable strains), and *Haemophilus influenzae* type b. Life-threatening and fatal infections with encapsulated bacteria have occurred in both vaccinated and unvaccinated patients treated with complement inhibitors. The initiation of FABHALTA is contraindicated in patients with unresolved serious infections caused by encapsulated bacteria.

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Today, Kim is taking FABHALTA—and enjoying a new perspective on life with PNH.

After years of uncertainty, Kim is able to embrace consistently "normal" Hb levels

BEFORE FABHALTA

Kim experienced below-normal Hb levels on various treatments

WITH FABHALTA

Since initiating treatment with FABHALTA in January of 2024, Kim shares that her **Hb levels are "consistently in the 12s and 13s"**

One treatment helps control both drivers of hemolysis: IVH and EVH[1]

BEFORE FABHALTA

Her previous treatments only treated IVH, but Kim also has EVH

WITH FABHALTA

Kim was excited to learn that **FABHALTA addresses both drivers of hemolysis** in PNH.

FABHALTA acts proximally in the alternative complement pathway to control both C3b-mediated extravascular hemolysis and terminal complement-mediated intravascular hemolysis.

Taking an oral monotherapy and enjoying freedom from infusion

BEFORE FABHALTA

After years of managing her infusion schedule, Kim was interested in a treatment without infusions

WITH FABHALTA

With an oral option to manage PNH, Kim's busy days are dedicated to **travel, Pilates, and spending time with her family and friends.**

Patients take 1 capsule (200 mg) twice daily and can be taken without regard to food.

Kim's Hb levels with FABHALTA

Week 1	Week 3	Week 23	Week 52
10.3 g/dL	12.3 g/dL	13.1 g/dL	13.4 g/dL

Individual testing in clinical practice and results may vary.
Laboratory values provided by the patient.

EVH, extravascular hemolysis; Hb, hemoglobin ; IVH, intravascular hemolysis.

IMPORTANT SAFETY INFORMATION (continued)
WARNINGS AND PRECAUTIONS (continued)
Serious Infections Caused by Encapsulated Bacteria (continued)

- Complete or update vaccination against encapsulated bacteria at least 2 weeks prior to the start of FABHALTA, according to the current ACIP recommendations for patients receiving a complement inhibitor. Revaccinate patients in accordance with ACIP recommendations considering the duration of therapy with FABHALTA. Note that ACIP recommends an administration schedule in patients receiving complement inhibitors that differs from the administration schedule in the vaccine prescribing information. If urgent FABHALTA therapy is indicated in a patient who is not up to date with vaccines against encapsulated bacteria according to ACIP recommendations, provide the patient with antibacterial drug prophylaxis and administer these vaccines as soon as possible. The benefits and risks of treatment with FABHALTA, as well as the benefits and risks of antibacterial drug prophylaxis in unvaccinated or vaccinated patients, must be considered against the known risks for serious infections caused by encapsulated bacteria.

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APPLY A head-to-head study of C5i-experienced (eculizumab or ravulizumab) adults with PNH[1]

Superior and substantial Hb increases were achieved with FABHALTA over C5is through the 24-week randomized treatment period

PRIMARY END POINTS

Significantly more patients achieved Hb improvements in the absence of RBC transfusions with FABHALTA vs C5is[1]

Patients with **Hb increase of ≥2 g/dL***

from baseline in the absence of RBC transfusions† after 24 weeks

RESPONSE RATES

82.3% FABHALTA (n=51/62; 95% CI, 70.5-90.8)

vs

0% C5is **(eculizumab or ravulizumab)** (n=0/35; 95% CI, 0-10.0)

(Difference‡: 81.5%; 95% CI, 71.6-91.4; *P*<0.0001)

Patients with **normalized§ Hb of ≥12 g/dL***

in the absence of RBC transfusions† after 24 weeks

RESPONSE RATES

67.7% FABHALTA (n=42/62; 95% CI, 54.7-79.1)

vs

0% C5is **(eculizumab or ravulizumab)** (n=0/35; 95% CI, 0-10.0)

(Difference‡: 66.6%; 95% CI, 54.6-78.6; *P*<0.0001)

SAFETY PROFILE OF FABHALTA

The adverse reactions reported in >5% of adults with PNH treated with FABHALTA vs C5is in APPLY (24-week treatment period) were[1]: headache (19% vs 3%), nasopharyngitis (16% vs 17%), diarrhea (15% vs 6%), abdominal pain (15% vs 3%), bacterial infection (11% vs 11%), nausea (10% vs 3%), viral infection (10% vs 31%), arthralgia (8% vs 3%), thrombocytopenia (6% vs 0%), dizziness (6% vs 0%), systemic hypertension (6% vs 0%), and lipid disorder (6% vs 0%).

APPLY was a 24-week, randomized,‖ open-label, active comparator–controlled, phase 3 trial to assess the efficacy and safety of switching to FABHALTA 200 mg twice daily compared with continuing on intravenous C5i therapy (US-approved and non–US-approved eculizumab or ravulizumab) in adults with PNH and residual anemia (mean Hb <10 g/dL) despite previous treatment with a stable regimen of C5i treatment for at least 6 months; 97 patients were randomized in an 8:5 ratio to either switch to FABHALTA 200 mg taken orally twice daily (n=62) or continue their C5i regimen (n=35: eculizumab, n=23; ravulizumab, n=12). The primary end points in the randomized period were the proportion of patients achieving Hb increase of ≥2 g/dL and the proportion of patients achieving Hb level of ≥12 g/dL,¶ both without the need for RBC transfusions.[1,2,†]

*Adjusted mean assessed between Weeks 18 and 24 (Days 126 and 168). Excludes values within 30 days post-transfusion.[1]
†Assessed between Days 14 and 168. Requiring RBCs refers to any patient receiving transfusions or meeting protocol-defined criteria.[2]
‡Adjusted difference in proportion.[1]
§Normalization defined as meeting the primary end point of Hb ≥12 g/dL.[2] Normal Hb levels vary but generally are between 12-16 g/dL for women and 13-18 g/dL for men.[3]
‖Randomization was stratified based on prior C5i treatment and transfusion history within the last 6 months.[1]
¶Assessed between Days 126 and 168.[1]
C5i, complement 5 inhibitor; Hb, hemoglobin; RBC, red blood cell.

IMPORTANT SAFETY INFORMATION (continued)
WARNINGS AND PRECAUTIONS (continued)
Serious Infections Caused by Encapsulated Bacteria (continued)

- Vaccination does not eliminate the risk of serious encapsulated bacterial infections, despite development of antibodies following vaccination. Closely monitor patients for early signs and symptoms of serious infection and evaluate patients immediately if an infection is suspected. Inform patients of these signs and symptoms and instruct patients to seek immediate medical care if they occur. Promptly treat known infections. Serious infection may become rapidly life-threatening or fatal if not recognized and treated early. Consider interruption of FABHALTA in patients who are undergoing treatment for serious infections, depending on the risks of interrupting treatment in the disease being treated.

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APPOINT **A study of complement inhibitor–naive adults with PNH[1]**

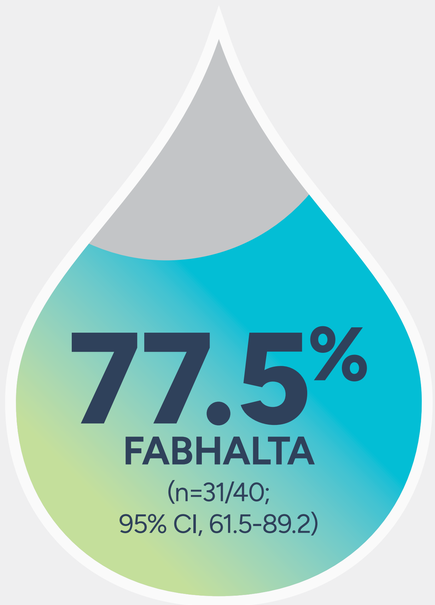
With FABHALTA oral monotherapy, substantial Hb improvements without the need for RBC transfusions are within reach

PRIMARY END POINT

Patients with sustained Hb increase of ≥2 g/dL* from baseline in the absence of RBC transfusions† after the 24-week core treatment period

RESPONSE RATE

Based on central laboratory Hb values.



SENSITIVITY ANALYSIS

87.5%

(n=35/40; 95% CI, 73.2-95.8)

Response rate based on the inclusion of local laboratory values when central laboratory values were not available.

*Assessed between Days 126 and 168.[1]

†Assessed between Days 14 and 168. Requiring RBCs refers to any patient receiving transfusions or meeting protocol-defined criteria.[4]

‡Based on observed and central laboratory data only. Adjusted mean assessed at a single Week 48 visit. Patients who received transfusions between Days 14 and 336 or were missing a Day 336 assessment were considered nonresponders.[5]

SAFETY PROFILE OF FABHALTA

The adverse reactions reported in >5% of adults with PNH treated with FABHALTA in APPOINT (24-week treatment period) were[1]: headache (28%), viral infection (18%), nasopharyngitis (15%), rash (10%), diarrhea (8%), abdominal pain (8%), and lipid disorder (8%).

APPOINT was a 24-week, phase 3, single-arm, open-label, uncontrolled study of FABHALTA 200 mg twice daily in adults (N=40) with PNH who were complement inhibitor–naive and had an RBC clone size ≥10%, a mean Hb <10 g/dL,§ and an LDH level >1.5 x ULN.‖ The primary end point in the core period was the proportion of patients achieving Hb increase of ≥2 g/dL* without the need for RBC transfusions.[1,4]

FABHALTA REMS: FABHALTA, a complement inhibitor, increases the risk of serious infections, especially those caused by encapsulated bacteria, such as *Streptococcus pneumoniae, Neisseria meningitidis*, and *Haemophilus influenzae* type b. Life-threatening and fatal infections with encapsulated bacteria have occurred in patients treated with complement inhibitors. These infections may become rapidly life-threatening or fatal if not recognized and treated early.

HCPs must be REMS certified to prescribe FABHALTA and patients must complete or update vaccinations before starting treatment.

See full Prescribing Information, including Boxed WARNING, for additional information.

§Confirmed by 2 measurements 2 to 8 weeks apart for patients not receiving an RBC transfusion during screening, or by 1 measurement during the first screening visit for patients receiving an RBC transfusion.[4]

‖Confirmed by at least 2 measurements 2 to 8 weeks apart during the screening period.[4]

Hb, hemoglobin; LDH, lactate dehydrogenase; RBC, red blood cell. ULN, upper limit of normal.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

FABHALTA REMS

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- Under the FABHALTA REMS, prescribers must enroll in the program. Prescribers must counsel patients about the risks, signs, and symptoms of serious infections caused by encapsulated bacteria, provide patients with the REMS educational materials, ensure patients are vaccinated against encapsulated bacteria, prescribe antibacterial drug prophylaxis if patients' vaccine status is not up to date and treatment must be started urgently, and provide instructions to always carry the Patient Safety Card during treatment and for 2 weeks following last dose of FABHALTA.
- Further information is available by telephone: 1-833-993-2242 or online at www.FABHALTA-REMS.com.

FABHALTA® (iptacopan) 200 mg capsules

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Indication and Important Safety Information

INDICATION

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CONTRAINDICATIONS

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- Vaccination does not eliminate the risk of serious encapsulated bacterial infections, despite development of antibodies following vaccination. Closely monitor patients for early signs and symptoms of serious infection and evaluate patients immediately if an infection is suspected. Inform patients of these signs and symptoms and instruct patients to seek immediate medical care if they occur. Promptly treat known infections. Serious infection may become rapidly life-threatening or fatal if not recognized and treated early. Consider interruption of FABHALTA in patients who are undergoing treatment for serious infections, depending on the risks of interrupting treatment in the disease being treated.

SEE ADDITIONAL IMPORTANT SAFETY INFORMATION ON THE NEXT PAGE

Indication and Important Safety Information (continued)

WARNINGS AND PRECAUTIONS (continued)

FABHALTA REMS

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Monitoring of PNH Manifestations After FABHALTA Discontinuation

- After discontinuing FABHALTA, closely monitor patients for at least 2 weeks after the last dose for signs and symptoms of hemolysis. These signs include elevated lactate dehydrogenase (LDH) levels along with sudden decrease in hemoglobin or PNH clone size, fatigue, hemoglobinuria, abdominal pain, dyspnea, major adverse vascular events (such as thrombosis, stroke, and myocardial infarction), dysphagia, or erectile dysfunction. If discontinuation of FABHALTA is necessary, consider alternative therapy.
- If hemolysis occurs after discontinuation of FABHALTA, consider restarting treatment with FABHALTA, if appropriate, or initiating another treatment for PNH.

Hyperlipidemia

- FABHALTA may increase total cholesterol, LDL cholesterol, and serum triglycerides.
- Of 88 FABHALTA-treated patients who had normal total cholesterol at baseline, 31 developed grade 1 hypercholesterolemia during the randomization or core treatment period and 1 patient worsened from baseline grade 1 to grade 2.
- Of 96 FABHALTA-treated patients with LDL cholesterol ≤ 130 mg/dL at baseline during the randomization or core treatment period, 14 patients developed LDL cholesterol > 130-160 mg/dL, 6 patients developed LDL cholesterol > 160-190 mg/dL and 4 patients developed LDL cholesterol > 190 mg/dL.
- Of 89 FABHALTA-treated patients with normal triglycerides during the randomization or core treatment period, 22 patients developed grade 1 elevated triglycerides. Three patients experienced an increase in triglycerides from grade 1 to grade 2.
- Of the 102 FABHALTA-treated patients in APPLY-PNH and APPOINT-PNH, 2 patients required cholesterol-lowering medications.
- Monitor serum lipid parameters periodically during treatment with FABHALTA and initiate cholesterol-lowering medications, if indicated.

ADVERSE REACTIONS

- The most common adverse reactions (≥10%) in adults with PNH receiving FABHALTA were headache, nasopharyngitis, diarrhea, abdominal pain, bacterial infection, viral infection, nausea, and rash.

DRUG INTERACTIONS

- Concomitant use of CYP2C8 inducers (eg, rifampin) may decrease iptacopan exposure, which may result in loss of or reduced efficacy of FABHALTA. Monitor the clinical response and discontinue use of the CYP2C8 inducer if loss of efficacy of FABHALTA is evident.
- Concomitant use of strong CYP2C8 inhibitors (eg, gemfibrozil) may increase iptacopan exposure, which may result in increased risk for adverse reactions with FABHALTA. Coadministration with a strong CYP2C8 inhibitor is not recommended.

USE IN SPECIFIC POPULATIONS

- Because of the potential for serious adverse reactions in a breastfed child, breastfeeding should be discontinued during treatment and for 5 days after the final dose.
- FABHALTA is not recommended in patients with severe hepatic impairment (Child-Pugh class C). No dose adjustment is required for patients with mild (Child-Pugh class A) or moderate (Child-Pugh class B) hepatic impairment.

Kim found FABHALTA—a groundbreaking oral monotherapy that helps deliver substantial Hb improvements

in both C5i-experienced and complement inhibitor–naive adults with PNH

GROUNDBREAKING Hb IMPROVEMENT[1]

- **APPLY** primary end points (FABHALTA vs C5is [eculizumab or ravulizumab]): response rates for sustained Hb increase of ≥2 g/dL: 82.3% (N=62) vs 0% (N=35) with C5is (difference: 81.5; 95% CI, 71.6-91.4; *P*<0.0001). Response rates for sustained Hb of ≥12 g/dL: 67.7% (N=62) vs 0% (N=35) with C5is (difference: 66.6; 95% CI, 54.6-78.6; *P*<0.0001). Differences reflect an adjusted difference in proportion.
- **APPOINT** single-arm study primary end point: response rates for sustained Hb increase ≥2 g/dL: 77.5% (N=40; 95% CI, 61.5-89.2).
- All primary end points were measured in the absence of red blood cell transfusions after 24 weeks.

COMPREHENSIVE HEMOLYSIS CONTROL[1] (both IVH and EVH)

MOST COMMON ADVERSE REACTIONS **in patients taking FABHALTA (incidence ≥10%)[1]:** headache, nasopharyngitis, diarrhea, abdominal pain, bacterial infection, viral infection, nausea, and rash

I didn't realize how bad I felt due to PNH, until I started to feel just a little bit better. In fact, I recently did my 1,000th Pilates class.

Individual results may vary.

DISCOVER THE DATA AT FABHALTA-HCP.COM/PNH

C5i, complement 5 inhibitor; CI, confidence interval. EVH, extravascular hemolysis; Hb, hemoglobin; IVH intravascular hemolysis.

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References: 1. Fabhalta. Prescribing information. Novartis Pharmaceuticals Corp. **2.** Data on file. Study CLNP023C12302 CSR. Novartis Pharmaceuticals Corp; 2022. **3.** Cappellini MD, Motta I. Anemia in clinical practice—definition and classification does hemoglobin change with aging? *Semin Hematol*. 2015;52(4):261-269. doi:10.1053/j.seminhematol.2015.07.006 **4.** Data on file. Study CLNP023C12301 CSR. Novartis Pharmaceuticals Corp; 2022.

NOVARTIS

Novartis Pharmaceuticals Corporation
East Hanover, New Jersey 07936-1080

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FA-11356790

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