Now approved and available

POMALYST (pomalidomide) capsules approved to treat Kaposi sarcoma

Indications

POMALYST® (pomalidomide) is a thalidomide analogue indicated for the treatment of adult patients:

- in combination with dexamethasone, for patients with multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor and have demonstrated disease progression on or within 60 days of completion of the last therapy.
- with AIDS-related Kaposi sarcoma (KS) after failure of highly active antiretroviral therapy (HAART) or in KS patients who are HIV-negative. This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

[DATE]

Bristol Myers Squibb is pleased to announce that POMALYST has a new indication related to Kaposi sarcoma:[1]

1. For the treatment of patients with AIDS-related Kaposi sarcoma after failure of highly active antiretroviral therapy (HAART), or
2. For the treatment of Kaposi sarcoma in patients who are HIV-negative.

This indication went through an accelerated approval process. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

POMALYST is the only once-daily oral FDA-approved treatment approved for Kaposi sarcoma (KS).[2,3]*

Selected Important Safety Information: Boxed WARNINGS

WARNING: EMBRYO-FETAL TOXICITY and VENOUS AND ARTERIAL THROMBOEMBOLISM

Embryo-Fetal Toxicity

- **POMALYST is contraindicated in pregnancy. POMALYST is a thalidomide analogue. Thalidomide is a known human teratogen that causes severe birth defects or embryo-fetal death. In females of reproductive potential, obtain 2 negative pregnancy tests before starting POMALYST treatment.**
- **Females of reproductive potential must use 2 forms of contraception or continuously abstain from heterosexual sex during and for 4 weeks after stopping POMALYST treatment.**

POMALYST is only available through a restricted distribution program called POMALYST REMS®.

Venous and Arterial Thromboembolism

- **Deep venous thrombosis (DVT), pulmonary embolism (PE), myocardial infarction, and stroke occur in patients with multiple myeloma treated with POMALYST. Prophylactic antithrombotic measures were employed in clinical trials. Thromboprophylaxis is recommended, and the choice of regimen should be based on assessment of the patient's underlying risk factors.**

Abbreviation: FDA, Food and Drug Administration.

*The recommended dosage of POMALYST for KS is 5 mg per day taken orally on Days 1-21 of repeated 28-day cycles. In the clinical study, patients were taking 3-mg and 2-mg capsules together.[4]

Please see additional Important Safety Information on the following pages and full Prescribing Information, including Boxed WARNINGS.

Pomalyst® (pomalidomide) capsules 1 · 2 · 3 · 4 mg

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POMALYST efficacy in Kaposi sarcoma (KS)[1]

POMALYST 5 mg once daily orally for the treatment of Kaposi sarcoma

An open-label, single-arm clinical study

- Clinical trial 12-C-0047 (NCT01495598) evaluated the safety and efficacy of pomalidomide
- Study consisted of 28 patients, both HIV-positive (18) and HIV-negative (10), with KS
- Patients received POMALYST 5 mg on Days 1-21 of repeated 28-day cycles, until disease progression or unacceptable toxicity
- Additional therapy: patients received thromboprophylaxis with aspirin 81 mg once daily throughout therapy; all HIV-positive patients also continued HAART
- The median age of the all-male total population was 52.5 years
- Overall, 75% of patients had advanced disease (T1) at the time of enrollment, 11% had ≥50 lesions, and 75% had received prior chemotherapy
- The trial excluded patients with symptomatic pulmonary or visceral KS, history of venous or arterial thromboembolism, or procoagulant disorders

Seventy-one percent overall response rate (ORR) with a median duration of 12.1 months (95% CI, 7.6, 16.8)

The major efficacy endpoint was ORR, which included complete response (CR), clinical complete response (cCR) and partial response (PR). Response was assessed by the investigator according to the AIDS Clinical Trial Group (ACTG) Oncology Committee response criteria for KS. The table that follows summarizes the efficacy results. The ORR was 71% (95% CI, 51, 87) and the median time to first response was 1.8 months (range: 0.9 to 7.6).

Selected Important Safety Information

CONTRAINDICATIONS

- **Pregnancy:** POMALYST can cause fetal harm and is contraindicated in females who are pregnant. If the patient becomes pregnant while taking this drug, the patient should be apprised of the potential risk to a fetus.
- **Hypersensitivity:** POMALYST is contraindicated in patients who have demonstrated severe hypersensitivity (e.g., angioedema, anaphylaxis) to pomalidomide or any of the excipients.

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POMALYST efficacy in Kaposi sarcoma (KS)[1] (cont'd)

	All Patients N = 28	HIV-Positive N = 18	HIV-Negative N = 10
ORR,[a] n (%) [95% CI]	20 (71) [51, 87]	12 (67) [41, 87]	8 (80) [44, 98]
CR,[a] n (%)	4 (14)	3 (17)	1 (10)
PR, n (%)	16 (57)	9 (50)	7 (70)
Duration of Response, KS[b] Months Median [95% CI][c]	12.1 [7.6, 16.8]	12.5 [6.5, 24.9]	10.5 [3.9, 24.2]
Duration of Response, KS (%)			
Percent Greater Than 12 Months	50	58	38
Percent Greater Than 24 Months	20	17	25

Abbreviations: CI, confidence interval; CR, complete response; ORR, overall response rate; PR, partial response.

[a]CR includes one HIV-negative patient who achieved a cCR.

[b]Calculated as date of first documented response to date of first documented disease progression, receipt of new treatment or second course of treatment, or death due to any cause, whichever occurs first. Median estimate is from Kaplan-Meier analysis.

[c]From Kaplan-Meier analysis.

ORR = CR + cCR + PR.

Selected Important Safety Information

WARNINGS AND PRECAUTIONS

- **Embryo-Fetal Toxicity & Females of Reproductive Potential: See Boxed WARNINGS**
  - — Males: Pomalidomide is present in the semen of patients receiving the drug. Males must always use a latex or synthetic condom during any sexual contact with females of reproductive potential while taking POMALYST and for up to 4 weeks after discontinuing POMALYST, even if they have undergone a successful vasectomy. Males must not donate sperm.
  - — Blood Donation: Patients must not donate blood during treatment with POMALYST and for 4 weeks following discontinuation of POMALYST therapy because the blood might be given to a pregnant female patient whose fetus must not be exposed to POMALYST.

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Adverse reactions (≥20%) during KS clinical trial

All and Grade 3 or 4 adverse reactions reported in KS patients

Adverse Reaction	Grades 1-4 N=28 %	Grade 3 or 4 N=28 %
Rash, maculo-papular	71	3.6
Constipation	71	0
Fatigue	68	0
Nausea	36	0
Diarrhea	32	3.6
Cough	29	0
Dyspnea	29	0
Peripheral edema	29	3.6
Upper respiratory tract infection	29	0
Muscle spasms	25	0
Hypothyroidism	21	0
Dry skin	21	0
Chills	21	0

Dose modifications due to adverse reactions

- Four patients (14%) had a dose interruption
  - The most frequent adverse reaction requiring dosage interruption was decreased neutrophil count, which occurred in 3 patients
- One patient (4%) had a dose reduction due to gout

Three patients (11%) discontinued POMALYST due to adverse reactions

Selected Important Safety Information

WARNINGS AND PRECAUTIONS (cont'd)

- **POMALYST REMS® Program: See Boxed WARNINGS**
  - Prescribers and pharmacies must be certified with the **POMALYST REMS** program by enrolling and complying with the REMS requirements; pharmacies must only dispense to patients who are authorized to receive POMALYST. Patients must sign a Patient-Physician Agreement Form and comply with REMS requirements; female patients of reproductive potential who are not pregnant must comply with the pregnancy testing and contraception requirements and males must comply with contraception requirements.
  - Further information about the **POMALYST REMS** program is available at **www.CelgeneRiskManagement.com** or by telephone at 1-888-423-5436.

Abbreviations: KS, Kaposi sarcoma; REMS, Risk Evaluation and Mitigation Strategy.

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Frequency of select laboratory abnormalities during KS clinical trial

Abnormalities worsening from baseline in ≥10% of patients who received POMALYST

Laboratory Abnormality	Grades 1-4* %	Grade 3 or 4* %
Hematology		
Decreased absolute neutrophil count	96	50
Decreased white blood cells	79	3.6
Decreased hemoglobin	54	0
Decreased platelets	54	0
Chemistry		
Elevated creatinine	86	3.6
Elevated glucose	57	7
Decreased albumin	54	0
Decreased phosphate	54	25
Decreased calcium	50	0
Increased alanine aminotransferase (ALT)	32	0
Increased aspartate aminotransferase (AST)	25	0
Elevated creatine kinase	25	7
Decreased magnesium	14	0
Elevated alkaline phosphate	14	3.6

*Denominator is the number of patients for whom there is a baseline and at least 1 post-baseline assessment for the laboratory parameter.

Selected Important Safety Information

WARNINGS AND PRECAUTIONS (cont'd)

- **Venous and Arterial Thromboembolism: See Boxed WARNINGS.** Patients with known risk factors, including prior thrombosis, may be at greater risk, and actions should be taken to try to minimize all modifiable factors (e.g., hyperlipidemia, hypertension, smoking). Thromboprophylaxis is recommended, and the choice of regimen should be based on assessment of the patient's underlying risk factors.

Abbreviation: KS, Kaposi sarcoma.

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The POMALYST REMS® program

POMALYST (pomalidomide) can cause fetal harm when administered to a pregnant woman and is contraindicated in pregnant females or females who are able to become pregnant. Females of reproductive potential may be treated with POMALYST if they take adequate precautions to avoid pregnancy.

Because of the embryo-fetal risk, POMALYST is only available under a restricted distribution program called POMALYST Risk Evaluation and Mitigation Strategy (REMS).

- Only prescribers and pharmacies certified with POMALYST REMS can prescribe and dispense the product to patients who are enrolled and meet all the conditions of the POMALYST REMS program

Female patients of reproductive potential must commit either to abstain continuously from heterosexual intercourse or to use 2 methods of reliable birth control, simultaneously, every time they have sex with a male.

If pregnancy does occur during treatment, immediately discontinue the drug. Under these conditions, refer patient to an obstetrician/gynecologist experienced in reproductive toxicity for further evaluation and counseling. Report any suspected fetal exposure to POMALYST to the FDA via the MedWatch program at 1-800-FDA-1088 and also to Celgene Corporation at 1-888-423-5436.

Males must always use a latex or synthetic condom during any sexual contact with females of reproductive potential while taking POMALYST and for up to 4 weeks after discontinuing POMALYST.

Patients should return unused POMALYST capsules to Celgene, their POMALYST prescriber, or their POMALYST dispensing pharmacy for disposal.

POMALYST is recommended in the NCCN Guidelines® for treatment of HIV-related KS[5]

NCCN Clinical Practice Guidelines in Oncology® recommend pomalidomide (POMALYST) + HAART as the only preferred subsequent systemic therapy option for relapsed or refractory AIDS-related KS.

Selected Important Safety Information

WARNINGS AND PRECAUTIONS (cont'd)

- **Increased Mortality with Pembrolizumab:** In clinical trials in patients with multiple myeloma, the addition of pembrolizumab to a thalidomide analogue plus dexamethasone resulted in increased mortality. Treatment of patients with multiple myeloma with a PD-1 or PD-L1 blocking antibody in combination with a thalidomide analogue plus dexamethasone is not recommended outside of controlled clinical trials.

Abbreviations: FDA, Food and Drug Administration; HAART, highly active antiretroviral therapy; KS, Kaposi sarcoma; NCCN, National Comprehensive Cancer Network.

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Dosing and administration[1]

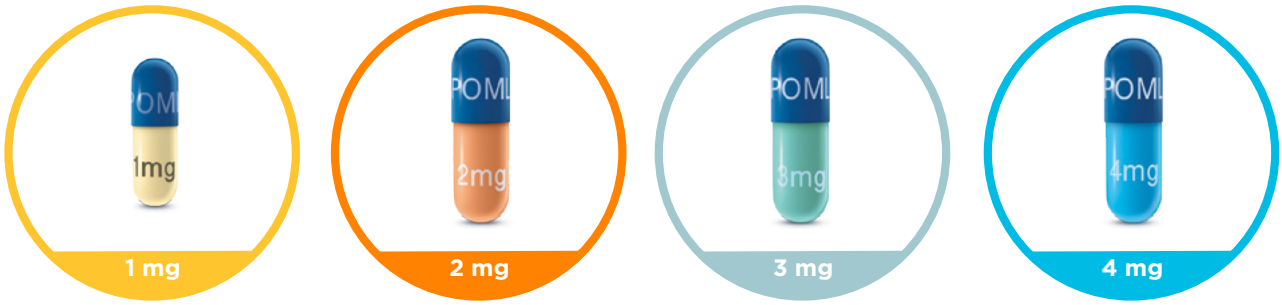
The recommended dosage of POMALYST (pomalidomide) is 5 mg once daily taken orally with or without food on Days 1-21 of repeated 28-day cycles until disease progression or unacceptable toxicity. Continue HAART as HIV treatment in patients with AIDS-related KS.

Initiate a new cycle of POMALYST in patients with KS when the neutrophil count is at least 1000 per mcL and the platelet count is at least 75,000 per mcL. Females of reproductive potential must have 2 negative pregnancy tests and be using 2 contraception methods before initiating POMALYST.

Important dosing information for POMALYST

- POMALYST may be taken with or without food. Inform patients not to break, chew or open the capsules. Swallow capsules whole with water
- Monitor CBCs every 2 weeks for the first 12 weeks and monthly thereafter. Withhold, reduce the dose, or permanently discontinue POMALYST based on the severity of the reaction
- Monitor liver function tests monthly. Stop POMALYST upon elevation of liver enzymes and evaluate. After return to baseline values, treatment at a lower dose may be considered
- Reduce POMALYST dose to 3 mg orally daily in patients with mild, moderate or severe hepatic impairment
- Avoid concomitant use of POMALYST with strong inhibitors of CYP1A2. If concomitant use of a strong CYP1A2 inhibitor is unavoidable, reduce POMALYST dose to 2 mg
- Reduce POMALYST dose to 4 mg orally daily in patients with severe renal impairment requiring dialysis. Take dose of POMALYST following hemodialysis on hemodialysis days

Multiple dosage strengths of POMALYST are available to enable tailored dosing



- 1 mg, dark blue opaque cap and yellow opaque body, imprinted “POML” on the cap in white ink and “1 mg” on the body in black ink
- 2 mg, dark blue opaque cap and orange opaque body, imprinted “POML” on the cap and “2 mg” on the body in white ink
- 3 mg, dark blue opaque cap and green opaque body, imprinted “POML” on the cap and “3 mg” on the body in white ink
- 4 mg, dark blue opaque cap and blue opaque body, imprinted “POML” on the cap and “4 mg” on the body in white ink

In the clinical study, 28 patients received POMALYST 5 mg, once daily for 21 of 28 days, until disease progression or unacceptable toxicity.

Abbreviation: CBC, complete blood count.

Note: Capsules shown are not actual size.

Please see additional Important Safety Information on the following pages and full Prescribing Information, including Boxed WARNINGS.

Pomalyst® (pomalidomide) capsules
1 · 2 · 3 · 4 mg

Dosing and administration[1] (cont'd)

Dose modifications for hematologic adverse reactions

Toxicity	Recommended Course
Neutropenia ANC 500 to less than 1000 per mcL	**Day 1 of cycle** • Withhold POMALYST until ANC is greater than or equal to 1000 per mcL • Resume POMALYST at same dose **During cycle** • Continue POMALYST at current dose
ANC less than 500 per mcL	• Withhold POMALYST until ANC is greater than or equal to 1000 per mcL • Resume POMALYST at same dose
Febrile Neutropenia ANC less than 1000 per mcL and single temperature greater than or equal to 38.3°C or ANC less than 1000 per mcL and sustained temperature greater than or equal to 38°C for more than 1 hour	• Withhold POMALYST until ANC is greater than or equal to 1000 per mcL • Resume POMALYST at dose 1 mg less than previous dose[a]
Thrombocytopenia Platelet count 25,000 to less than 50,000 per mcL	**Day 1 of cycle** • Withhold POMALYST until platelet count is greater than or equal to 50,000 per mcL • Resume POMALYST at same dose **During cycle** • Continue POMALYST at current dose
Platelet count less than 25,000 per mcL	• Permanently discontinue POMALYST

Abbreviation: ANC, absolute neutrophil count.
[a]Permanently discontinue POMALYST if unable to tolerate 1 mg once daily.

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Dosing and administration[1] (cont'd)

Additional dosing adjustments

For nonhematologic adverse reactions

- Permanently discontinue POMALYST for angioedema, anaphylaxis, Grade 4 rash, skin exfoliation, bullae, or any other severe dermatologic reaction
- For other Grade 3 or 4 toxicities, hold treatment and restart treatment at 1 mg less than the previous dose when toxicity has resolved to less than or equal to Grade 2 at the physician's discretion

For patients with hepatic impairment

- For patients with Kaposi sarcoma with mild, moderate, or severe hepatic impairment (Child-Pugh class A, B, or C), the recommended dosage is 3 mg orally daily

Selected Important Safety Information

WARNINGS AND PRECAUTIONS (cont'd)

- **Hematologic Toxicity:** In the POMALYST multiple myeloma (MM) trials, neutropenia (46%) was the most frequently reported Grade 3 or 4 adverse reaction, followed by anemia and thrombocytopenia. Monitor complete blood counts weekly for the first 8 weeks and monthly thereafter. Patients may require dose interruption and/or modification. In the Kaposi sarcoma (KS) trial, hematologic toxicities were the most common all Grades and Grade 3 or 4 adverse reactions. Fifty percent of patients had Grade 3 or 4 neutropenia. Monitor complete blood counts every 2 weeks for the first 12 weeks and monthly thereafter. Withhold, reduce the dose or permanently discontinue POMALYST based on the severity of the reaction.

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Ordering information for POMALYST (pomalidomide)

Diagnosis codes

- C46.1 indicates a diagnosis of Kaposi sarcoma of soft tissue. It is a billable/specific ICD-10-CM code
- C46.7 indicates a diagnosis of Kaposi sarcoma of other sites. It is a billable/specific ICD-10-CM code
- C46.9 indicates a diagnosis of Kaposi sarcoma, unspecified. It is a billable/specific ICD-10-CM code

ICD-10-CM C46.1, ICD-10-CM C46.7, and ICD-10-CM C46.9 can all be grouped with Diagnostic Related Group(s) (MS-DRG v37.0).

- 606 Minor skin disorders with mcc
- 607 Minor skin disorders without mcc
- 974 HIV with major related condition with mcc
- 975 HIV with major related condition with cc
- 976 HIV with major related condition without cc/mcc

Supply[1]

Dosage Strength	Quantity	NDC Number
1 mg	Bottles of 21	(NDC 59572-501-21)
	Bottles of 100	(NDC 59572-501-00)
2 mg	Bottles of 21	(NDC 59572-502-21)
	Bottles of 100	(NDC 59572-502-00)
3 mg	Bottles of 21	(NDC 59572-503-21)
	Bottles of 100	(NDC 59572-503-00)
4 mg	Bottles of 21	(NDC 59572-504-21)
	Bottles of 100	(NDC 59572-504-00)

Storage, handling and disposal

- Store at 20°C-25°C (68°F-77°F); excursions permitted to 15°C-30°C (59°F-86°F)
- Care should be exercised in handling of POMALYST. POMALYST capsules should not be opened or crushed. If powder from POMALYST contacts the skin, wash the skin immediately and thoroughly with soap and water. If POMALYST contacts the mucous membranes, flush thoroughly with water

Selected Important Safety Information

WARNINGS AND PRECAUTIONS (cont'd)

- **Hepatotoxicity:** Hepatic failure, including fatal cases, has occurred in patients treated with POMALYST. Elevated levels of alanine aminotransferase and bilirubin have also been observed in patients treated with POMALYST. Monitor liver function tests monthly. Stop POMALYST upon elevation of liver enzymes. After return to baseline values, treatment at a lower dose may be considered.

Abbreviations: CC, complication or comorbidity; ICD-10-CM, *International Classification of Diseases*, Tenth Revision, Clinical Modification; MCC, major complication or comorbidity; NDC, National Drug Code.

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CELGENE PATIENT SUPPORT®

A single source for access support

Celgene Patient Support® provides

- A single Specialist assigned to help patients in your geographic area
- Assistance with understanding patient insurance coverage for POMALYST (pomalidomide)
- Information about financial assistance for POMALYST

Financial assistance

Depending on a patient's insurance situation, there are programs and organizations that may help pay for POMALYST.

Celgene Commercial Co-pay Program

- Reduces co-pay responsibility to $25 or less for POMALYST (subject to annual benefit limits) for eligible patients with commercial or private insurance (including healthcare exchanges)*

Celgene Patient Assistance Program (PAP)

For qualified patients who are uninsured or underinsured, POMALYST may be available at no cost†

Independent third-party organizations

For patients who are unable to afford their medication (including patients with Medicare, Medicaid, or other government-sponsored insurance), independent third-party organizations may be able to help‡

There are 3 simple ways to enroll in Celgene Patient Support®

Call us at 1-800-931-8691,
Monday-Friday, 8 AM - 8 PM ET
(*translation services available*)

Enroll online at
www.celgenepatientsupport.com

E-mail or fax
a completed enrollment form to
patientsupport@celgene.com or
fax 1-800-822-2496

*Eligibility requirements and restrictions apply. Please see full Terms and Conditions on the Celgene Patient Support® website.

†Patients must meet specified financial and insurance eligibility requirements to qualify for assistance. Please see full Eligibility Requirements on the Celgene Patient Support® website.

‡Financial and medical eligibility requirements vary by organization.

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Additional Important Safety Information

WARNINGS AND PRECAUTIONS (cont'd)

- **Severe Cutaneous Reactions:** Severe cutaneous reactions including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported. DRESS may present with a cutaneous reaction (such as rash or exfoliative dermatitis), eosinophilia, fever, and/or lymphadenopathy with systemic complications such as hepatitis, nephritis, pneumonitis, myocarditis, and/or pericarditis. These reactions can be fatal. Consider POMALYST interruption or discontinuation for Grade 2 or 3 skin rash. Permanently discontinue POMALYST for Grade 4 rash, exfoliative or bullous rash, or any other severe cutaneous reactions such as SJS, TEN or DRESS.
- **Dizziness and Confusional State:** In patients taking POMALYST in clinical trials, 14% experienced dizziness (1% Grade 3 or 4) and 7% a confusional state (3% Grade 3 or 4). Instruct patients to avoid situations where dizziness or confusional state may be a problem and not to take other medications that may cause dizziness or confusional state without adequate medical advice.
- **Neuropathy:** In patients taking POMALYST in the MM clinical trials, 18% experienced neuropathy (2% Grade 3 in one trial) and 12% peripheral neuropathy.
- **Second Primary Malignancies:** Cases of acute myelogenous leukemia have been reported in patients receiving POMALYST as an investigational therapy outside of multiple myeloma.
- **Tumor Lysis Syndrome (TLS):** TLS may occur in patients treated with POMALYST. Patients at risk are those with high tumor burden prior to treatment. These patients should be monitored closely and appropriate precautions taken.
- **Hypersensitivity:** Hypersensitivity, including angioedema, anaphylaxis, and anaphylactic reactions to POMALYST have been reported. Permanently discontinue POMALYST for angioedema or anaphylaxis.

ADVERSE REACTIONS

Multiple Myeloma:

The most common adverse reactions for POMALYST (≥30%) included fatigue and asthenia, neutropenia, anemia, constipation, nausea, diarrhea, dyspnea, upper-respiratory tract infections, back pain, and pyrexia.

In the phase III trial, nearly all patients treated with POMALYST + low-dose dex experienced at least one adverse reaction (99%). Adverse reactions (≥15% in the POMALYST + low-dose dex arm and ≥2% higher than control) included neutropenia (51%), fatigue and asthenia (47%), upper respiratory tract infection (31%), thrombocytopenia (30%), pyrexia (27%), dyspnea (25%), diarrhea (22%), constipation (22%), back pain (20%), cough (20%), pneumonia (19%), bone pain (18%), edema peripheral (17%), peripheral neuropathy (17%), muscle spasms (15%), and nausea (15%). Grade 3 or 4 adverse reactions (≥15% in the POMALYST + low-dose dex arm and ≥1% higher than control) included neutropenia (48%), thrombocytopenia (22%), and pneumonia (16%).

Kaposi Sarcoma:

The most common adverse reactions including laboratory abnormalities (≥30%) are decreased absolute neutrophil count or white blood cells, elevated creatinine or glucose, rash, constipation, fatigue, decreased hemoglobin, platelets, phosphate, albumin, or calcium, increased ALT, nausea, and diarrhea.

Please see additional Important Safety Information on next page and full Prescribing Information, including Boxed WARNINGS.

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Additional Important Safety Information (cont'd)

ADVERSE REACTIONS (cont'd)

Kaposi Sarcoma (cont'd):

In the KS trial, adverse reactions were evaluated in 28 patients who received treatment with POMALYST. Adverse reactions (N=28) ≥20% included maculopapular rash (71%), constipation (71%), fatigue (68%), nausea (36%), diarrhea (32%), cough (29%), dyspnea (29%), peripheral edema (29%), upper respiratory tract infection (29%), muscle spasms (25%), hypothyroidism (21%), dry skin (21%), and chills (21%). Grade 3 or 4 adverse reactions included maculopapular rash (3.6%), diarrhea (3.6%) and peripheral edema (3.6%). Grade 3 or 4 laboratory abnormalities ≥5% worsening from baseline included decreased absolute neutrophil (50%), elevated glucose (7%), decreased phosphate (25%) and elevated creatine kinase (7%).

DRUG INTERACTIONS

Avoid concomitant use of POMALYST with strong CYP1A2 inhibitors. If concomitant use of a strong CYP1A2 inhibitor is unavoidable, reduce POMALYST dose to 2 mg.

USE IN SPECIFIC POPULATIONS

- **Pregnancy: See Boxed WARNINGS.** If pregnancy does occur during treatment, immediately discontinue the drug and refer patient to an obstetrician/gynecologist experienced in reproductive toxicity for further evaluation and counseling. There is a POMALYST pregnancy exposure registry that monitors pregnancy outcomes in females exposed to POMALYST during pregnancy as well as female partners of male patients who are exposed to POMALYST. This registry is also used to understand the root cause for the pregnancy. Report any suspected fetal exposure to POMALYST to the FDA via the MedWatch program at 1-800-FDA-1088 and also to Celgene Corporation at 1-888-423-5436.
- **Lactation:** There is no information regarding the presence of pomalidomide in human milk, the effects of POMALYST on the breastfed child, or the effects of POMALYST on milk production. Pomalidomide was excreted in the milk of lactating rats. Because many drugs are excreted in human milk and because of the potential for adverse reactions in a breastfed child from POMALYST, advise women not to breastfeed during treatment with POMALYST.
- **Pediatric Use:** Safety and effectiveness have not been established in pediatric patients.
- **Geriatric Use:**
  - Multiple Myeloma (MM): No dosage adjustment is required for POMALYST based on age. Patients >65 years of age were more likely than patients ≤65 years of age to experience pneumonia.
  - Kaposi sarcoma (KS): The clinical study did not include sufficient numbers of patients aged 65 and over to determine whether they respond differently from younger patients.
- **Renal Impairment:** For MM patients with severe renal impairment requiring dialysis, reduce POMALYST dosage to 3 mg orally daily or for KS, reduce POMALYST dosage to 4 mg orally daily. Take dose of POMALYST following hemodialysis on hemodialysis days.
- **Hepatic Impairment:** For MM patients with mild to moderate hepatic impairment, reduce POMALYST dosage to 3 mg orally daily and to 2 mg orally daily in patients with severe hepatic impairment. For KS in patients with mild, moderate, or severe hepatic impairment, reduce POMALYST dosage to 3 mg orally daily.
- **Smoking Tobacco:** Advise patients that smoking may reduce the efficacy of POMALYST. Cigarette smoking reduces pomalidomide AUC due to CYP1A2 induction.

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Please see full Prescribing Information, including Boxed WARNINGS.

This letter was developed by Bristol Myers Squibb and is intended for payers and other formulary decision makers within the US.

References: 1. POMALYST [package insert]. Summit, NJ: Celgene Corp. **2.** Polizzotto MN, Uldrick TS, Wyvill KM, et al. Pomalidomide for symptomatic Kaposi's sarcoma in people with and without HIV infection: a phase I/II study [published correction appears in *J Clin Oncol*. 2018;36(19):2008]. *J Clin Oncol*. 2016;34(34):4125-4131. **3.** Schneider JW, Dittmer DP. Diagnosis and treatment of Kaposi sarcoma. *Am J Clin Dermatol*. 2017;18(4):529-539. **4.** Data on file. Bristol-Myers Squibb Co; 2020. **5.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for AIDS-Related Kaposi Sarcoma V.2.2020. © National Comprehensive Cancer Network, Inc. 2020. All rights reserved. Accessed February 20, 2020. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use, or application and disclaims any responsibility for their application or use in any way.

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