Empliciti
(elotuzumab) FOR INJECTION FOR INTRAVENOUS USE 300 MG & 400 MG VIALS

My Disease & Treatment

This brochure can help you learn about your disease, treatment, and how to get ongoing support.

"You've got to toughen up and be strong. Because you've got to fight this."

– Angela, patient with MM

Use this brochure to help you:

- Learn about relapsed/refractory multiple myeloma (MM)
- Understand your treatment
- Find ongoing support

What is EMPLICITI® (elotuzumab)?

EMPLICITI is a prescription medicine used to treat multiple myeloma in combination with the medicines:

- REVLIMID® (lenalidomide) and dexamethasone in adults who have received one to three prior treatments for their multiple myeloma.
- POMALYST® (pomalidomide) and dexamethasone in adults who have received at least two prior treatments including REVLIMID and a proteasome inhibitor.

It is not known if EMPLICITI, REVLIMID, or POMALYST is safe and effective in children.

What's Inside

Please read the Patient Information in the full Prescribing Information for EMPLICITI and the Medication Guide in the full Prescribing Information for REVLIMID and POMALYST, including Boxed WARNINGS for REVLIMID and POMALYST.

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DISEASE DISCOVERY

What is relapsed/refractory multiple myeloma?

As you may know, multiple myeloma (MM) is a type of blood cancer that affects the plasma cells in your bone marrow. When your plasma cells are healthy, they work as part of your immune system to fight infection and disease.

In MM, plasma cells become abnormal and turn into cancerous myeloma cells. These cells can go undetected and multiply, crowding out healthy cells in the marrow.

Instead of making normal antibodies, in most patients, myeloma cells overproduce a substance called M protein, which can't fight infection.

Over time, it's common for a person with MM to go through periods of response to treatment and periods of relapse. If MM cells no longer respond to your treatment, your MM is considered to be "relapsed and/or refractory."

To find out if your disease is progressing, your doctor will monitor the levels of M protein in your blood. A large increase in this protein, or M spike, can indicate a relapse.

For more information about MM, go to EMPLICITI.com.

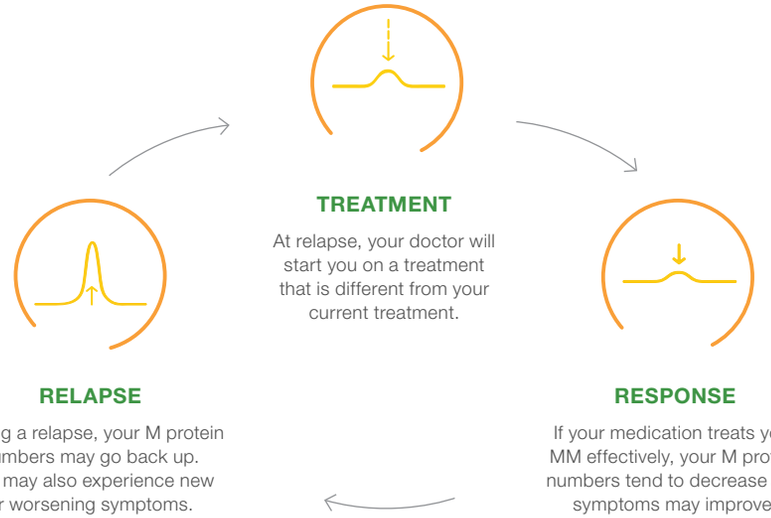
If you are not sure what a word means, ask your doctor about it at your next appointment. Additional information is available in the Key Terms section on pages 23-24.

Why does multiple myeloma keep coming back?

Currently, there is no cure for MM. Treatment can help reduce the number of myeloma cells in your body. However, these cells often stop responding to medication and can begin to grow uncontrollably again—and the cycle of MM restarts.

Relapsing MM is progressive and cyclic

It's common for someone with MM to go through periods of response to treatment and periods of relapse.



Please see the additional Important Safety Information throughout and on pages 25-33, and read the Patient Information in the full Prescribing Information for EMPLICITI. Please read the Medication Guide in the full Prescribing Information for REVLIMID and POMALYST, including Boxed WARNINGS for REVLIMID and POMALYST.

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ABOUT EMPLICITI® (elotuzumab)

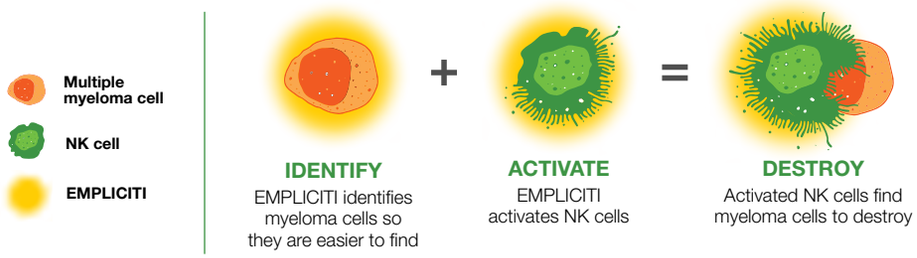
How does EMPLICITI work?

EMPLICITI is an **immunotherapy** medicine that works with your own immune system to fight multiple myeloma.

EMPLICITI works in 2 ways:

- It activates a key type of white blood cell in your immune system, called a **natural killer (NK) cell**.
- It identifies myeloma cells so they are more easily recognized by NK cells. That way, activated NK cells can find myeloma cells to destroy.

EMPLICITI can help your immune system destroy myeloma cells.



If you have questions about your disease or treatment, use the Notes pages in this brochure to write them down for your next doctor's appointment.

Important Safety Information (continued)

Before you receive EMPLICITI, tell your healthcare provider about all of your medical conditions, including if you:

- have an infection
- are pregnant or plan to become pregnant. It is not known if EMPLICITI may harm your unborn baby. However, REVLIMID® (lenalidomide) and POMALYST® (pomalidomide) may cause birth defects or death of an unborn baby.

Important Safety Information (continued)

Before you receive EMPLICITI, tell your healthcare provider about all of your medical conditions, including if you: (continued)

- **Before receiving EMPLICITI with REVLIMID and dexamethasone, or EMPLICITI with POMALYST and dexamethasone, females and males must agree to the instructions in the Lenalidomide REMS program or the POMALYST REMS® program, depending on which combination your doctor has prescribed for you. The programs have specific requirements about birth control (contraception), pregnancy testing, blood donation, and sperm donation that you need to know. Talk to your healthcare provider to learn more about REVLIMID or POMALYST.**

Please see the additional Important Safety Information throughout and on pages 25-33, and read the Patient Information in the full Prescribing Information for EMPLICITI. Please read the Medication Guide in the full Prescribing Information for REVLIMID and POMALYST, including Boxed WARNINGS for REVLIMID and POMALYST.

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How will I receive EMPLICITI® (elotuzumab)?

EMPLICITI is given through an intravenous (IV) infusion by your healthcare team. An IV infusion is when medicine is given directly into the bloodstream through a vein—usually in the arm, hand, or through an IV port.

SCHEDULE APPOINTMENT > **BRING SOMETHING TO DO** > **RECEIVE EMPLICITI**

Important Safety Information (continued)

Before you receive EMPLICITI, tell your healthcare provider about all of your medical conditions, including if you: (continued)

- are breastfeeding or plan to breastfeed. It is not known if EMPLICITI passes into breast milk. You should not breastfeed during treatment with EMPLICITI with REVLIMID and dexamethasone or EMPLICITI with POMALYST and dexamethasone.

How do I know if EMPLICITI is working?

Your healthcare team can determine how your body is responding to EMPLICITI in several ways—for example, they may check the amount of **M proteins** in your blood, or for a change in size or number of bone lesions.

Your healthcare team will monitor you closely to make sure you are responding to treatment.

Download the ***Planning My Routine*** brochure on **EMPLICITI.com** to help you keep track of your dosing schedule.

Important Safety Information (continued)

Before you receive EMPLICITI, tell your healthcare provider about all of your medical conditions, including if you: (continued)

- **Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Please see the additional Important Safety Information throughout and on pages 25-33, and read the Patient Information in the full Prescribing Information for EMPLICITI. Please read the Medication Guide in the full Prescribing Information for REVLIMID and POMALYST, including Boxed WARNINGS for REVLIMID and POMALYST.

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EPd:
EMPLICITI + POMALYST® (pomalidomide) + dexamethasone

Adults with multiple myeloma who have received at least 2 prior treatments, including REVLIMID® (lenalidomide) and a proteasome inhibitor, may receive:

EMPLICITI + POMALYST + dexamethasone

How was EPd studied?

A clinical trial studied 117 patients with relapsed or refractory multiple myeloma. 60 of the patients received EPd, and 57 patients received POMALYST + dexamethasone (Pd) alone. Patients in the study had at least 2 prior treatments for multiple myeloma, including REVLIMID and a proteasome inhibitor.

This study evaluated 2 key areas:

1. **Progression-free survival (PFS):** measures how long a patient lives without the disease getting worse. This was one of two main goals of the study.
2. **Overall response rate (ORR):** measures how many patients responded to treatment overall. This was the second main goal of the study.

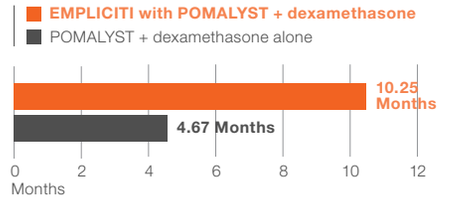
EMPLICITI may not work for everyone. Ask your doctor if EMPLICITI is right for you. Individual results may vary.

How effective was EPd?

Patients who received EMPLICITI with Pd had:

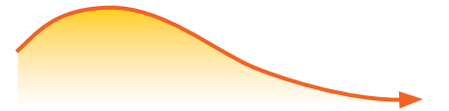
Longer PFS vs Pd.

Half of the patients who received EPd went 10.25 months without their multiple myeloma spreading, growing, or getting worse, compared with 4.67 months for patients who took Pd alone.



Lower risk of worsening disease vs Pd.

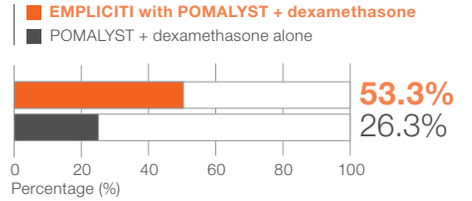
After at least 9.1 months of follow-up, patients who received EPd were at 46% less risk of their disease progressing or of passing away, compared with patients who took Pd alone.



46% less risk of disease progression

Higher ORR vs Pd.

53.3% of patients responded to treatment with EPd, compared to 26.3% who took Pd alone.



Important Safety Information (continued)

Serious side effects that can occur with EMPLICITI treatment are:

Infusion reactions

- Infusion reactions can happen during your infusion or within 24 hours after your infusion of EMPLICITI. Your healthcare provider will give you medicines before each infusion of EMPLICITI to help reduce the risk of an infusion reaction.
- If you have an infusion reaction while receiving EMPLICITI, your healthcare provider will slow or stop your infusion and treat your reaction. If you have a severe infusion reaction your healthcare provider may stop your treatment completely.

Important Safety Information (continued)

Serious side effects that can occur with EMPLICITI treatment are: (continued)

- Tell your healthcare provider or get medical help right away if you have any of these symptoms after your infusion with EMPLICITI: fever, chills, rash, chest pain, trouble breathing, dizziness, light-headedness.

Please see the additional Important Safety Information throughout and on pages 25-33, and read the Patient Information in the full Prescribing Information for EMPLICITI. Please read the Medication Guide in the full Prescribing Information for REVLIMID and POMALYST, including Boxed WARNINGS for REVLIMID and POMALYST.

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What are the most common side effects of EPd?

EMPLICITI in combination with POMALYST® (pomalidomide) and dexamethasone (EPd) compared with POMALYST and dexamethasone (Pd) alone.

Most common side effects*	Patients who received EPd (60 patients)	Patients who took Pd alone (55 patients)
constipation	22%	11%
high blood sugar	20%	15%
pneumonia	18%	13%
diarrhea	18%	9%
respiratory tract infection	17%	9%
bone pain	15%	9%
difficulty breathing, shortness of breath	15%	7%
muscle spasms	13%	5%
swelling in the hands or lower legs	13%	7%
low lymphocyte count	10%	1.8%

*At least 10% of patients who received EPd experienced the side effects listed in the table above. Patients experienced those side effects at a 5% or greater rate than patients who took Pd alone.

You may have treatment-related changes to your blood levels.

EMPLICITI in combination with POMALYST and dexamethasone (EPd) compared with POMALYST and dexamethasone (Pd) alone.

Blood level changes†	Patients who received EPd (60 patients)	Patients who took Pd alone (55 patients)
low number of lymphocytes	98%	91%
low number of white cells	80%	87%
low number of platelets	78%	73%
low level of albumin	65%	56%
low level of calcium	58%	40%
high level of glucose	40%	25%
low level of sodium	40%	18%
low level of potassium	23%	16%

†At least 10% of patients who received EPd experienced the side effects listed in the table above. Patients experienced those side effects at a 5% or greater rate than patients who took Pd alone.

These are not all the possible side effects of EMPLICITI with POMALYST and dexamethasone. If you have questions, ask your healthcare provider and read Important Safety Information about EMPLICITI below.

Important Safety Information (continued)

Serious side effects that can occur with EMPLICITI treatment are: (continued)

Infections

- Those receiving EMPLICITI with REVLIMID and dexamethasone or EMPLICITI with POMALYST and dexamethasone may develop infections; some can be serious.

Important Safety Information (continued)

Serious side effects that can occur with EMPLICITI treatment are: (continued)

- Tell your healthcare provider right away if you have any of the signs and symptoms of an infection, including: fever, flu-like symptoms, cough, shortness of breath, burning with urination, or a painful skin rash.

Please see the additional Important Safety Information throughout and on pages 25-33, and read the Patient Information in the full Prescribing Information for EMPLICITI. Please read the Medication Guide in the full Prescribing Information for REVLIMID and POMALYST, including Boxed WARNINGS for REVLIMID and POMALYST.

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What is the EPd treatment schedule?

Your EMPLICITI treatment schedule is divided into cycles that are 28 days (4 weeks) long. A cycle is a set number of days you are on treatment and also includes the time you spend resting between treatments.

EMPLICITI is usually given 1 time every week for cycles 1 and 2 (28-day cycles). After the first 2 cycles, **EMPLICITI is given once every 4 weeks** when used with POMALYST® (pomalidomide) and dexamethasone. POMALYST and dexamethasone are also given during these cycles as part of the treatment.

Before each infusion, your healthcare provider will give you medicines to help reduce the risk of an infusion reaction.

Take your dose of dexamethasone exactly as prescribed. Keep in mind the dose of oral dexamethasone may vary based on your age and whether EMPLICITI is given that day.

CYCLES 1 & 2 (28 DAYS EACH)									
EMPLICITI	**DAY 1**		**DAY 8**		**DAY 15**		**DAY 22**		DAYS **23-28** REST PERIOD
POMALYST	DAYS 1-21								
oral dexamethasone	DAY 1		DAY 8		DAY 15		DAY 22		

CYCLES 3 & UP (28 DAYS EACH)									
EMPLICITI	**DAY 1**								DAYS **23-28** REST PERIOD
POMALYST	DAYS 1-21								
oral dexamethasone	DAY 1		DAY 8		DAY 15		DAY 22		

How long does each EMPLICITI infusion take?

The length of each EMPLICITI infusion will depend on your body weight and how many times you have received EMPLICITI in the past. If infusion reactions occur or become worse, it may take more time to receive your EMPLICITI infusion.

Important Safety Information (continued)

Serious side effects that can occur with EMPLICITI treatment are: (continued)

Risk of new cancers (malignancies)

- Those receiving EMPLICITI with REVLIMID and dexamethasone or EMPLICITI with POMALYST and dexamethasone have a risk of developing new cancers.

Important Safety Information (continued)

Serious side effects that can occur with EMPLICITI treatment are: (continued)

- Talk with your healthcare provider about your risk of developing new cancers if you receive EMPLICITI.
- Your healthcare provider will check you for new cancers during your treatment with EMPLICITI.

Please see the additional Important Safety Information throughout and on pages 25-33, and read the Patient Information in the full Prescribing Information for EMPLICITI. Please read the Medication Guide in the full Prescribing Information for REVLIMID and POMALYST, including Boxed WARNINGS for REVLIMID and POMALYST.

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ERd:
EMPLICITI + REVLIMID® (lenalidomide) + dexamethasone

Adults with multiple myeloma who have received 1 to 3 prior treatments for their multiple myeloma may receive:

EMPLICITI + REVLIMID + dexamethasone

How was ERd studied?

A clinical trial studied 646 patients with multiple myeloma. 321 of the patients received ERd, and 325 of the patients received Rd alone. All of them had already received 1 to 3 prior multiple myeloma treatments.

This study evaluated 2 key areas:

1. **Progression-free survival (PFS):** measures how long a patient lives without the disease getting worse. This was one of two main goals of the study.
2. **Overall response rate (ORR):** measures how many patients responded to treatment overall. This was the second main goal of the study.

The main analysis for PFS took place at 2 years. Patients still benefiting from treatment continued in the study, and a follow-up analysis was done at 5 years. Both evaluations were based on the entire population of 646 patients.

Important Safety Information (continued)

Serious side effects that can occur with EMPLICITI treatment are: (continued)

Liver problems

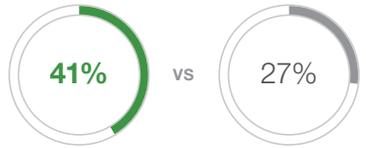
- EMPLICITI may cause liver problems. Your healthcare provider will do blood tests to check your liver during treatment with EMPLICITI.

How effective was ERd?

The clinical study found that:

More patients who received ERd vs Rd were living with their disease under control.

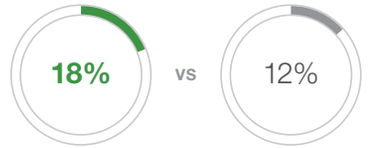
At the time of the main analysis at 2 years:



41% chance that patients who received ERd were living progression free

27% chance that patients who received Rd alone were living progression free

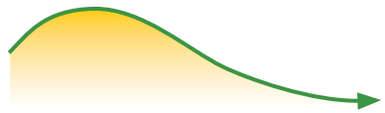
At the 5-year follow-up:



18% chance that patients who received ERd were living progression free

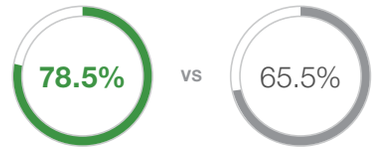
12% chance that patients who received Rd alone were living progression free

Patients who received ERd had lower risk of disease progression vs Rd.
After at least 2 years of follow-up, patients who received ERd were at 30% less risk of their disease progressing or of passing away from any cause, compared with patients who took Rd alone. After at least 5 years of follow-up, results were similar.



30% less risk of disease progression

Patients who received ERd had higher ORR vs Rd.
EMPLICITI may not work for everyone. Ask your doctor if EMPLICITI is right for you. Individual results may vary.



78.5% of patients responded to treatment with ERd

65.5% of patients responded to treatment with Rd alone

Important Safety Information (continued)

Serious side effects that can occur with EMPLICITI treatment are: (continued)

- Tell your healthcare provider if you have signs and symptoms of liver problems, including: tiredness, weakness, loss of appetite, yellowing of your skin or eyes, color changes in your stools, confusion, or swelling of the stomach area.

Please see the additional Important Safety Information throughout and on pages 25-33, and read the Patient Information in the full Prescribing Information for EMPLICITI. Please read the Medication Guide in the full Prescribing Information for REVLIMID and POMALYST, including Boxed WARNINGS for REVLIMID and POMALYST.

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What are the most common side effects of ERd?

EMPLICITI in combination with REVLIMID® (lenalidomide) and dexamethasone (ERd) compared with REVLIMID and dexamethasone (Rd) alone.

Most common side effects*	Patients who received ERd (318 patients)	Patients who took Rd alone (317 patients)
fatigue	62%	52%
diarrhea	47%	36%
fever	37%	25%
constipation	36%	27%
cough	34%	19%
numbness, weakness, tingling, or burning pain in your arms or legs	27%	21%
sore throat or runny nose	25%	19%
upper respiratory tract infection	23%	17%
decreased appetite	21%	13%
pneumonia	20%	14%

*At least 10% of patients who received ERd experienced the side effects listed in the table above. Patients experienced those side effects at a 5% or greater rate than patients who took Rd alone.

Important Safety Information (continued)

The most common side effects of EMPLICITI when used with REVLIMID and dexamethasone include:

- fatigue
- diarrhea
- fever
- constipation
- cough

You may have treatment-related changes to your blood levels.

EMPLICITI in combination with REVLIMID and dexamethasone (ERd) compared with REVLIMID and dexamethasone (Rd) alone.

Blood level changes†	Patients who received ERd (318 patients)	Patients who took Rd alone (317 patients)
low number of lymphocytes	99%	98%
low number of white cells	91%	88%
low number of platelets	84%	78%
low level of albumin	73%	66%
elevated alkaline phosphatase	39%	30%
high level of glucose	89%	85%
low level of calcium	78%	77%
low bicarbonate	63%	45%
high level of potassium	32%	22%

†At least 10% of patients who received ERd experienced the side effects listed in the table above. Patients experienced those side effects at a 5% or greater rate than patients who took Rd alone.

These are not all the possible side effects of EMPLICITI with REVLIMID and dexamethasone. If you have questions, ask your healthcare provider and read Important Safety Information about EMPLICITI below.

Important Safety Information (continued)

The most common side effects of EMPLICITI when used with REVLIMID and dexamethasone include: (continued)

- numbness, weakness, tingling, or burning pain in your arms or legs
- sore throat or runny nose
- upper respiratory tract infection
- decreased appetite
- pneumonia

Please see the additional Important Safety Information throughout and on pages 25-33, and read the Patient Information in the full Prescribing Information for EMPLICITI. Please read the Medication Guide in the full Prescribing Information for REVLIMID and POMALYST, including Boxed WARNINGS for REVLIMID and POMALYST.

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What is the ERd treatment schedule?

Your EMPLICITI treatment schedule is divided into cycles that are 28 days (4 weeks) long. A cycle is a set number of days you are on treatment and also includes the time you spend resting between treatments.

EMPLICITI is usually given 1 time every week for cycles 1 and 2 (28-day cycles), and **1 time every 2 weeks** for cycles 3 and up (28-day cycles) when used with REVLIMID® (lenalidomide) and dexamethasone. REVLIMID and dexamethasone are also given during these cycles as part of the treatment.

Before each infusion, your healthcare provider will give you medicines to help reduce the risk of an infusion reaction.

Take your dose of dexamethasone exactly as prescribed. Keep in mind the dose of oral dexamethasone may vary based on whether EMPLICITI is given that day.

CYCLES 1 & 2 (28 DAYS EACH)									
EMPLICITI	**DAY 1**		**DAY 8**		**DAY 15**		**DAY 22**		DAYS **23-28** REST PERIOD
REVLIMID	DAYS 1-21								
oral dexamethasone	DAY 1		DAY 8		DAY 15		DAY 22		

CYCLES 3 & UP (28 DAYS EACH)									
EMPLICITI	**DAY 1**				**DAY 15**				DAYS **23-28** REST PERIOD
REVLIMID	DAYS 1-21								
oral dexamethasone	DAY 1		DAY 8		DAY 15		DAY 22		

How long does each EMPLICITI infusion take?

The length of each EMPLICITI infusion will depend on your body weight and how many times you have received EMPLICITI in the past. If infusion reactions occur or become worse, it may take more time to receive your EMPLICITI infusion.

Important Safety Information (continued)

The most common side effects of EMPLICITI when used with POMALYST and dexamethasone include:

- constipation
- high blood sugar

Important Safety Information (continued)

These are not all of the possible side effects of EMPLICITI. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Please see the additional Important Safety Information throughout and on pages 25-33, and read the Patient Information in the full Prescribing Information for EMPLICITI. Please read the Medication Guide in the full Prescribing Information for REVLIMID and POMALYST, including Boxed WARNINGS for REVLIMID and POMALYST.

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FINDING SUPPORT

What financial resources are available?

Bristol Myers Squibb (BMS) is committed to helping patients gain access to their prescribed BMS medications.

That's why we offer the BMS Access Support® program, which provides resources to help patients understand their insurance coverage and find information on sources of financial support, including co-pay assistance for eligible commercially insured patients.

How BMS Access Support May Help
Find out how BMS can work with you to help access a prescribed BMS medication.

Financial Support Options
There may be programs and services that could help with the cost of treatment. Learn about what options are available.

Additional Resources
We provide videos, tools, and other resources that may help with your access and reimbursement needs.

Have questions about our services?

Call Bristol Myers Squibb Access Support at **1-800-861-0048**, 8 AM to 8 PM ET, Monday-Friday

Visit **www.BMSAccessSupport.com**

Where can I go for support?

There are a number of organizations that provide support and education for patients and caregivers. These include:

- **American Cancer Society (ACS):** cancer.org, 1-800-ACS-2345 (1-800-227-2345)
- **CancerCare:** cancercare.org, 1-800-813-HOPE (1-800-813-4673)
- **Cancer Hope Network:** cancerhopenetwork.org, 1-800-552-4366
- **Caring Bridge:** caringbridge.org, 1-651-452-7940
- **International Myeloma Foundation:** myeloma.org, 1-800-452-CURE (1-800-452-2873)
- **The Leukemia & Lymphoma Society (LLS):** lls.org, 1-800-955-4572
- **Meals on Wheels America:** mealsonwheelsamerica.org, 1-888-998-6325
- **Multiple Myeloma Research Foundation (MMRF):** themmrf.org, 1-203-229-0464
- **The Myeloma Beacon:** myelomabeacon.org
- **Myeloma Crowd:** myelomacrowd.org
- **National Cancer Institute (NCI):** cancer.gov, 1-800-4-CANCER (1-800-422-6237)

Support and guidance for caregivers:

- **Cancer Support Community:** cancersupportcommunity.org, 1-888-793-9355
- **Caregiver Action Network:** caregiveraction.org, 1-855-CARE-640 (1-855-227-3640)
- **National Alliance for Caregiving:** caregiving.org, 1-202-918-1013

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Empliciti (elotuzumab) FOR INJECTION FOR INTRAVENOUS USE 300 MG & 400 MG VIALS

What are key terms?

Here are some of the key terms and definitions found throughout this brochure.

Antibodies
Specialized protein cells in the immune system that recognize harmful organisms and help fight infection.

Bone marrow
Soft tissue found inside your bones where new blood cells are produced.

Dexamethasone
A steroid used in the treatment of multiple myeloma, often in combination with other medications.

Immunotherapy
A type of treatment that works with your immune system to help control certain cancers. It is different because it is not surgery, radiation, or traditional chemotherapy.

Immune system
A network of cells and organs that protect the body from disease.

M proteins
Abnormal antibodies made by multiple myeloma cells.

Multiple myeloma (MM)
A disease where plasma cells become cancerous and grow out of control.

Myeloma cells
Abnormal plasma cells.

Natural killer (NK) cell
A type of white blood cell that helps fight infection or disease and can be important for destroying cancerous cells.

Overall response rate (ORR)
How patients respond to treatment overall.

Overall survival (OS)
The length of time that a patient lives after the start of treatment.

Plasma cells
White blood cells that make substances which fight infections.

Progression-free survival (PFS)
The length of time that a patient lives with MM without it getting worse.

White blood cells
Cells found in the blood and lymph tissue that help fight infections and diseases.

What is EMPLICITI® (elotuzumab)?

EMPLICITI is a prescription medicine used to treat multiple myeloma in combination with the medicines:

- REVLIMID® (lenalidomide) and dexamethasone in adults who have received one to three prior treatments for their multiple myeloma.
- POMALYST® (pomalidomide) and dexamethasone in adults who have received at least two prior treatments including REVLIMID and a proteasome inhibitor.

What is REVLIMID?

REVLIMID is a prescription medicine used to treat adults with multiple myeloma in combination with the medicine dexamethasone, or as maintenance treatment after autologous hematopoietic stem cell transplantation (a type of stem cell transplant that uses your own stem cells). REVLIMID should not be used to treat people who have chronic lymphocytic leukemia (CLL) unless they are participants in a controlled clinical trial.

What is POMALYST?

POMALYST is a prescription medicine, taken along with the medicine dexamethasone, used to treat adults with multiple myeloma who have previously received at least 2 medicines to treat multiple myeloma, including a proteasome inhibitor and lenalidomide, and whose disease has become worse during treatment or within 60 days of finishing the last treatment.

It is not known if EMPLICITI, REVLIMID, or POMALYST is safe and effective in children.

Important Safety Information

WARNINGS FOR REVLIMID: Risk to unborn babies, risk of low blood counts and blood clots.

WARNINGS FOR POMALYST: Risk to unborn babies, and blood clots.

What is the most important information I should know about REVLIMID & POMALYST?

Before you begin taking REVLIMID or POMALYST, you must read and agree to all of the instructions in the Lenalidomide REMS or POMALYST REMS® program. Before prescribing REVLIMID or POMALYST, your healthcare provider (HCP) will explain the Lenalidomide REMS or POMALYST REMS program to you and have you sign the Patient-Physician Agreement Form.

Important Safety Information (continued)

What is the most important information I should know about REVLIMID & POMALYST? (continued)

REVLIMID & POMALYST can cause serious side effects, including:

- **Possible birth defects (deformed babies) or death of an unborn baby.** Females who are pregnant or plan to become pregnant must not take REVLIMID or POMALYST.
  - **REVLIMID & POMALYST are similar to the medicine thalidomide (THALOMID®)**, which is known to cause severe life-threatening birth defects. REVLIMID & POMALYST have not been tested in pregnant females. REVLIMID & POMALYST have harmed unborn animals in animal testing.
  - **Females must not get pregnant:**
    - For at least 4 weeks before starting REVLIMID or POMALYST
    - While taking REVLIMID or POMALYST
    - During any breaks (interruptions) in your treatment with REVLIMID or POMALYST
    - For at least 4 weeks after stopping REVLIMID or POMALYST
  - **Females who can become pregnant:**
    - Will have pregnancy tests weekly for 4 weeks, then every 4 weeks if your menstrual cycle is regular, or every 2 weeks if your menstrual cycle is irregular. If you miss your period or have unusual bleeding, you will need to have a pregnancy test and receive counseling.
    - Must agree to use 2 acceptable forms of effective birth control at the same time, for at least 4 weeks before, while taking, during any breaks (interruptions) in treatment, and for at least 4 weeks after stopping REVLIMID or POMALYST.
    - Talk with your healthcare provider to find out about options for acceptable forms of birth control that you may use to prevent pregnancy during and after treatment with REVLIMID or POMALYST.
  - **If you become pregnant while taking REVLIMID or POMALYST, stop taking it right away and call your healthcare provider.** If your healthcare provider is not available, you can call REMS Call Center at 1-888-423-5436.

Please see the additional Important Safety Information throughout and on pages 25-33, and read the Patient Information in the full Prescribing Information for EMPLICITI. Please read the Medication Guide in the full Prescribing Information for REVLIMID and POMALYST, including Boxed WARNINGS for REVLIMID and POMALYST.

Empliciti (elotuzumab) FOR INJECTION FOR INTRAVENOUS USE 300 MG & 400 MG VIALS

Important Safety Information (continued)

What is the most important information I should know about REVLIMID® (lenalidomide) & POMALYST® (pomalidomide)? (continued)

Healthcare providers and patients should report all cases of pregnancy to:
- FDA MedWatch at 1-800-FDA-1088
- REMS Call Center at 1-888-423-5436

There is a pregnancy exposure registry that monitors the outcomes of females who take REVLIMID or POMALYST during pregnancy, or if their male partner takes REVLIMID or POMALYST and they are exposed during pregnancy. You can enroll in this registry by calling Celgene Corporation, a Bristol Myers Squibb company, at the phone number listed above.

- **REVLIMID & POMALYST can pass into human semen:**
  - Males, including those who have had a vasectomy, must always use a latex or synthetic condom during any sexual contact with a pregnant female or a female that can become pregnant while taking REVLIMID or POMALYST, during any breaks (interruptions) in your treatment with REVLIMID or POMALYST, and for 4 weeks after stopping REVLIMID or POMALYST.
  - Do not have unprotected sexual contact with a female who is or could become pregnant. Tell your healthcare provider if you do have unprotected sexual contact with a female who is or could become pregnant.
  - Do not donate sperm while taking REVLIMID or POMALYST, during any breaks (interruptions) in your treatment, and for up to 4 weeks after stopping REVLIMID or POMALYST. If a female becomes pregnant with your sperm, the baby may be exposed to REVLIMID or POMALYST and may be born with birth defects.

Men, if your female partner becomes pregnant, you should call your healthcare provider right away.

- **Do not donate blood** while you take REVLIMID or POMALYST, during any breaks (interruptions) in your treatment, and for 4 weeks after stopping REVLIMID or POMALYST. If someone who is pregnant gets your donated blood, her baby may be exposed to REVLIMID or POMALYST and may be born with birth defects.

- **Low white blood cells (neutropenia) and low platelets (thrombocytopenia).** REVLIMID causes low white blood cells and low platelets in most people. You may need a blood transfusion or certain medicines if your blood counts drop too low.

Important Safety Information (continued)

What is the most important information I should know about REVLIMID & POMALYST? (continued)

Your healthcare provider should check your blood counts often, especially during the first several months of treatment with REVLIMID, and then at least monthly. Tell your healthcare provider if you develop any bleeding or bruising during treatment with REVLIMID.

- **Blood clots in your arteries, veins, and lungs, heart attack, and stroke can happen if you take REVLIMID or POMALYST.**
  - Most people who take REVLIMID or POMALYST will also take a blood thinner medicine to help prevent blood clots.
  - Before taking REVLIMID or POMALYST, tell your healthcare provider:
  - If you have had a blood clot in the past.
  - If you have high blood pressure, smoke, or if you have been told you have a high level of fat in your blood (hyperlipidemia).
  - About all the medicines you take. Certain other medicines can also increase your risk for blood clots.

Call your healthcare provider or get medical help right away if you get any of the following during treatment with REVLIMID or POMALYST:

- **Signs or symptoms of a blood clot in the lung, arm, or leg may include:** shortness of breath, chest pain, or arm or leg swelling.
- **Signs or symptoms of a heart attack may include:** chest pain that may spread to the arms, neck, jaw, back, or stomach area (abdomen); feeling sweaty, shortness of breath, feeling sick, or vomiting.
- **Signs or symptoms of stroke may include:** sudden numbness or weakness, especially on one side of the body, severe headache or confusion, or problems with vision, speech, or balance.
- A red, itchy skin rash
- Peeling of your skin or blisters
- Severe itching
- Fever

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Important Safety Information (continued)

What is the most important information I should know about REVLIMID® (lenalidomide) & POMALYST® (pomalidomide)? (continued)

Get emergency medical help right away if you develop any of the following signs or symptoms during treatment with REVLIMID or POMALYST:

- swelling of your lips, mouth, tongue, or throat
- trouble breathing or swallowing
- raised red areas on your skin (hives)
- a very fast heartbeat
- you feel dizzy or faint

Who should not take REVLIMID or POMALYST?

Do not take REVLIMID or POMALYST if you:

- Are pregnant, plan to become pregnant, or become pregnant during treatment with REVLIMID or POMALYST. **See "What is the most important information I should know about REVLIMID & POMALYST?"**
- Are allergic to lenalidomide or pomalidomide or any of the ingredients in REVLIMID or POMALYST.

What should I tell my healthcare provider (HCP) before taking EMPLICITI, REVLIMID, or POMALYST?

Before you take EMPLICITI, REVLIMID, or POMALYST, tell your healthcare provider about all of your medical conditions, including if you:

- smoke cigarettes (POMALYST may not work as well in people who smoke)
- have liver problems
- have kidney problems or receive hemodialysis treatment
- have thyroid problems
- have an infection
- have had a serious skin rash with thalidomide treatment. You should not take REVLIMID.
- are lactose intolerant. REVLIMID contains lactose.
- are pregnant or plan to become pregnant. It is not known if EMPLICITI may harm your unborn baby. However, REVLIMID & POMALYST may cause birth defects or death of an unborn baby.
- are breastfeeding. Do not breastfeed during treatment with EMPLICITI and REVLIMID and dexamethasone or EMPLICITI and POMALYST and dexamethasone.

Important Safety Information (continued)

What should I tell my healthcare provider (HCP) before taking EMPLICITI, REVLIMID, or POMALYST? (continued)

- **Tell your HCP about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. REVLIMID and other medicines or POMALYST and other medicines may affect each other, causing serious side effects. Talk with your HCP before taking any new medicines.
- Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist.

How should I take REVLIMID or POMALYST?

Take REVLIMID or POMALYST exactly as prescribed and follow all the instructions of the Lenalidomide REMS & POMALYST REMS program.

- Swallow REVLIMID or POMALYST capsules whole with water 1 time a day. **Do not break, chew, or open your capsules.**
- REVLIMID or POMALYST may be taken with or without food.
- Take REVLIMID or POMALYST at the same time each day.
- If you are on hemodialysis, take POMALYST after hemodialysis, on hemodialysis days.
- Do not open or break REVLIMID or POMALYST capsules or handle them any more than needed. If you touch a broken REVLIMID or POMALYST capsule or the medicine in the capsule, wash the area of your body right away with soap and water.
- If you miss a dose of REVLIMID or POMALYST and it has been less than 12 hours since your regular time, take REVLIMID or POMALYST as soon as you remember. If it has been more than 12 hours, just skip your missed dose. **Do not** take 2 doses at the same time.
- If you take too much REVLIMID or POMALYST, call your HCP right away.
- **Do not share REVLIMID & POMALYST with other people.** It may cause birth defects and other serious problems.

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Important Safety Information (continued)

What are the possible side effects of EMPLICITI, REVLIMID® (lenalidomide) & POMALYST® (pomalidomide)?

- **See "What is the most important information I should know about REVLIMID & POMALYST?"**
- **EMPLICITI, REVLIMID, and POMALYST can cause serious side effects, including:**
  - **Increased risk of death in people who have chronic lymphocytic leukemia (CLL).** People with CLL who take REVLIMID have an increased risk of death compared with people who take the medicine chlorambucil. REVLIMID may cause you to have serious heart problems that can lead to death, including atrial fibrillation, heart attack, or heart failure. You should not take REVLIMID if you have CLL unless you are participating in a controlled clinical trial.
  - **Low white blood cells (neutropenia), low platelets (thrombocytopenia), and low red blood cells (anemia) are common with POMALYST, but can also be serious.** You may need a blood transfusion or certain medicines if your blood counts drop too low. Your blood counts should be checked by your healthcare provider (HCP) weekly for the first 8 weeks of treatment and monthly after that.
  - **Severe liver problems, including liver failure and death.** Your HCP should do blood tests to check your liver function during your treatment with EMPLICITI, REVLIMID, and POMALYST. Tell your HCP right away if you develop any of the following symptoms of liver problems: yellowing of your skin or the white parts of your eyes (jaundice); dark or brown (tea-colored) urine; color changes in your stool; pain or swelling on the upper right side of your stomach area (abdomen); confusion; bleeding or bruising more easily than normal, or feeling very tired.
  - **Infusion Reactions.** Infusion reactions can happen during your infusion or within 24 hours after your infusion of EMPLICITI. Your healthcare provider will give you medicines before each infusion of EMPLICITI to help reduce the risk of an infusion reaction. If you have an infusion reaction while receiving EMPLICITI, your healthcare provider will slow or stop your infusion and treat your reaction. If you have a severe infusion reaction your healthcare provider may stop your treatment completely. Tell your healthcare provider or get

Important Safety Information (continued)

What are the possible side effects of EMPLICITI, REVLIMID, and POMALYST? (continued)

medical help right away if you have any of these symptoms after your infusion with EMPLICITI: fever, chills, rash, chest pain, trouble breathing, dizziness, or light-headedness.

- **Infections.** Those receiving EMPLICITI with REVLIMID and dexamethasone or EMPLICITI with POMALYST and dexamethasone may develop infections; some can be serious. Tell your healthcare provider right away if you have any of the signs and symptoms of an infection, including: fever, flu-like symptoms, cough, shortness of breath, burning with urination, or a painful skin rash. **Severe allergic and severe skin reactions** can happen with REVLIMID & POMALYST and may cause death.
- **Dizziness and confusion.** Avoid taking other medicines that may cause dizziness and confusion during treatment with POMALYST. Avoid situations that require you to be alert until you know how POMALYST affects you.
- **Nerve damage.** Stop taking POMALYST and call your HCP if you develop numbness, tingling, pain, or a burning sensation in your hands, legs, or feet.
- **Risk of new cancers (malignancies).** New cancers, including certain blood cancers (acute myelogenous leukemia or AML) have been seen in people who received POMALYST. Those receiving EMPLICITI with REVLIMID and dexamethasone or EMPLICITI with POMALYST and dexamethasone have a risk of developing new cancers. Your healthcare provider will check you for new cancers during your treatment with EMPLICITI with REVLIMID and dexamethasone, or EMPLICITI with POMALYST and dexamethasone. Talk with your HCP about your risk of developing new cancers.
- **Tumor Lysis Syndrome (TLS).** TLS is caused by the fast breakdown of cancer cells. TLS can cause kidney failure and the need for dialysis treatment, abnormal heart rhythm, seizure, and sometimes death. Your HCP may do blood tests to check you for TLS.
- **Worsening of your tumor (tumor flare reaction) can happen with REVLIMID and may cause death.** Tell your healthcare provider if you get any of these symptoms of tumor flare reaction while taking REVLIMID: tender,

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Important Safety Information (continued)

What are the possible side effects of EMPLICITI, REVLIMID® (lenalidomide), and POMALYST® (pomalidomide)? (continued)

swollen lymph nodes; low-grade fever, pain, or rash.

- **Thyroid problems.** Your healthcare provider may check your thyroid function before you start taking REVLIMID and during treatment with REVLIMID.
- **Risk of early death in MCL.** In people who have Mantle Cell Lymphoma (MCL), there may be a risk of dying sooner (early death) when taking REVLIMID. Talk with your healthcare provider about any concerns and possible risk factors.

- The most common side effects of EMPLICITI when used with REVLIMID and dexamethasone include fatigue, diarrhea, fever, constipation, cough, numbness, weakness, tingling, or burning pain in your arms or legs, sore throat or runny nose, upper respiratory tract infection, decreased appetite, and pneumonia.
- The most common side effects of EMPLICITI when used with POMALYST and dexamethasone include constipation and high blood sugar.
- The most common side effects of REVLIMID include diarrhea, rash, nausea, constipation, tiredness or weakness, fever, itching, swelling of your arms, hands, legs, feet and skin, sleep problems (insomnia), headache, muscle cramps or spasms, shortness of breath, cough, sore throat, and other symptoms of a cold, upper respiratory tract infection or bronchitis, inflammation of the stomach and intestine ("stomach flu"), nose bleed, shaking or trembling (tremor), joint aches, and pain in your back or stomach-area (abdomen).
- The most common side effects of POMALYST include tiredness and weakness, constipation, nausea, diarrhea, shortness of breath, upper respiratory tract infection, back pain, and fever.
- These are not all the possible side effects of EMPLICITI, REVLIMID, and POMALYST. Your HCP may tell you to decrease your dose, temporarily stop or permanently stop taking REVLIMID or POMALYST if you develop certain serious side effects during treatment. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Notes:

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My Disease & Treatment

To learn about your disease and receiving EMPLICITI® (elotuzumab), visit EMPLICITI.com.

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