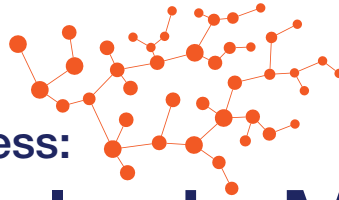




2021

Virtual Congress:



Hematologic Malignancies™

# Exhibition Guide

Thursday, October 14 – Saturday, October 16, 2021

## VIRTUAL EXHIBITION HALL LIVE HOURS

Thursday, October 14, 2021

10:15 – 11:00 AM

12:50 – 1:20 PM

2:35 – 3:05 PM

Friday, October 15, 2021

10:15 – 11:00 AM

12:35 – 1:05 PM

2:20 – 2:50 PM

Saturday, October 16, 2021

10:15 – 11:00 AM

12:35 – 1:05 PM

2:20 – 2:50 PM



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# Exhibition Hall

## Premium Exhibits

**Adaptive Biotechnologies**

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## Patient Advocacy Pavilion

**Aplastic Anemia and MDS International Foundation**

**Bone Marrow & Cancer Foundation**

**CLL Society**

**First Descents**

**HealthTree Foundation/Myeloma Crowd**

**International Myeloma Foundation (IMF)**

**Leukemia & Lymphoma Society (LLS)**

**The Myelodysplastic Syndromes (MDS) Foundation, Inc.**

**Triage Cancer**

All attendees are invited to visit these booths via access through the Digitell platform. All registered attendees can use the log-in information provided for access to the Congress.

# Exhibitor Showcase Presentations

## Non-CE Presentations

Thursday, October 14 4:45 - 5:15 PM	<b>Updates to Long Term Data for Tafasitamab in combination with Lenalidomide for NTE R/R DLBCL patients</b> <i>Presented by MorphoSys</i>
Friday, October 15 4:30 - 5:00 PM	<b>Evolving Treatment Approaches in MDS &amp; CMML</b> <i>Presented by Taiho Oncology</i>
Saturday, October 16 4:30 - 5:00 PM	<b>Use of a Targeted Agent for Previously Untreated or R/R CLL</b> <i>Presented by AstraZeneca</i>

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# BRUKINSA—THE BTK INHIBITOR FOR MCL DEMONSTRATED TO PROVIDE COMPLETE AND SUSTAINED INHIBITION<sup>1,2</sup>



## STUDY 206 | PET-BASED<sup>1</sup>

**84%**  
ORR  
(95% CI: 74, 91)

**59%**  
CR

**19.5<sub>mo</sub>**  
MEDIAN DOR  
(95% CI: 16.6, NE)

## STUDY 003 | CT-BASED<sup>1</sup>

**84%**  
ORR  
(95% CI: 67, 95)

**22%**  
CR

**18.5<sub>mo</sub>**  
MEDIAN DOR  
(95% CI: 12.6, NE)

24-hour inhibition of BTK was maintained at 100% in PBMCs and 94% to 100% in lymph nodes when taken at the recommended total daily dose of 320 mg. The clinical significance of 100% inhibition has not been established.<sup>1,2</sup>

Median follow-up time was 18.4 months for Study 206 and 18.8 months for Study 003<sup>3</sup>

BRUKINSA® (zanubrutinib) is a kinase inhibitor indicated for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy. 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.

**The most common adverse reactions (≥ 20%)** included neutrophil count decreased, platelet count decreased, upper respiratory tract infection, white blood cell count decreased, hemoglobin decreased, rash, bruising, diarrhea, and cough.

The efficacy of BRUKINSA was IRC-assessed in 2 clinical trials that included a total of 118 adult patients with MCL who received at least 1 prior therapy. Tumor response was according to the 2014 Lugano classification for both studies, and the primary efficacy endpoint was ORR as assessed by an IRC. Study BGB-3111-206 (Study 206): N=86, Phase 2, open-label, global, multicenter, single-arm trial; PET scans were required for response assessment. Study BGB-3111-AU-003 (Study 003): N=32, Phase 1/2, open-label, global, multicenter, single-arm trial; PET scans were not required for response assessment and the majority of patients were assessed by CT scan. BTK=Bruton's tyrosine kinase; CI=confidence interval; CR=complete response; CT=computed tomography; DOR=duration of response; IRC=independent review committee; NE=not estimable; ORR=overall response rate; PBMCs=peripheral blood mononuclear cells; PET=positron emission tomography.

## IMPORTANT SAFETY INFORMATION

### WARNINGS AND PRECAUTIONS

#### Hemorrhage

Fatal and serious hemorrhagic events have occurred in patients with hematological malignancies treated with BRUKINSA monotherapy. Grade 3 or higher bleeding events including intracranial and gastrointestinal hemorrhage, hematuria and hemothorax have been reported in 2% of patients treated with BRUKINSA monotherapy. Bleeding events of any grade, including purpura and petechiae, occurred in 50% of patients treated with BRUKINSA monotherapy.

Bleeding events have occurred in patients with and without concomitant antiplatelet or anticoagulation therapy. Co-administration of BRUKINSA with antiplatelet or anticoagulant medications may further increase the risk of hemorrhage.

Monitor for signs and symptoms of bleeding. Discontinue BRUKINSA if intracranial hemorrhage of any grade occurs. Consider the benefit-risk of withholding BRUKINSA for 3-7 days pre- and post-surgery depending upon the type of surgery and the risk of bleeding.

#### Infections

Fatal and serious infections (including bacterial, viral, or fungal) and opportunistic infections have occurred in patients with hematological malignancies treated with BRUKINSA monotherapy. Grade 3 or higher infections occurred in 23% of patients treated with BRUKINSA monotherapy. The most common Grade 3 or higher infection was pneumonia. Infections due to hepatitis B virus (HBV) reactivation have occurred.

Consider prophylaxis for herpes simplex virus, pneumocystis jiroveci pneumonia and other infections according to standard of care in patients who are at increased risk for infections. Monitor and evaluate patients for fever or other signs and symptoms of infection and treat appropriately.

#### Cytopenias

Grade 3 or 4 cytopenias, including neutropenia (27%), thrombocytopenia (10%) and anemia (8%) based on laboratory measurements, were reported in patients treated with BRUKINSA monotherapy.

Monitor complete blood counts during treatment and treat using growth factor or transfusions, as needed.

#### Second Primary Malignancies

Second primary malignancies, including non-skin carcinoma, have occurred in 9% of patients treated with BRUKINSA monotherapy. The most frequent second primary malignancy was skin cancer (basal cell carcinoma and squamous cell carcinoma of skin), reported in 6% of patients. Advise patients to use sun protection.

#### Cardiac Arrhythmias

Atrial fibrillation and atrial flutter have occurred in 2% of patients treated with BRUKINSA monotherapy. Patients with cardiac risk factors, hypertension, and acute infections may be at increased risk. Grade 3 or higher events were reported in 0.6% of patients treated with BRUKINSA monotherapy. Monitor signs and symptoms for atrial fibrillation and atrial flutter and manage as appropriate.

#### Embryo-Fetal Toxicity

Based on findings in animals, BRUKINSA can cause fetal harm when administered to a pregnant woman. Administration of zanubrutinib to pregnant rats during the period of organogenesis caused embryo-fetal toxicity including malformations at exposures that were 5 times higher than those reported in patients at the recommended dose of 160 mg twice daily. Advise women to avoid becoming pregnant while taking BRUKINSA and for at least 1 week after the last dose. Advise men to avoid fathering a child during treatment and for at least 1 week after the last dose.

If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus.

#### ADVERSE REACTIONS

The most common adverse reactions in > 10% of patients who received BRUKINSA were decreased neutrophil count (53%), decreased platelet count (39%), upper respiratory tract infection (38%), decreased white blood cell count (30%), decreased hemoglobin (29%), rash (25%), bruising (23%), diarrhea (20%), cough (20%), musculoskeletal pain (19%), pneumonia (18%), urinary tract infection (13%), hematuria (12%), fatigue (11%), constipation (11%), and hemorrhage (10%).

Of the 118 patients with MCL treated with BRUKINSA, 8 (7%) patients discontinued treatment due to adverse reactions in the trials. The most frequent adverse reaction leading to treatment discontinuation was pneumonia (3.4%). One (0.8%) patient experienced an adverse reaction leading to dose reduction (hepatitis B).

#### DRUG INTERACTIONS

**CYP3A Inhibitors:** When BRUKINSA is co-administered with a strong CYP3A inhibitor, reduce BRUKINSA dose to 80 mg once daily. For coadministration with a moderate CYP3A inhibitor, reduce BRUKINSA dose to 80 mg twice daily.

**CYP3A Inducers:** Avoid coadministration with moderate or strong CYP3A inducers.

#### SPECIFIC POPULATIONS

**Hepatic Impairment:** The recommended dose of BRUKINSA for patients with severe hepatic impairment is 80 mg orally twice daily.

#### INDICATION

BRUKINSA is a kinase inhibitor indicated for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy.

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.

**References:** 1. BRUKINSA [package insert]. BeiGene, Ltd; 2019. 2. Tam C, Trotman J, Opat S, et al. Phase 1 study of the selective BTK inhibitor zanubrutinib in B-cell malignancies and safety and efficacy evaluation in CLL. *Blood*. 2019;134(11):851-859. 3. Data on file. BeiGene, Ltd. 2019.

Please see Brief Summary of full Prescribing Information on the following pages.



**BRIEF SUMMARY OF PRESCRIBING INFORMATION  
FOR BRUKINSA® (zanubrutinib)**

**SEE PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION**

**1 INDICATIONS AND USAGE**

BRUKINSA is indicated for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy.

This indication is approved under accelerated approval based on overall response rate [see *Clinical Studies (14.1)*]. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

**4 CONTRAINDICATIONS:** None.

**5 WARNINGS AND PRECAUTIONS**

**5.1 Hemorrhage**

Fatal and serious hemorrhagic events have occurred in patients with hematological malignancies treated with BRUKINSA monotherapy. Grade 3 or higher bleeding events including intracranial and gastrointestinal hemorrhage, hematuria, and hemothorax have been reported in 2% of patients treated with BRUKINSA monotherapy. Bleeding events of any grade, including purpura and petechiae, occurred in 50% of patients treated with BRUKINSA monotherapy.

Bleeding events have occurred in patients with and without concomitant antiplatelet or anticoagulation therapy. Co-administration of BRUKINSA with antiplatelet or anticoagulant medications may further increase the risk of hemorrhage.

Monitor for signs and symptoms of bleeding. Discontinue BRUKINSA if intracranial hemorrhage of any grade occurs. Consider the benefit-risk of withholding BRUKINSA for 3-7 days pre- and post-surgery depending upon the type of surgery and the risk of bleeding.

**5.2 Infections**

Fatal and serious infections (including bacterial, viral, or fungal) and opportunistic infections have occurred in patients with hematological malignancies treated with BRUKINSA monotherapy. Grade 3 or higher infections occurred in 23% of patients treated with BRUKINSA monotherapy. The most common Grade 3 or higher infection was pneumonia. Infections due to hepatitis B virus (HBV) reactivation have occurred.

Consider prophylaxis for herpes simplex virus, pneumocystis jiroveci pneumonia, and other infections according to standard of care in patients who are at increased risk for infections. Monitor and evaluate patients for fever or other signs and symptoms of infection and treat appropriately.

**5.3 Cytopenias**

Grade 3 or 4 cytopenias, including neutropenia (27%), thrombocytopenia (10%), and anemia (8%) based on laboratory measurements, were reported in patients treated with BRUKINSA monotherapy.

Monitor complete blood counts during treatment and treat using growth factor or transfusions, as needed.

**5.4 Second Primary Malignancies**

Second primary malignancies, including non-skin carcinoma, have occurred in 9% of patients treated with BRUKINSA monotherapy. The most frequent second primary malignancy was skin cancer (basal cell carcinoma and squamous cell carcinoma of skin), reported in 6% of patients. Advise patients to use sun protection.

**5.5 Cardiac Arrhythmias**

Atrial fibrillation and atrial flutter have occurred in 2% of patients treated with BRUKINSA monotherapy. Patients with cardiac risk factors, hypertension, and acute infections may be at increased risk. Grade 3 or higher events were reported in 0.6% of patients treated with BRUKINSA monotherapy. Monitor signs and symptoms for atrial fibrillation and atrial flutter and manage as appropriate.

**5.6 Embryo-Fetal Toxicity**

Based on findings in animals, BRUKINSA can cause fetal harm when administered to a pregnant woman. Administration of zanubrutinib to pregnant rats during the period of organogenesis caused embryo-fetal toxicity, including malformations at exposures that were 5 times higher than those reported in patients at the recommended dose of 160 mg twice daily. Advise women to avoid becoming pregnant while taking BRUKINSA and for at least 1 week after the last dose. Advise men to avoid fathering a child during treatment and for at least 1 week after the last dose. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus [see *Use in Specific Populations (8.1)*].

**6 ADVERSE REACTIONS**

The following clinically significant adverse reactions are discussed in more detail in other sections of the labeling:

- Hemorrhage [see *Warnings and Precautions (5.1)*]
- Infections [see *Warnings and Precautions (5.2)*]
- Cytopenias [see *Warnings and Precautions (5.3)*]
- Second Primary Malignancies [see *Warnings and Precautions (5.4)*]
- Cardiac Arrhythmias [see *Warnings and Precautions (5.5)*]

**6.1 Clinical Trials Experience**

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The data in the WARNINGS AND PRECAUTIONS reflect exposure to BRUKINSA as a single agent at 160 mg twice daily in 524 patients in clinical trials BGB-3111-AU-003, BGB-3111-206, BGB-3111-205, BGB-3111-210, and BGB-3111-1002 and to BRUKINSA at 320 mg once daily in 105 patients in trials BGB-3111-AU-003 and BGB-3111-1002. Among 629 patients receiving BRUKINSA, 79% were exposed for 6 months or longer and 61% were exposed for greater than one year.

In this pooled safety population, the most common adverse reactions in > 10% of patients who received BRUKINSA were neutrophil count decreased (53%), platelet count decreased (39%), upper respiratory tract infection (38%), white blood cell count decreased (30%), hemoglobin decreased (29%), rash (25%), bruising (23%), diarrhea (20%), cough (20%), musculoskeletal pain (19%), pneumonia (18%), urinary tract infection (13%), hematuria (12%), fatigue (11%), constipation (11%), and hemorrhage (10%).

**Mantle Cell Lymphoma (MCL)**

The safety of BRUKINSA was evaluated in 118 patients with MCL who received at least one prior therapy in two single-arm clinical trials, BGB-3111-206 [NCT03206970] and BGB-3111-AU-003 [NCT02343120] [see *Clinical Studies (14.1)*]. The median age of patients who received BRUKINSA in studies BGB-3111-206 and BGB-3111-AU-003 was 62 years (range: 34 to 86), 75% were male, 75% were Asian, 21% were White, and 94% had an ECOG performance status of 0 to 1. Patients had a median of 2 prior lines of therapy (range: 1 to 4). The BGB-3111-206 trial required a platelet count  $\geq 75 \times 10^9/L$  and an absolute neutrophil count  $\geq 1 \times 10^9/L$  independent of growth factor support, hepatic enzymes  $\leq 2.5 \times$  upper limit of normal, total bilirubin  $\leq 1.5 \times$  ULN. The BGB-3111-AU-003 trial required a platelet count  $\geq 50 \times 10^9/L$  and an absolute neutrophil count  $\geq 1 \times 10^9/L$  independent of growth factor support, hepatic enzymes  $\leq 3 \times$  upper limit of normal, total bilirubin  $\leq 1.5 \times$  ULN. Both trials required a CLcr  $\geq 30$  mL/min. Both trials excluded patients with prior allogeneic hematopoietic stem cell transplant, exposure to a BTK inhibitor, known infection with HIV, and serologic evidence of active hepatitis B or hepatitis C infection and patients requiring strong CYP3A inhibitors or strong CYP3A inducers. Patients received BRUKINSA 160 mg twice daily or 320 mg once daily. Among patients receiving BRUKINSA, 79% were exposed for 6 months or longer and 68% were exposed for greater than one year.

Fatal events within 30 days of the last dose of BRUKINSA occurred in 8 (7%) of 118 patients with MCL. Fatal cases included pneumonia in 2 patients and cerebral hemorrhage in one patient.

Serious adverse reactions were reported in 36 patients (31%). The most frequent serious adverse reactions that occurred were pneumonia (11%) and hemorrhage (5%).

Of the 118 patients with MCL treated with BRUKINSA, 8 (7%) patients discontinued treatment due to adverse reactions in the trials. The most frequent adverse reaction leading to treatment discontinuation was pneumonia (3.4%). One (0.8%) patient experienced an adverse reaction leading to dose reduction (hepatitis B).

Table 3 summarizes the adverse reactions in BGB-3111-206 and BGB-3111-AU-003.

**Table 3: Adverse Reactions ( $\geq 10\%$ ) in Patients Receiving BRUKINSA in BGB-3111-206 and BGB-3111-AU-003 Trials**

Body System	Adverse Reaction	Percent of Patients (N=118)	
		All Grades %	Grade 3 or Higher %
Blood and lymphatic system disorders	Neutropenia and Neutrophil count decreased	38	15
	Thrombocytopenia and Platelet count decreased	27	5
	Leukopenia and White blood count decreased	25	5
	Anemia and Hemoglobin decreased	14	8
Infections and infestations	Upper respiratory tract infection <sup>¶</sup>	39	0
	Pneumonia <sup>§</sup>	15	10 <sup>^</sup>
	Urinary tract infection	11	0.8
Skin and subcutaneous tissue disorders	Rash <sup>  </sup>	36	0
	Bruising <sup>*</sup>	14	0
Gastrointestinal disorders	Diarrhea	23	0.8
	Constipation	13	0
Vascular disorders	Hypertension	12	3.4
	Hemorrhage <sup>†</sup>	11	3.4 <sup>^</sup>

**Table 3: Adverse Reactions (≥ 10%) in Patients Receiving BRUKINSA in BGB-3111-206 and BGB-3111-AU-003 Trials (continued)**

Musculoskeletal and connective tissue disorders	Musculoskeletal pain <sup>‡</sup>	14	3.4
Metabolism and nutrition disorders	Hypokalemia	14	1.7
Respiratory, thoracic and mediastinal disorders	Cough	12	0

<sup>^</sup> Includes fatal adverse reaction

<sup>\*</sup> Bruising includes all related terms containing bruise, bruising, contusion, ecchymosis

<sup>†</sup> Hemorrhage includes all related terms containing hemorrhage, hematoma

<sup>‡</sup> Musculoskeletal pain includes musculoskeletal pain, musculoskeletal discomfort, myalgia, back pain, arthralgia, arthritis

<sup>§</sup> Pneumonia includes pneumonia, pneumonia fungal, pneumonia cryptococcal, pneumonia streptococcal, atypical pneumonia, lung infection, lower respiratory tract infection, lower respiratory tract infection bacterial, lower respiratory tract infection viral

<sup>||</sup> Rash includes all related terms containing rash

<sup>¶</sup> Upper respiratory tract infection includes upper respiratory tract infection, upper respiratory tract infection viral

Other clinically significant adverse reactions that occurred in < 10% of patients with mantle cell lymphoma include major hemorrhage (defined as ≥ Grade 3 hemorrhage or CNS hemorrhage of any grade) (5%), hyperuricemia (6%) and headache (4.2%).

**Table 4: Selected Laboratory Abnormalities\* (> 20%) in Patients with MCL in Studies BGB-3111-206 and BGB-3111-AU-003**

Laboratory Parameter	Percent of Patients (N=118)	
	All Grades (%)	Grade 3 or 4 (%)
Neutrophils decreased	45	20
Platelets decreased	40	7
Hemoglobin decreased	27	6
Lymphocytosis <sup>†</sup>	41	16
<b>Chemistry abnormalities</b>		
Blood uric acid increased	29	2.6
ALT increased	28	0.9
Bilirubin increased	24	0.9

\* Based on laboratory measurements.

<sup>†</sup> Asymptomatic lymphocytosis is a known effect of BTK inhibition.

## 7 DRUG INTERACTIONS

### 7.1 Effect of Other Drugs on BRUKINSA

**Table 5: Drug Interactions that Affect Zanubrutinib**

<b>Moderate and Strong CYP3A Inhibitors</b>	
<i>Clinical Impact</i>	• Co-administration with a moderate or strong CYP3A inhibitor increases zanubrutinib C <sub>max</sub> and AUC [see <i>Clinical Pharmacology (12.3)</i> ] which may increase the risk of BRUKINSA toxicities.
<i>Prevention or management</i>	• Reduce BRUKINSA dosage when co-administered with moderate or strong CYP3A inhibitors [see <i>Dosage and Administration (2.3)</i> ].
<b>Moderate and Strong CYP3A Inducers</b>	
<i>Clinical Impact</i>	• Co-administration with a moderate or strong CYP3A inducer decreases zanubrutinib C <sub>max</sub> and AUC [see <i>Clinical Pharmacology (12.3)</i> ] which may reduce BRUKINSA efficacy.
<i>Prevention or management</i>	• Avoid co-administration of BRUKINSA with moderate or strong CYP3A inducers [see <i>Dosage and Administration (2.3)</i> ].

## 8 USE IN SPECIFIC POPULATIONS

### 8.1 Pregnancy

#### Risk Summary

Based on findings in animals, BRUKINSA can cause fetal harm when administered to pregnant women. There are no available data on BRUKINSA use in pregnant women to evaluate for a drug-associated risk of major birth defects, miscarriage or adverse maternal or fetal outcomes. In animal reproduction studies, oral administration of zanubrutinib to pregnant rats during the period of organogenesis was associated with fetal heart malformation at approximately 5-fold human exposures (see *Data*). Women should be advised to avoid pregnancy while taking BRUKINSA. If BRUKINSA is used during pregnancy, or if the patient becomes pregnant while taking BRUKINSA, the patient should be apprised of the potential hazard to the fetus.

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

#### Data

##### Animal Data

Embryo-fetal development toxicity studies were conducted in both rats and rabbits. Zanubrutinib was administered orally to pregnant rats during the period of organogenesis at doses of 30, 75, and 150 mg/kg/day. Malformations in the heart (2- or 3-chambered hearts) were noted at all dose levels in the absence of maternal toxicity. The dose of 30 mg/kg/day is approximately 5 times the exposure (AUC) in patients receiving the recommended dose of 160 mg twice daily.

Administration of zanubrutinib to pregnant rabbits during the period of organogenesis at 30, 70, and 150 mg/kg/day resulted in post-implantation loss at the highest dose. The dose of 150 mg/kg is approximately 32 times the exposure (AUC) in patients at the recommended dose and was associated with maternal toxicity.

In a pre- and post-natal developmental toxicity study, zanubrutinib was administered orally to rats at doses of 30, 75, and 150 mg/kg/day from implantation through weaning. The offspring from the middle and high dose groups had decreased body weights preweaning, and all dose groups had adverse ocular findings (e.g. cataract, protruding eye). The dose of 30 mg/kg/day is approximately 5 times the AUC in patients receiving the recommended dose.

### 8.2 Lactation

#### Risk Summary

There are no data on the presence of zanubrutinib or its metabolites in human milk, the effects on the breastfed child, or the effects on milk production. Because of the potential for serious adverse reactions from BRUKINSA in a breastfed child, advise lactating women not to breastfeed during treatment with BRUKINSA and for at least two weeks following the last dose.

### 8.3 Females and Males of Reproductive Potential

#### Pregnancy Testing

Pregnancy testing is recommended for females of reproductive potential prior to initiating BRUKINSA therapy.

#### Contraception

##### Females

BRUKINSA can cause embryo-fetal harm when administered to pregnant women [see *Use in Specific Populations (8.1)*]. Advise female patients of reproductive potential to use effective contraception during treatment with BRUKINSA and for at least 1 week following the last dose of BRUKINSA. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be informed of the potential hazard to a fetus.

##### Males

Advise men to avoid fathering a child while receiving BRUKINSA and for at least 1 week following the last dose of BRUKINSA.

### 8.4 Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

### 8.5 Geriatric Use

Of the 641 patients in clinical studies with BRUKINSA, 49% were ≥ 65 years of age, while 16% were ≥ 75 years of age. No overall differences in safety or effectiveness were observed between younger and older patients.

### 8.6 Renal Impairment

No dosage modification is recommended in patients with mild to moderate renal impairment (CL<sub>cr</sub> ≥ 30 mL/min, estimated by Cockcroft-Gault). Monitor for BRUKINSA adverse reactions in patients with severe renal impairment (CL<sub>cr</sub> < 30 mL/min) or on dialysis [see *Clinical Pharmacology (12.3)*].

### 8.7 Hepatic Impairment

Dosage modification of BRUKINSA is recommended in patients with severe hepatic impairment [see *Dosage and Administration (2.2)*]. The safety of BRUKINSA has not been evaluated in patients with severe hepatic impairment. No dosage modification is recommended in patients with mild to moderate hepatic impairment. Monitor for BRUKINSA adverse reactions in patients with hepatic impairment [see *Clinical Pharmacology (12.3)*].

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# About Our Exhibitors

## **Adaptive Biotechnologies**

Adaptive Biotechnologies is a commercial-stage biotech company focused on harnessing the inherent biology of the adaptive immune system to transform the diagnosis and treatment of disease. Our proprietary immune medicine platform reveals and translates the massive genetics of the adaptive immune system with scale, precision and speed. Adaptive's goal is to develop and commercialize immune-driven diagnostics and therapeutics tailored to each individual patient.

## **ADC Therapeutics**

ADC Therapeutics is a commercial-stage biotechnology company improving the lives of cancer patients with its next-generation, targeted antibody drug conjugates (ADCs). ADC Therapeutics is advancing its proprietary PBD-based ADC technology to transform the treatment paradigm for patients with hematologic malignancies and solid tumors.

## **Amgen**

Amgen Oncology is committed to the relentless pursuit of breakthroughs for cancer patients and their families. Our portfolio features many first-in-class oncology/hematology medicines and innovative therapies for difficult-to-treat cancers.

## **Astellas Pharma US, Inc.**

Astellas is committed to turning innovative science into medical solutions that bring value and hope to patients and their families. Keeping our focus on addressing unmet medical needs and conducting our business with ethics and integrity enables us to improve the health of people throughout the U.S. and around the world.

## **AstraZeneca**

AstraZeneca is a global, science-led biopharmaceutical company that focuses on the discovery, development and commercialization of prescription medicines, primarily for the treatment of diseases in three therapy areas - Oncology, Cardiovascular, Renal & Metabolism and Respiratory & Immunology. For more information, please visit [www.astrazeneca-us.com](http://www.astrazeneca-us.com) and follow us on Twitter @AstraZenecaUS.

## **Bristol Myers Squibb**

Bristol Myers Squibb is a leading global biopharma company focused on discovering, developing and delivering innovative medicines for patients with serious diseases in areas including oncology, hematology, immunology, cardiovascular and neuroscience. Our employees work every day to transform patients' lives through science.

## **EUSA Pharma**

EUSA Pharma is a global biopharmaceutical company focused on oncology and rare disease, continuously striving to confront gaps in patient care. Our ambition drives us to provide medical treatments that support real change to improve lives. EUSA Pharma is committed to delivering solutions that can have a meaningful effect on life, helping patients across a range of therapeutic areas.

## **Genentech, Inc.**

For more than 40 years, we've been following the science & seeking solutions to unmet medical needs. As a proud member of the Roche Group, we make medicines to treat patients with serious medical conditions.

### **Access the Virtual Exhibition Hall:**

All attendees are invited to visit these booths via access through the Digitell platform. All registered attendees can use the log-in information provided for access to the Congress.

# About Our Exhibitors

## **GSK Medical**

GSK is focused on maximizing patient survival through transformational medicines. GSK's oncology pipeline is focused on immuno-oncology, cell therapy, cancer epigenetics and synthetic lethality. Our goal is to achieve a sustainable flow of new treatments based on a diversified portfolio of investigational medicines utilizing modalities such as small molecules, antibodies, antibody drug conjugates and cells, either alone or in combination.

## **Harborside**

Harborside is a medical media company whose products, partnerships and solutions have made it a destination that has earned the trust of clinicians, professional societies, and healthcare marketers. Harborside publishes *JNCCN—Journal of the National Comprehensive Cancer Network*, *The ASCO Post* and *Journal of the Advanced Practitioner in Oncology (JADPRO)*. For more information, please visit [HarborsideNexus.com](http://HarborsideNexus.com).

## **Incyte**

Incyte is a Wilmington, Delaware-based, global biopharmaceutical company focused on finding solutions for serious unmet medical needs through the discovery, development and commercialization of proprietary therapeutics. For additional information on Incyte, please visit [Incyte.com](http://Incyte.com) and follow @Incyte.

## **Karyopharm Therapeutics Inc.**

Karyopharm Therapeutics Inc. is a commercial-stage pharmaceutical company pioneering novel cancer therapies and dedicated to the discovery, development, and commercialization of novel first-in-class drugs directed against nuclear export and related targets for the treatment of cancer and other major diseases. Karyopharm's Selective Inhibitor of Nuclear Export (SINE) compounds function by binding with and inhibiting the nuclear export protein XPO1. The company was founded in 2008 with a vision of pioneering a potentially new approach to treating patients with certain blood cancers.

## **Kite, a Gilead Company**

Kite, a Gilead Company, is a biopharmaceutical company based in Santa Monica, California. For more information about Kite, please visit [www.powerofkite.com](http://www.powerofkite.com).

## **Novartis**

Novartis is reimagining medicine to improve and extend people's lives. As a leading global medicines company, we use innovative science and digital technologies to create transformative treatments in areas of great medical need. In our quest to find new medicines, we consistently rank among the world's top companies investing in research and development. Novartis products reach more than 800 million people globally and we are finding innovative ways to expand access to our latest treatments. About 109,000 people of more than 145 nationalities work at Novartis around the world. Find out more at [www.novartis.com](http://www.novartis.com).

## **Oncopeptides, Inc.**

Oncopeptides was established solely to develop therapies for difficult-to-treat hematological diseases, and we are committed to bringing patients the treatments they need and the hope they deserve.

## **Pfizer Hematology**

At Pfizer Oncology, we are committed to advancing medicines wherever we believe we can make a meaningful difference in the lives of people living with cancer. Today, we have an industry-leading portfolio of 24 approved innovative cancer medicines and biosimilars across more than 30 indications, including breast, genitourinary, colorectal, blood and lung cancers, as well as melanoma.

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# About Our Exhibitors

## **Pharmacyclics LLC, An AbbVie Company**

Pharmacyclics is an AbbVie company based in Silicon Valley, California and focused on developing and commercializing small-molecule medicines for the treatment of cancers and immune-mediated diseases for which there is great unmet medical need. We seek to discover innovative therapies to improve standards of care and strive to help our patients rediscover the Magic of Normal.

## **Seagen Inc.**

Seagen Inc. is a global biotechnology company that discovers, develops, and commercializes medicines for cancer. The company has a pipeline of therapies at various stages of preclinical testing, clinical testing, and development. For more information visit [www.seagen.com](http://www.seagen.com).

## **Servier Pharmaceuticals**

Servier Pharmaceuticals is a commercial-stage pharmaceuticals company with a passion for innovation and improving the lives of patients, their families and caregivers. In the United States, Servier Pharmaceuticals is committed to building a robust portfolio, starting with oncology, with future growth driven by innovation in other areas of unmet medical need, leveraging Servier's global portfolio and seeking acquisitions, licensing deals and partnerships.

## **Taiho Oncology**

Taiho Oncology, Inc. is a different kind of pharmaceutical company. We have deep roots and unmatched agility that enable us to fulfill our purpose – making treatments for oncology. For almost two decades, Taiho Oncology has served as a clinical organization, where the people are the center of everything we do. Together we work urgently to discover and develop treatments that address today's unmet patient needs and apply the science behind them. As the field of oncology treatment evolves, we evolve with it. Technology, dedicated investigators and established facilities – these vast resources empower us. It's our work; it's our passion; it's our legacy.

## **Takeda**

At Takeda Oncology, we aspire to cure cancer, with inspiration from patients and innovation from everywhere. We are structured within Takeda to ensure a tight connection from research to development to commercialization and rapidly meet the needs of the cancer community, optimizing our ability to bring transformative medicines to market. With demonstrated leadership in the treatment of hematologic cancers and solid tumors, we propel cutting-edge science around the power of innate immunity to enhance and broaden the impact of immunotherapy.

We complement our deep in-house expertise with symbiotic partnerships to unlock promising science wherever it emerges. For more information: [www.takedaoncology.com](http://www.takedaoncology.com).

### **Access the Virtual Exhibition Hall:**

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# Patient Advocacy Pavilion

## **Aplastic Anemia and MDS International Foundation**

The Aplastic Anemia & MDS International Foundation is the world's leading non-profit health organization dedicated to supporting patients and their families who are living with aplastic anemia, myelodysplastic syndromes (MDS) and paroxysmal nocturnal hemoglobinuria (PNH) and related bone marrow failure diseases. We are a patient-focused, patient-centered organization serving patients and families throughout the three phases of bone marrow failure diseases:

- The life-changing phase of diagnosis
- The life threatening phase of treatment
- The lifelong phase of living with a chronic disease

The Aplastic Anemia & MDS International Foundation provides answers, support and hope to thousands of patients and their families around the world.

## **Bone Marrow & Cancer Foundation**

The Bone Marrow & Cancer Foundation, founded in 1992, is dedicated to improving the quality of life for cancer and transplant patients and their families by providing vital financial assistance, comprehensive resources, educational information, physician referrals, and emotional support programs.

Guided by a medical advisory board of nationally-recognized cancer specialists and working with hospitals across the United States, the Bone Marrow & Cancer Foundation is the only organization of its kind that does not limit assistance to a specific disease, type of transplant or age range. For the past 29 years, the Foundation has connected patients and their families with the services they need—from diagnosis through survivorship—to make effective decisions about treatment and its aftermath. All of the Foundation's programs and services are offered to patients and their families free of charge.

## **CLL Society**

CLL Society is an inclusive, patient-centric, physician-curated nonprofit organization that addresses the unmet needs of the chronic lymphocytic leukemia (CLL) community through patient education, advocacy, support, and research. We envision a world in which the entire CLL community can equitably access quality education, support, and care to lead healthier and richer lives. We encourage and support smart patients, providers, clinical trials, research, healthcare delivery systems, and therapies. We believe SMART PATIENTS GET SMART CARE™. Learn more at [cllsociety.org](http://cllsociety.org).

The CLL Society CLL/SLL Patient Education Toolkit is a professionally designed binder featuring pull-out sheets on dozens of topics that will provide your patients with just-in-time information to reinforce the education and care you are already providing. Each binder has a take-home paper version of the best available information pertinent to the current state of their CLL journey. This is a free resource for healthcare providers.

## **First Descents**

First Descents provides life-changing outdoor adventures for young adults impacted by cancer and other serious health conditions.

## **HealthTree Foundation/Myeloma Crowd**

HealthTree Foundation is a patient-driven, non-profit organization that empowers patients with rare diseases at each step of their disease journey – from diagnosis, throughout education, care and on to a cure.

### **Access the Virtual Exhibition Hall:**

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# Patient Advocacy Pavilion

## **International Myeloma Foundation (IMF)**

Founded in 1990, the International Myeloma Foundation (IMF) is the first and largest myeloma-specific charity in the world. With more than 525,000 members in 140 countries, the IMF serves myeloma patients, family members, and the medical community. The IMF provides a wide range of programs in the areas of Research, Education, Support, and Advocacy. The IMF Diversity Initiative's M-POWER project is partnering with cities across the U.S. to improve survival outcomes in African-American patients with multiple myeloma. Because myeloma is diagnosed twice as often in African Americans as in other individuals, M-POWER is empowering healthcare professionals, community leaders, neighborhoods, and families to break down barriers to excellent myeloma treatment by raising awareness.

## **Leukemia & Lymphoma Society (LLS)**

The Leukemia & Lymphoma Society® (LLS) is a global leader in the fight against cancer. The LLS mission: Cure leukemia, lymphoma, Hodgkin's disease and myeloma, and improve the quality of life of patients and their families. LLS funds lifesaving blood cancer research around the world, provides free information and support services, and is the voice for all blood cancer patients seeking access to quality, affordable, coordinated care.

[www.lls.org/PatientSupport](http://www.lls.org/PatientSupport)

## **The Myelodysplastic Syndromes (MDS) Foundation, Inc.**

The MDS Foundation is a global non-profit advocacy organization that for over 25 years has supported patients and their families as well as healthcare providers in the fields of MDS and its related diseases.

Our Vision - Every MDS patient will benefit from our initiatives and research as early as possible.

Our Mission - MDS Foundation supports and educates patients, their communities, and healthcare providers, and contributes to innovative research in the fields of MDS and its related continuum of diseases to better diagnose, control and ultimately cure these diseases.

## **Triage Cancer**

Triage Cancer provides education on legal and practical issues that may impact individuals diagnosed with cancer and their caregivers. Through free in-person and online educational events, materials, animated videos, and state-specific resources, Triage Cancer provides expert content on issues related to work, insurance, disability benefits, finances, estate planning, medical decision-making, and more. Triage Cancer also provides free one-on-one help to assist individuals understand their options and possible next steps through the Legal & Financial Navigation program, as well as [CancerFinances.org](http://CancerFinances.org), which helps people navigate finances after cancer.

### **Access the Virtual Exhibition Hall:**

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# MyelomaCrowd by HealthTree

At [myelomacrowd.org](http://myelomacrowd.org) and [healthtree.org](http://healthtree.org)



myelomacrowd.org  
Streaming News



HealthTree  
University



Myeloma Coach  
Mentoring Tool



HealthTree  
Cure Hub Patient Portal



Myeloma  
Community Events



Community  
Forums



Myeloma Specialist  
Directory



Muscles for  
Myeloma



Supporting myeloma patients and caregivers at every step of their myeloma journey



## WE'RE HERE TO HELP YOUR PATIENTS.

A blood cancer diagnosis can be overwhelming for your patients. Blood cancer patients, including those with leukemia, lymphoma and myeloma, can find hope, education, guidance and support from The Leukemia & Lymphoma Society (LLS).

Our Information Specialists complement the care you provide with FREE, in-depth personalized services that connect patients to financial assistance, patient education (including booklets, podcasts and webinars), online and in-person support, and the LLS Clinical Trial Support Center for assistance with clinical trials.

Patients and families can contact us at **800.955.4572** or go to [www.LLS.org/patient-support](http://www.LLS.org/patient-support).



LEUKEMIA &  
LYMPHOMA  
SOCIETY®

**BEATING CANCER IS IN OUR BLOOD.®**

# OUT LIVING IT

## OUR REACH

**10,000+**

PARTICIPANTS SERVED

**2,000+**

PARTICIPANTS ANNUALLY

**150+**

PROGRAMS ANNUALLY

**500+**

HOSPITAL PARTNERSHIPS

First Descents provides life-changing outdoor adventures for young adults impacted by cancer. FD empowers participants to surf, kayak and climb beyond their diagnosis, and connect with others doing the same. Our programs are free of charge, adaptive, and no prior experience is necessary.

Learn more at [firstdescents.org](http://firstdescents.org)



## Did You Know?

**The Myelodysplastic Syndromes (MDS) Foundation, Inc.** was

established by an international group of

physicians and researchers to provide an ongoing exchange of information relating to MDS.

Until the Foundation was set up, no formal working group had been devoted to MDS. Since its inception, we have conducted 15 international symposia in Austria, England, the United States (Chicago, Washington, DC), Spain (Barcelona, Valencia), Czech Republic, Sweden, France, Japan, Italy, Greece, Scotland, and Germany. The 16th International Congress will be held in Toronto, Canada on September 23-26, 2021.

A major **MDS Foundation** effort is our international information network. This network provides patients with referrals to Centers of Excellence, contact names for available clinical trials, sharing of new research and treatment options between physicians, and extension of educational support to physicians, nurses, pharmacists and patients.

In response to the needs expressed by patients, families, and healthcare professionals, we have established patient advocacy groups, research funding, and professional educational initiatives.

The MDS Foundation is a publicly supported organization, exempt from federal income tax under section 501(C)(3) of the IRS code.

Learn more about  
**The Myelodysplastic Syndromes Foundation, Inc.**  
and find additional resources here:  
[www.mds-foundation.org](http://www.mds-foundation.org)



# Dear Health Care Provider,

The CLL Society is pleased to offer you a CLL-specific **PATIENT EDUCATION TOOLKIT, free of charge.**

To preview the ToolKIT content you'll receive in the mail, go to: [cllsociety.org/kit](http://cllsociety.org/kit)

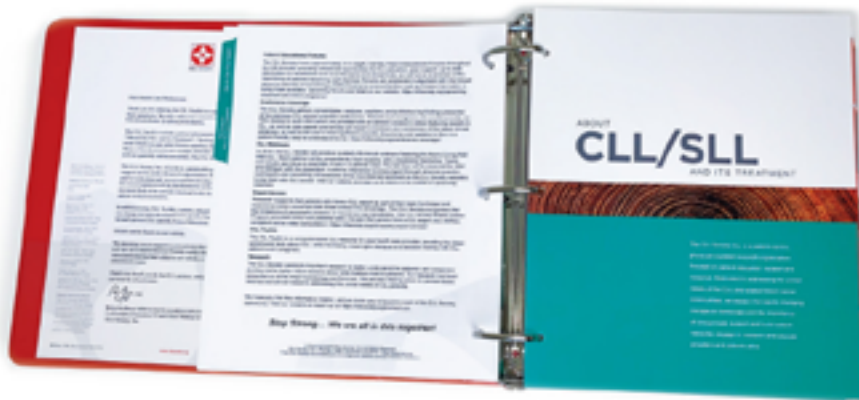
Please note that the actual ToolKIT contains multiple copies of handouts on each topic, allowing you to share time-appropriate information with your patients.

Order your free copy online to share with patients at [cllsociety.org/patient-education-toolkit-registration/](http://cllsociety.org/patient-education-toolkit-registration/).

We'll mail your ToolKIT and email you when updates are available.



- Curated, patient-friendly content written by CLL experts
- Supplements your patient education
- Patients leave your office with the specific handouts you choose
- Easy to download replacement pages when supplies run low
- Materials are updated whenever the therapeutic or regulatory landscape changes



**CLL SOCIETY**

*Smart Patients Get Smart Care™*

[cllsociety.org](http://cllsociety.org)

## **CANCERFINANCES.ORG**

A FREE TOOLKIT FOR NAVIGATING FINANCES AFTER CANCER

We know that cancer is expensive. This site will guide you through key topics that may impact your financial situation. Why trust CancerFinances.org?

**We dream of a world where everyone has access to information and resources needed to find their best path forward. Beyond diagnosis.**



### **YOU'RE NOT ALONE. WE CAN HELP.**

Designed so you feel like you're getting the one-on-one help you deserve, our toolkit covers a number of topics, including:

- Health Insurance
- Employment
- Disability Insurance
- Estate Planning
- Family Planning
- Financial Assistance Resources
- Life Insurance
- Clinical Trials
- Caregiving
- Genetics & Genomics
- Education
- Managing Finances & Medical Bills







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FACTOR

 XPOVIO<sup>®</sup>  
(selinexor)

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## YOUR PARTNER IN PATIENT CARE

### RESOURCES FOR PROFESSIONALS

- Scientific Symposium
- Satellite Symposiums: ASH and ONS
- Regional Bone Marrow Failure Symposia
- Free Online CME Programs at: [www.aamds.org/CME](http://www.aamds.org/CME)
- Research Grants
- MDS Tool Kit

### RESOURCES FOR YOUR PATIENTS

- Patient and Family Conferences
- Patient Education Webinars
- Podcasts for Patients
- Patient Education Materials
- Patient HelpLine
- Peer Support Network
- Patient Support Groups

For more information, contact  
**Alice Houk**, Senior Director of Patient and  
Professional Services, [houk@aamds.org](mailto:houk@aamds.org)

[www.aamds.org](http://www.aamds.org)  [#aamdsif](https://twitter.com/aamdsif)



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to learn more



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**The International Myeloma Foundation M-POWER project** is empowering health-care professionals, community leaders, neighborhoods, and families in cities across the country to help improve the short- and long-term outcomes of African-American patients with multiple myeloma.

**For more information, visit us at <https://mpower.myeloma.org>**

A photograph of a female doctor in a white coat with a stethoscope, smiling and talking to an older woman and a man in a light blue shirt.

**NCCN Virtual Reimbursement Resource Room**  
Reimbursement help and services available to patients with cancer navigating the oncology landscape.

The logo for the National Comprehensive Cancer Network (NCCN), consisting of a blue square with the letters "NCCN" in white.

National Comprehensive Cancer Network®

**[NCCN.org/reimbursement](https://www.nccn.org/reimbursement)**

# Below is a List of Resources Available to **You.**

## Scientific Resources, Medical Inquiries, and Research Support

- Pharmacyclics provides our medical community with timely, comprehensive medical information as well as data updates from national and regional conferences on approved Pharmacyclics products and relevant disease states.
- We assist current clinical research sites for company-sponsored trials with continued education of the study team on the study design, protocol activities, and data read-outs.

## Partnerships for Education

We provide non-promotional educational programs on approved Pharmacyclics products and supported disease states, including:



Disease state education



Clinical trial design overview



Product clinical overview, including efficacy, safety, and adverse event management



Medical conference data reviews


We are here for you and are happy to provide you with balanced and evidence-based scientific answers to your questions at our Medical Information website where you can submit your questions or search our medical information database.

[www.PharmacyclicsMedInfo.com](http://www.PharmacyclicsMedInfo.com)

 **pharmacyclics**<sup>®</sup>  
An AbbVie Company



The NCCN Clinical Practice Guidelines in Oncology (NCCN GUIDELINES<sup>®</sup>) for Multiple Myeloma recommend melphalan flufenamide + dexamethasone as a therapy option for previously treated multiple myeloma in patients who have received 4 prior lines and are triple-class refractory.<sup>1,a</sup>



# DISCOVER PEPAXTO A DIFFERENT BREED OF POWER

For adult patients with triple-class refractory multiple myeloma who have received 4 prior lines

<sup>a</sup>See NCCN Guidelines<sup>®</sup> for specific recommendation. The 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.

## INDICATION

PEPAXTO is indicated in combination with dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and one CD38-directed monoclonal antibody. This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

### Limitation of Use

PEPAXTO is not indicated and is not recommended for use as a conditioning regimen for transplant outside of controlled clinical trials.

## IMPORTANT SAFETY INFORMATION

PEPAXTO is contraindicated in patients with a history of serious allergic reaction to melphalan flufenamide or melphalan.

Please see additional Important Safety Information throughout.



**Pepaxto**<sup>®</sup>  
(melphalan flufenamide)  
injection for intravenous use 20 mg/vial



**Cancer patients need critical information.**

**NCCN Guidelines for Patients® are funded solely by donations and generous support to the NCCN Foundation.**

**You can help now!**

**Donate Now**



# Annual **2022** Conference

**SAVE THE DATE**

March 31 - April 2

Planning to return to Orlando, FL for an in-person experience! Virtual components are also planned!

[NCCN.org/conference](https://www.nccn.org/conference)



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Cancer Network®