



# Reshape Your Tomorrows by **Targeting PV** at **Its Source**



## **What is BESREMi?**

BESREMi is a prescription medicine that is used to treat adults with polycythemia vera

## **IMPORTANT SAFETY INFORMATION**

### **What is the most important information I should know about BESREMi?**

**BESREMi can cause serious side effects that may cause death or may worsen certain serious diseases that you may already have. Tell your healthcare provider right away if you have any serious side effects during treatment with BESREMi. If symptoms get worse, or become severe and continue, your healthcare provider may tell you to stop taking BESREMi. These symptoms may go away in some people after they stop taking BESREMi.**

**Please see additional Important Safety Information throughout and accompanying full Prescribing Information, including Boxed Warning and Medication Guide.**

## What Is PV?

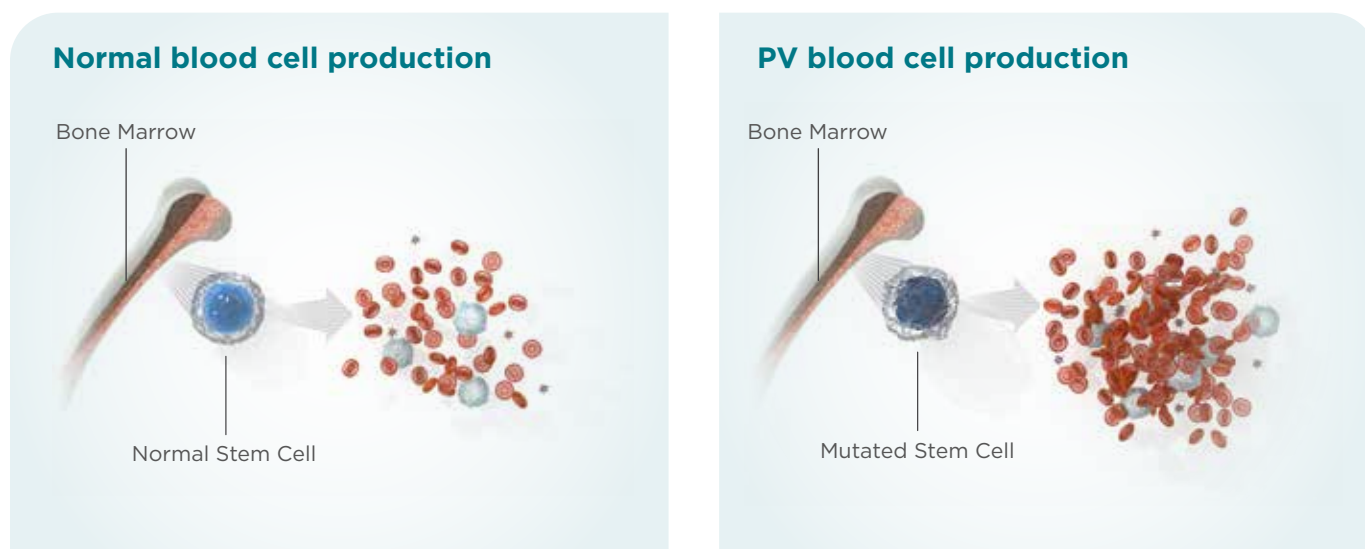
**Polycythemia vera (pol-e-sy-THEE-me-uh VEER-uh, PV) is a rare and chronic blood cancer. It's part of a group of blood cancers called myeloproliferative neoplasms (my-e-lo-pro-lif-er-a-tive neo-plasms), or MPNs.**

Stem cells make all the blood cells in your body: red and white blood cells, and platelets. Your body needs a certain amount of each one. Normally, your body keeps everything in balance.

Stem cells in the bone marrow are the ones that make all types of blood cells in your body.

PV occurs when a single stem cell in the bone marrow develops a mutation (or DNA change) and starts to make too many blood cells. For most people, this DNA change is caused by something called a *JAK2* mutation.

### It All Starts in the Bone Marrow



## PV Symptoms Are Different for Everyone

Some common PV symptoms are listed below. People living with PV may experience one or any combination of these symptoms.



Itchy skin, especially after a warm bath or shower



Numbness in the hands, feet, arms, or legs (might also be described as tingling, burning, or weakness)



A feeling of fullness soon after eating (or bloating or pain in your upper left abdomen)



Unusual bleeding (nosebleeds, bleeding gums)



Painful swelling of one joint (often the big toe)



Shortness of breath and difficulty breathing when lying down

Some people may also have vague symptoms. These symptoms may be related to PV, but they could also be brought on by other conditions. They include:



Headache



Dizziness



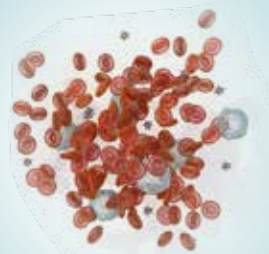
Fatigue (needing to nap during the day, or not having the energy to do things you usually do)



Blurred vision

## What Do You Need to Know About Treating PV?

If you're living with PV, keeping your red and white blood cell and platelet counts under control is very important. In addition to putting you at risk for a thrombotic event (like a blood clot, heart attack, or stroke), PV can also progress to other conditions like myelofibrosis (mie-uh-loh-fie-brOH-suhs, scarring in the bone marrow) and leukemia.



Having too many blood cells, especially red blood cells, puts you at risk for serious health problems. This is because too many red blood cells cause your blood to thicken. When blood is too thick, it doesn't flow the way it needs to through your body. That's when thrombotic events can occur.

### Did you know?

In one study, **39% of people** with PV had a history of thrombotic events.

## PV: the Big Picture

For years, management of PV has focused on:

- Making sure that your hematocrit (he-mat-o-crit), or Hct, level is normal
  - The Hct test measures how much of your blood is made up of red blood cells
- Managing symptoms to improve quality of life

Your doctor can also measure your complete hematologic response (CHR), which considers:

- All blood cell counts (red, white, and platelets)
- Time since last phlebotomy (fluh-bot-uh-mee)
- Spleen size
- Thrombotic events

Talk with your doctor about why considering CHR is important.





## How BESREMi Works

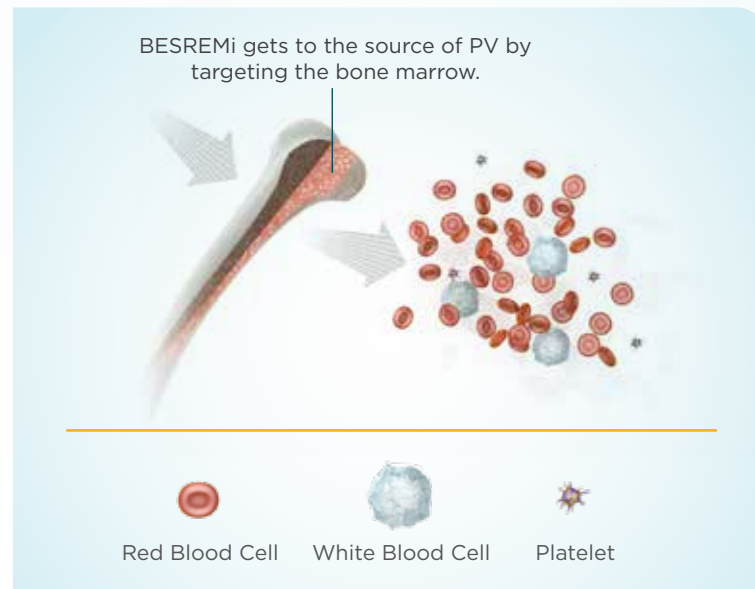
BESREMi is the only FDA-approved treatment indicated for PV that targets the source of the disease.

### Now Is the Time

Wherever you are in your PV journey, it's important that you understand your treatment options. Consider talking with your doctor about a treatment that **targets PV at its source**.

### Target the Source

BESREMi is the only FDA-approved treatment indicated for PV that targets the bone marrow and may help control blood cell counts. That's what makes BESREMi different—it addresses **the cause of PV**.



### An Innovative Approach

BESREMi is **not chemotherapy**. It's an innovative, long-acting interferon that you take once every 2 weeks. After maintaining stable blood levels for 1 year, you may be able to take BESREMi once every 4 weeks.

## IMPORTANT SAFETY INFORMATION (continued)

### What is the most important information I should know about BESREMi? (continued)

- Mental health problems, including suicide: BESREMi may cause you to develop mood or behavior problems that may get worse during treatment with BESREMi or after your last dose, including irritability (getting upset easily), restlessness and agitation, confusion, depression (feeling low, feeling bad about yourself or feeling hopeless), unusually grand ideas, acting aggressive, acting impulsively, or thoughts of hurting yourself or others, or thoughts of suicide. If you develop any of these symptoms, you, your caregiver, or family member should call your healthcare provider immediately. Your healthcare provider should carefully monitor you during treatment with BESREMi.
- New or worsening autoimmune problems: BESREMi may cause autoimmune problems (a condition where the body's immune cells attack other cells or organs in the body), including thyroid problems, increased blood sugar (hyperglycemia), and type I diabetes. In some people who already have an autoimmune problem, it may get worse during your treatment with BESREMi. Tell your healthcare provider if you have tiredness, are urinating often, or if you are very thirsty.

## BESREMi Was Studied in a Broad Range of Patients With PV

A clinical study of BESREMi in adults diagnosed with PV looked at efficacy (how much it helped), dosing, and safety.

### Patients were included regardless of:

- History of cardiovascular events
- Prior treatment with hydroxyurea (HU), a type of chemotherapy

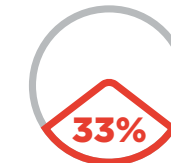
Length of study  
**7.5 years**

### Of the patients who took BESREMi in the clinical study:



35 to 82  
Years

Age range



33%

Treated with HU



22%

Had a previous  
thrombotic event

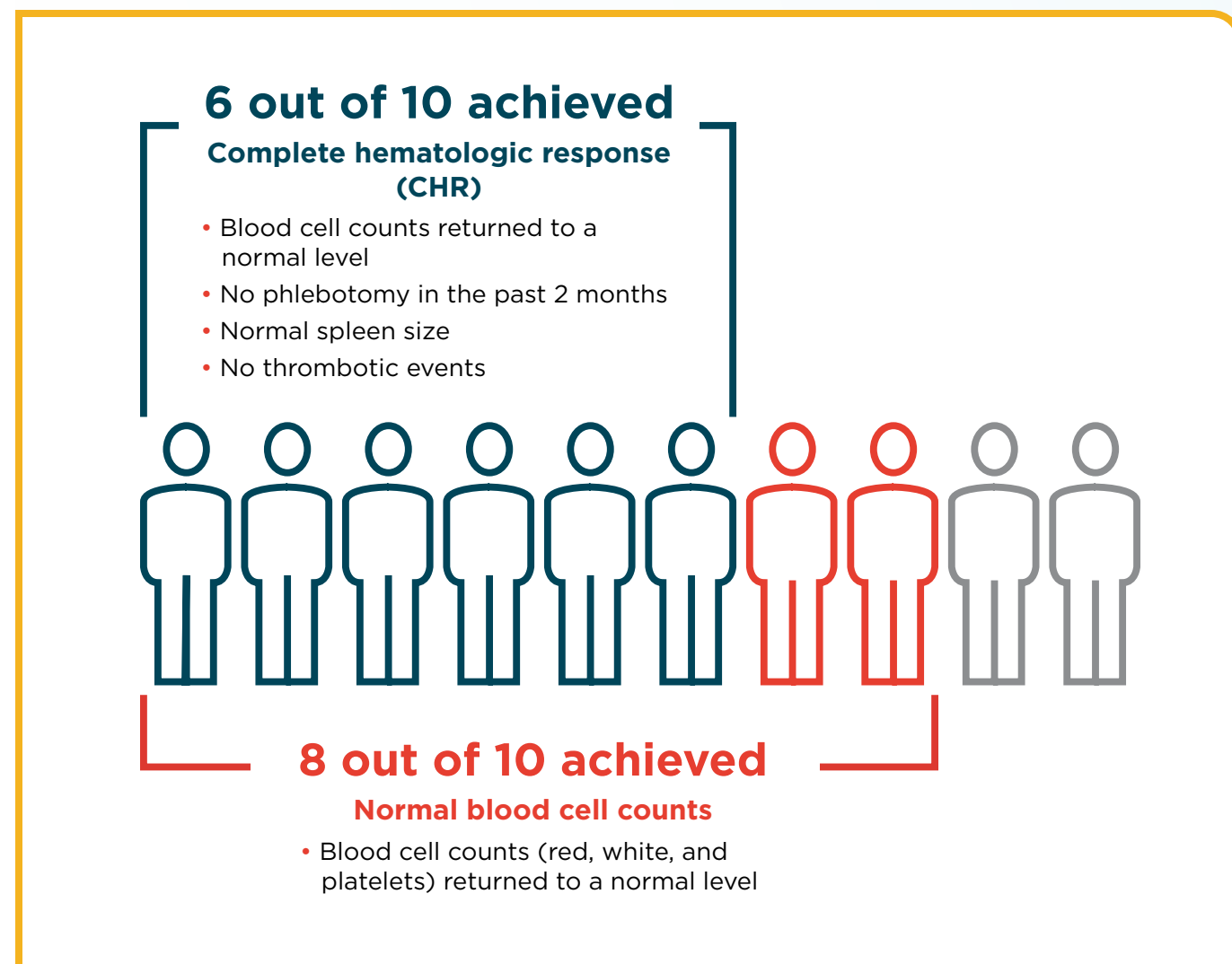
## IMPORTANT SAFETY INFORMATION (continued)

### What is the most important information I should know about BESREMi? (continued)

- Heart problems: BESREMi may cause heart problems, including problems with your heart muscle (cardiomyopathy), heart attack, abnormal heart rhythm (atrial fibrillation), and decreased blood flow to your heart. You should not use BESREMi if you have high blood pressure that is not controlled, congestive heart failure, a serious abnormal heart rhythm, narrowing of the arteries to your heart, certain types of chest pain (angina), or a recent stroke or heart attack. If you have a heart problem before you start using BESREMi, your healthcare provider should monitor you closely during treatment with BESREMi.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information, including Boxed Warning and Medication Guide.

## Meaningful Outcomes



### IMPORTANT SAFETY INFORMATION (continued)

#### Who should not use BESREMi?

Do not use BESREMi if you:

- have or had severe mental health problems, especially severe depression, thoughts of suicide, or attempted suicide
- have or had a serious or untreated autoimmune disease
- have had a serious allergic reaction to another interferon product or to any of the ingredients in BESREMi. Symptoms of a serious allergic reaction may include itching, swelling of your face, tongue, throat, trouble breathing, feeling dizzy or faint, and chest pain
- have certain types of liver problems
- have received a transplant and take immunosuppressive medicines

## Long-Term Results

Complete hematologic response (CHR) was maintained over **7.5 years**.

### IMPORTANT SAFETY INFORMATION (continued)

**Before using BESREMi, tell your healthcare provider about all of your medical conditions, including if you:**

- are being treated for a mental illness or had treatment in the past for any mental illness, including depression and have had thoughts of hurting yourself or others
- have type 1 diabetes
- have or ever had any problems with your heart, including heart attack or high blood pressure
- have or ever had bleeding problems, a blood clot, or low blood cell counts
- have a condition that suppresses your immune system, such as certain cancers
- have hepatitis B or HIV infection
- have kidney or liver problems
- are pregnant or plan to become pregnant. BESREMi may harm your unborn baby and may cause loss of your pregnancy (miscarriage).
  - Before you start using BESREMi your healthcare provider should do a pregnancy test.
  - You should use effective birth control during treatment and for at least 8 weeks after your final dose of BESREMi. Talk to your healthcare provider about birth control choices for you during treatment with BESREMi.
  - BESREMi can affect your menstrual cycles and may cause your menstrual periods to stop.
  - Tell your healthcare provider if you become pregnant during treatment with BESREMi.
- are breastfeeding or plan to breastfeed. It is not known if BESREMi passes into your breast milk. You should not breastfeed during treatment and for 8 weeks after your final dose of BESREMi.

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## Getting Started With BESREMI

**BESREMI is an injectable at-home treatment that you administer just once every 2 weeks.**



The recommended starting dosage of BESREMI is 100 micrograms (or 50 micrograms in patients currently taking hydroxyurea [HU]) every 2 weeks.

Your doctor may increase your prescribed dose until your blood cell counts are stable.



**Your first prescription will be shipped to your home. Always check with your doctor before taking BESREMI to make sure that you are taking the correct dose.**

**For step-by-step instructions on how to give yourself a BESREMI injection, visit [BESREMI.com](http://BESREMI.com).**

### IMPORTANT SAFETY INFORMATION (continued)

#### What are the possible side effects of BESREMI?

BESREMI can cause serious side effects including:

- **Decreased blood cell counts:** Your healthcare provider should check your blood cell counts before you start and during treatment with BESREMI. If your blood cell counts are too low you can develop anemia, infections or have problems with bleeding or bruising. Call your healthcare provider right away if you develop weakness and tiredness, bruising easily, nose bleeds often, fever, chills, burning and painful urination, urinating often, or coughing up yellow or pink mucus (phlegm)
- **Serious allergic reactions and skin reactions:** Get medical help right away if you get any of the following symptoms: skin rash or hives; itching; swelling of the face, eyes, lips, tongue or throat; trouble breathing; chest pain; or feeling faint
- **Eye problems:** BESREMI can cause severe eye problems with your retinas that can lead to vision loss or blindness. You should have an eye exam before and during treatment with BESREMI if you have diabetes or high blood pressure and also have retinal problems. Your healthcare provider may stop BESREMI if you develop new or worse eye problems during treatment with BESREMI.

### BESREMI Treatment Support and Education

We understand that, at first, you may feel a little nervous about injecting BESREMI. Our goal is to help make you feel as comfortable as possible.

PharmaEssentia SOURCE Nurse Case Managers can provide personalized support by:

- Teaching you how to give yourself a BESREMI injection
- Explaining what you might expect during BESREMI treatment

### Helping You Navigate Your Insurance and Financial Support Options

Sometimes insurance can be hard to understand. Our PharmaEssentia SOURCE Nurse Case Managers can:

- Find resources for financial support
- Answer questions you might have

**Call PharmaEssentia SOURCE at 800-700-5053 between 8:00 AM and 8:00 PM ET, Monday through Friday, or visit [PharmaEssentiaSOURCE.com](http://PharmaEssentiaSOURCE.com).**

### IMPORTANT SAFETY INFORMATION (continued)

#### What are the possible side effects of BESREMI? (continued)

- **Liver problems:** BESREMI can cause increases in liver enzymes and liver damage. Your healthcare provider should do blood tests to monitor your liver enzymes and liver function before you start and during treatment with BESREMI.
- **Kidney problems:** Your healthcare provider will do blood tests to check your kidney function before starting and during treatment with BESREMI. Tell your healthcare provider right away if you develop any symptoms of a kidney problem, including changes in the amount or color of your urine, blood in your urine, swelling in your ankles, or loss of appetite. Your healthcare provider may stop BESREMI if you develop severe kidney problems.
- **Tooth and gum (periodontal) problems:** BESREMI can cause tooth and gum problems which can lead to tooth loss. BESREMI can also cause problems with dry mouth that can damage your teeth and the lining of the mouth during long-term treatment with BESREMI. It is important for you to brush your teeth well, two times each day and have regular dental examinations during treatment with BESREMI.
- **Skin problems:** BESREMI can cause skin problems. Signs and symptoms of a skin problem with BESREMI include itching, hair loss, rash, redness, psoriasis, acne, thickening of the skin, or excessive sweating. Call your healthcare provider if you develop a rash that is bothersome or covers a large skin area.

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## BESREMi—the Only FDA-Approved Treatment Indicated for PV That Targets the Source

- Treat your PV with BESREMi for long-term control of your blood cell counts
  - BESREMi was studied for 7.5 years in a broad range of patients with PV
- BESREMi is not chemotherapy. It is an injectable, long-acting interferon you take once every 2 weeks at home
- PharmaEssentia SOURCE™ provides support options and dedicated Nurse Case Managers to guide you through your BESREMi treatment

**You have more options to fight PV—ask your doctor about BESREMi today, or visit [BESREMi.com](https://www.besremi.com) for more information.**

### **IMPORTANT SAFETY INFORMATION** (continued)

#### **What are the possible side effects of BESREMi?** (continued)

The most common side effects of BESREMi include:

- flu like symptoms including tiredness, weakness, fever, chills, muscle aches, and joint pain
- itching
- sore throat

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