You are invited to attend a VIRTUAL VYLOY® National Broadcast

VYLOY®
zolbetuximab-clzb
for injection 100mg vial

Learn about the first CLDN18.2-targeted therapy available in the U.S. for patients with locally advanced unresectable or metastatic HER2-negative gastric or gastroesophageal junction (GEJ) adenocarcinoma

KEY OBJECTIVES:

- Educate HCPs on the administration of this monoclonal antibody
- Discuss VYLOY and its appropriate use to treat patients with CLDN 18.2 positive gastric and GEJ cancers

PRESENTED BY:

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WHEN:

Thursday, December 5, 2024

Choose One:

BROADCAST 1

EASTERN	CENTRAL	MOUNTAIN	PACIFIC
12:30pm	**11:30am**	**10:30am**	**9:30am**

BROADCAST 2

EASTERN	CENTRAL	MOUNTAIN	PACIFIC
7:00pm	**6:00pm**	**5:00pm**	**4:00pm**

BROADCAST 3

EASTERN	CENTRAL	MOUNTAIN	PACIFIC
9:00pm	**8:00pm**	**7:00pm**	**6:00pm**

RSVP TODAY!

AstellasRegistration.com/VYLOY

INDICATION

VYLOY, in combination with fluoropyrimidine- and platinum-containing chemotherapy, is indicated for the first-line treatment of adults with locally advanced unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-negative gastric or gastroesophageal junction (GEJ) adenocarcinoma whose tumors are claudin (CLDN) 18.2 positive as determined by an FDA-approved test.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Hypersensitivity reactions, including serious anaphylaxis reactions, and serious and fatal infusion-related reactions (IRR) have been reported in clinical studies when VYLOY has been administered. **Any grade hypersensitivity reactions,** including anaphylactic reactions, occurring with VYLOY in combination with mFOLFOX6 or CAPOX was 18%. **Severe (Grade 3 or 4) hypersensitivity reactions,** including anaphylactic reactions, occurred in 2% of patients. Seven patients (1.3%) permanently discontinued VYLOY for hypersensitivity reactions, including two patients (0.4%) who permanently discontinued VYLOY due to anaphylactic reactions. Seventeen (3.2%) patients required dose interruption, and three patients (0.6%) required infusion rate reduction due to hypersensitivity reactions. **All grade IRRs** occurred in 3.2% in patients administered VYLOY in combination with mFOLFOX6 or CAPOX. Severe (Grade 3) IRRs occurred in 2 (0.4%) patients who received VYLOY. An IRR led to permanent discontinuation of VYLOY in 2 (0.4%) patients and dose interruption in 7 (1.3%) patients. The infusion rate was reduced for VYLOY for 2 (0.4%) patients due to an IRR. Monitor patients during infusion with VYLOY and for 2 hours after completion of infusion or longer if clinically indicated, for hypersensitivity reactions with symptoms and signs that are highly suggestive of anaphylaxis (urticaria, repetitive cough, wheeze and throat tightness/ change in voice). Monitor patients for signs and symptoms of IRRs including nausea, vomiting, abdominal pain, salivary hypersecretion, pyrexia, chest discomfort, chills, back pain, cough and hypertension. If a severe or life-threatening hypersensitivity or IRR reaction occurs, discontinue VYLOY permanently, treat symptoms according to standard medical care, and monitor until symptoms resolve. For any Grade 2 hypersensitivity or IRR, interrupt the VYLOY infusion until Grade ≤1, then resume at a reduced infusion rate for the remaining infusion. Follow Grade 2 management for Grade 3 infusion-related nausea and vomiting. Premedicate the patient with antihistamines for the subsequent infusions, and closely monitor the patient for symptoms and signs of a hypersensitivity reaction. The infusion rate may be gradually increased as tolerated.

Severe Nausea and Vomiting. VYLOY is emetogenic. Nausea and vomiting occurred more often during the first cycle of treatment. **All grade nausea and vomiting** occurred in 82% and 67% respectively of patients treated with VYLOY in combination with mFOLFOX6 and 69% and 66% in combination with CAPOX, respectively. **Severe (Grade 3) nausea** occurred in 16% and 9% of patients treated with VYLOY in combination with mFOLFOX6 or CAPOX respectively. **Severe (Grade 3) vomiting** occurred in 16% and 12% of patients treated with VYLOY in combination with mFOLFOX6 or CAPOX. Nausea led to permanent discontinuation of

Please see additional Important Safety Information on next page and click here for full Prescribing Information for VYLOY.

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IMPORTANT SAFETY INFORMATION

VYLOY in combination with mFOLFOX6 or CAPOX in 18 (3.4%) patients and dose interruption in 147 (28%) patients. Vomiting led to permanent discontinuation of VYLOY in combination with mFOLFOX6 or CAPOX in 20 (3.8%) patients and dose interruption in 150 (28%) patients. Pretreat with antiemetics prior to each infusion of VYLOY. Manage patients during and after infusion with antiemetics or fluid replacement. Interrupt the infusion, or permanently discontinue VYLOY based on severity.

ADVERSE REACTIONS

Most common adverse reactions (≥15%): Nausea, vomiting, fatigue, decreased appetite, diarrhea, peripheral sensory neuropathy, abdominal pain, constipation, decreased weight, hypersensitivity reactions, and pyrexia.

Most common laboratory abnormalities (≥15%): Decreased neutrophil count, decreased leucocyte count, decreased albumin, increased creatinine, decreased hemoglobin, increased glucose, decreased lymphocyte count, increased aspartate aminotransferase, decreased platelets, increased alkaline phosphatase, increased alanine aminotransferase, decreased glucose, decreased sodium, increased phosphate, decreased potassium, and decreased magnesium.

SPOTLIGHT Study: 279 patients with locally advanced unresectable or metastatic HER2-negative gastric or GEJ adenocarcinoma whose tumors were CLDN18.2 positive who received at least one dose of VYLOY in combination with mFOLFOX6

Serious adverse reactions occurred in 45% of patients treated with VYLOY in combination with mFOLFOX6; the **most common serious adverse reactions** (≥2%) were vomiting (8%), nausea (7%), neutropenia (2.9%), febrile neutropenia (2.9%), diarrhea (2.9%), intestinal obstruction (3.2%), pyrexia (2.5%), pneumonia (2.5%), respiratory failure (2.2%), pulmonary embolism (2.2%), decreased appetite (2.1%) and sepsis (2.0%). **Fatal adverse reactions** occurred in 5% of patients who received VYLOY in combination with mFOLFOX6 including sepsis (1.4%), pneumonia (1.1%), respiratory failure (1.1%), intestinal obstruction (0.7%), acute hepatic failure (0.4%), acute myocardial infarction (0.4%), death (0.4%), disseminated intravascular coagulation (0.4%), encephalopathy (0.4%), and upper gastrointestinal hemorrhage (0.4%). Permanent discontinuation of VYLOY due to an adverse reaction occurred in 20% of patients; the **most common adverse reactions leading to discontinuation** (≥2%) were nausea and vomiting. Dosage interruptions of VYLOY due to an adverse reaction occurred in 75% of patients; the **most common adverse reactions leading to dose interruption** (≥5%) were nausea, vomiting, neutropenia, abdominal pain, fatigue, and hypertension.

GLOW Study: 254 patients with locally advanced unresectable or metastatic HER2-negative gastric or GEJ adenocarcinoma whose tumors were CLDN18.2 positive who received at least one dose of VYLOY in combination with CAPOX

Serious adverse reactions occurred in 47% of patients treated with VYLOY in combination with CAPOX; the **most common serious adverse reactions** (≥2%) were vomiting (6%), nausea (4.3%), decreased appetite (3.9%), decreased platelet count (3.1%), upper gastrointestinal hemorrhage (2.8%), diarrhea (2.8%), pneumonia (2.4%), pulmonary embolism (2.3%), and pyrexia (2.0%). **Fatal adverse reactions** occurred in 8% of patients who received VYLOY in combination with CAPOX including sepsis (1.2%), pneumonia (0.4%), death (0.8%), upper gastrointestinal hemorrhage (0.8%), cerebral hemorrhage (0.8%), abdominal infection (0.4%), acute respiratory distress syndrome (0.4%), cardio-respiratory arrest (0.4%), decreased platelet count (0.4%), disseminated intravascular coagulation (0.4%), dyspnea (0.4%), gastric perforation (0.4%), hemorrhagic ascites (0.4%), procedural complication (0.4%), sudden death (0.4%), and syncope (0.4%). Permanent discontinuation of VYLOY due to an adverse reaction occurred in 19% of patients; the **most common adverse reaction leading to discontinuation** (≥2%) was vomiting. Dosage interruption of VYLOY due to an adverse reaction occurred in 55% of patients; the **most common adverse reactions leading to dose interruption** (≥2%) were nausea, vomiting, neutropenia, thrombocytopenia, anemia, fatigue, infusion-related reaction, and abdominal pain.

SPECIFIC POPULATIONS

Lactation Advise lactating women not to breastfeed during treatment with VYLOY and for 8 months after the last dose.

For full Prescribing Information for VYLOY® (zolbetuximab-clzb) visit: https://www.astellas.com/us/system/files/vyloy_pi.pdf

Astellas will not pay for or provide alcohol at this speaker program.

Astellas Pharma US, Inc. ("Astellas") is subject to U.S. Federal and State transparency laws that require Astellas to track and report meals and other transfers of value provided to certain U.S. health care professionals (including physicians). To comply with these obligations, for attendees who receive any portion of the meal provided at this program, Astellas will report the attendee's name and the value of the meal received. Astellas offers you the option to attend the event but not receive the meal. Please ask the Program Organizer for more information about this opt-out option.

Additional restrictions apply to the following individuals:

For U.S. Healthcare Providers in Vermont or those affiliated with the U.S. Department of Veterans Affairs or Department of Defense: Several states and federal agencies in the United States restrict your interactions with Astellas, including the provision of in-kind benefits (such as meals) at company-sponsored events. If you are a healthcare professional in Vermont or are affiliated with the U.S. Department of Veterans Affairs, Department of Defense, or other federal executive branch entity, Astellas policy prohibits providing you a meal at this program. If you would like to attend, but not partake in the meal, please refer to the opt-out option below.

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For State Government Employees: State ethics laws may prohibit you from accepting a meal. Astellas policy prohibits:
(1) **Colorado State Employees** from accepting from Astellas more than $50 annually in transfers of value, including meals; (2) **Louisiana State Employees** from accepting a meal that exceeds $60 in value; and (3) **New York State Employees** from accepting a meal that exceeds $15 in value. If you would like to attend, but not partake in the meal, please refer to the opt-out option below.

For Foreign Healthcare Providers: Some foreign countries restrict the provision of or require the reporting of in- kind benefits (such as meals) to health care professionals at company-sponsored events. Astellas has policies and procedures that are intended to help ensure compliance with these requirements and restrictions. To help ensure compliance with applicable requirements, Astellas policy prohibits providing a meal to you in conjunction with this event. If you would like to attend, but not partake in the meal, please refer to the opt-out option below.

Opt-Out Option: Astellas offers an opt-out option that allows you to still attend this event but not receive the meal. Please ask the Program Organizer for more information about the opt-out option.

Astellas has adopted the PhRMA Code on Interactions with Healthcare Professionals, which is designed to foster ethical relationships with healthcare professionals. In accordance with the PhRMA Code, we will not pay for the expenses of a healthcare professional's spouse or guest, and such individuals should not attend the program, unless they have a bona fide professional interest in the information being shared at the program. We appreciate your understanding and support of our commitment to these ethical standards.

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