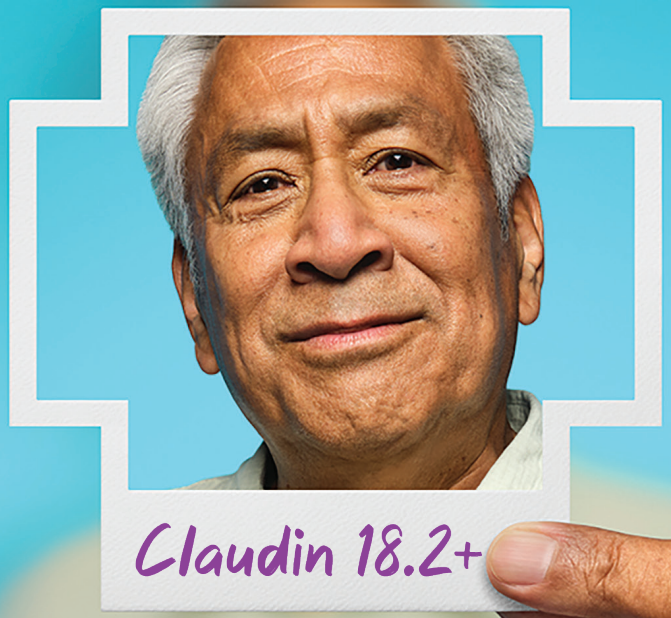
Focus on **who may benefit from treatment** with VYLOY.



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INDICATION

VYLOY™ (zolbetuximab), in combination with fluoropyrimidine- and platinum-containing chemotherapy, is indicated for the first-line treatment of adult patients with locally advanced unresectable or metastatic HER2-negative gastric or gastro-oesophageal junction adenocarcinoma whose tumours are Claudin (CLDN) 18.2 positive.

SELECTED SAFETY INFORMATION

VYLOY has **WARNINGS AND PRECAUTIONS** for: **Hypersensitivity reactions** (Monitor patients during and for at least 2 hours after infusion with VYLOY. Interrupt, slow the rate of infusion or permanently discontinue VYLOY based on severity and type of reaction. Premedicate with antihistamines for subsequent infusions after a hypersensitivity reaction); **Infusion related reactions** (Monitor patients for signs and symptoms of an IRR. Interrupt, slow the rate of infusion or permanently discontinue VYLOY based on severity of the IRR. Premedicate with antihistamines for subsequent infusions after an IRR); **Nausea and vomiting** (Premedicate patients with antiemetics prior to each infusion. Interrupt, slow the rate of infusion or permanently discontinue VYLOY based on the severity of the nausea and/or vomiting. Manage patients during and after infusion with antiemetics or fluid replacement).

astellas ONCOLOGY

Please see Important Safety Information on pages 14-15.

Lauren | Female, Age 72

Wife, grandmother

Retired interior designer

Painter

Hypothetical case, not an actual patient.

Please see Important Safety Information on pages 14-15.

Diagnosis: Locally Advanced Unresectable Gastric Cancer

PRESENTATION

Symptoms

- Upper abdominal pain, intermittent chest pressure lasting approximately 5 weeks

Medical History

- Gastroesophageal reflux disease (GERD), prior *H. pylori* infection, osteoarthritis

Relevant Family History

- Brother died from colon cancer at 66 years old

WORK UP

Notable Lab Results

- CBC, Hb 11.8 g/dL
- Normal WBC and PLT count, kidney and liver function, electrolyte, and CEA tests
- Normal stress test

Endoscopy/ Biopsy Results

- 3.7 cm mass in body of the stomach
- Biopsy demonstrated adenocarcinoma and intestinal-type histology

ECOG PS

- 1

Biomarker Testing

- Status unknown at diagnosis

How could biomarker testing help inform your first-line treatment strategy for Lauren?

CBC=complete blood count; **CEA**=carcinoembryonic antigen; **ECOG PS**=Eastern Cooperative Oncology Group Performance Status; **Hb**=hemoglobin; **PLT**=platelets; **WBC**=white blood cells.

Diagnosis: Metastatic Gastric Cancer

PRESENTATION

Symptoms

- Epigastric pain, decreased appetite, weight loss, and fatigue

Medical History

- Longstanding history of GERD, consumes 10-15 alcoholic beverages/week, prior gastrectomy and relapsed with metastatic disease

Relevant Family History

- None

WORK UP

Notable Lab Result

- CBC, WBC 3.2 x 10^3/µL
- CBC, PLT 125 x 10^3/µL
- ALT 130 U/L; AST 220 U/L
- Bilirubin 1.8 mg/dL
- Normal Hb, electrolyte, and CEA tests

Endoscopy/ Biopsy Results

- 1.5 cm lesion in the stomach
- Biopsy demonstrated adenocarcinoma and intestinal-type histology

Imaging Results

- One lesion in the stomach; regional lymph node involvement; multiple lesions in the liver

ECOG PS

- 1

Biomarker Testing

- CLDN18.2-positive*
- HER2-negative
- PD-L1 CPS <5

How would you focus your first-line treatment strategy on Paul?

*Moderate to strong membranous CLDN18 staining by IHC in ≥75% of tumour cells.[1]

ALT=alanine aminotransferase; **AST**=aspartate aminotransferase; **CBC**=complete blood count; **CEA**=carcinoembryonic antigen; **CLDN18.2**=Claudin 18.2; **CPS**=combined positive score; **ECOG PS**=Eastern Cooperative Oncology Group Performance Status; **GERD**=gastroesophageal reflux disease; **Hb**=hemoglobin; **HER2**=human epidermal growth factor receptor 2; **IHC**=immunohistochemistry; **PD-L1**=programmed death ligand 1; **PLT**=platelets; **WBC**=white blood cells.

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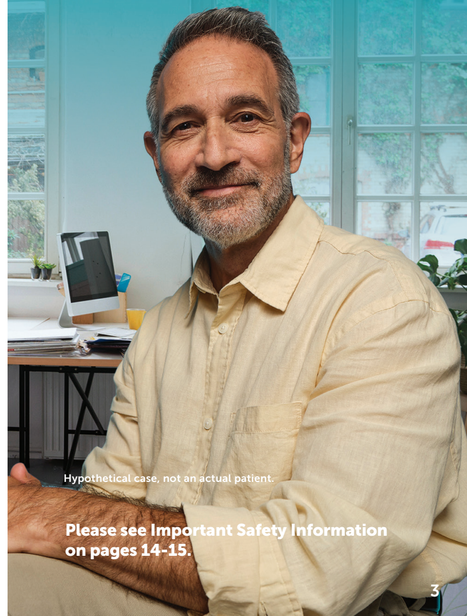
Paul | Male, Age 55

Husband, father of one

Salesperson

Playing music



Hypothetical case, not an actual patient.

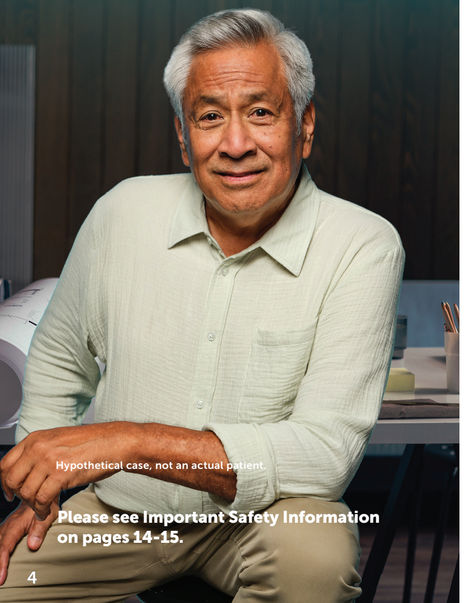
Please see Important Safety Information on pages 14-15.

James | Male, Age 61

Divorced, father of two

Engineer

Traveling



Hypothetical case, not an actual patient.

Please see Important Safety Information on pages 14-15.

Diagnosis: Metastatic Gastric Cancer

PRESENTATION

Symptoms

- Abrupt weight loss, decreased appetite, bloating after meals, and recurring upset stomach; worsening symptoms over approximately 3 months

Medical History

- Barrett's esophagus, overweight, BMI 27.4, prior gastrectomy and relapsed with metastatic disease

Relevant Family History

- Father died from gastric cancer at 50 years old

WORK UP

Notable Lab Results

- CBC, Hb 10.4 g/dL
- ALT 70 U/L; AST 180 U/L
- Bilirubin 1.7 mg/dL
- Normal WBC and PLT count, electrolyte, and CEA tests

Endoscopy/ Biopsy Results

- 2 cm mass in body of the stomach
- Biopsy demonstrated adenocarcinoma and diffuse-type histology

Imaging Results

- One gastric mass; 2 lesions in the lower left lung

ECOG PS

- 1

Biomarker Testing

- CLDN18.2-positive*
- HER2-negative
- PD-L1 CPS >5

How would you focus your first-line treatment strategy on Jorge?

*Moderate to strong membranous CLDN18 staining by IHC in ≥75% of tumour cells.[1]

ALT=alanine aminotransferase; **AST**=aspartate aminotransferase; **BMI**=body mass index; **CBC**=complete blood count; **CEA**=carcinoembryonic antigen; **CLDN18.2**=Claudin 18.2; **CPS**=combined positive score; **ECOG PS**=Eastern Cooperative Oncology Group Performance Status; **Hb**=hemoglobin; **HER2**=human epidermal growth factor receptor 2; **PLT**=platelets; **PD-L1**=programmed death ligand 1; **WBC**=white blood cells.

Diagnosis: Locally Advanced Unresectable Gastro-oesophageal Junction Cancer

PRESENTATION

Symptoms

- Weight loss, indigestion, decreased appetite, and difficulty swallowing lasting approximately 2 months

Medical History

- Longstanding smoker, otherwise healthy

Relevant Family History

- None

WORK UP

Notable Lab Results

- CBC, Hb 10.6 g/dL
- CEA 18.2 ng/mL
- Normal WBC and PLT count, kidney and liver function, and electrolyte tests

Endoscopy/ Biopsy Results

- 3.1 cm mass extending into the gastro-oesophageal junction
- Biopsy demonstrated adenocarcinoma and diffuse-type histology

Imaging Results

- One large mass; prominent lymph nodes

ECOG PS

- Borderline 0-1

Biomarker Testing

- CLDN18.2-positive*
- HER2-negative
- PD-L1 CPS <5

How would you focus your first-line treatment strategy on Oliver?

*Moderate to strong membranous CLDN18 staining by IHC in ≥75% of tumour cells.[1]

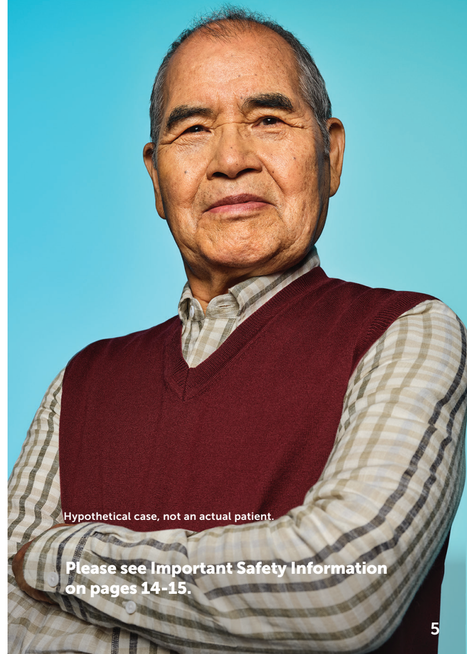
CBC=complete blood count; **CEA**=carcinoembryonic antigen; **CLDN18.2**=Claudin 18.2; **ECOG PS**=Eastern Cooperative Oncology Group Performance Status; **Hb**=hemoglobin; **HER2**=human epidermal growth factor receptor 2; **PLT**=platelets; **WBC**=white blood cells.

Oliver | Male, Age 67

Husband, grandfather

Graphic designer

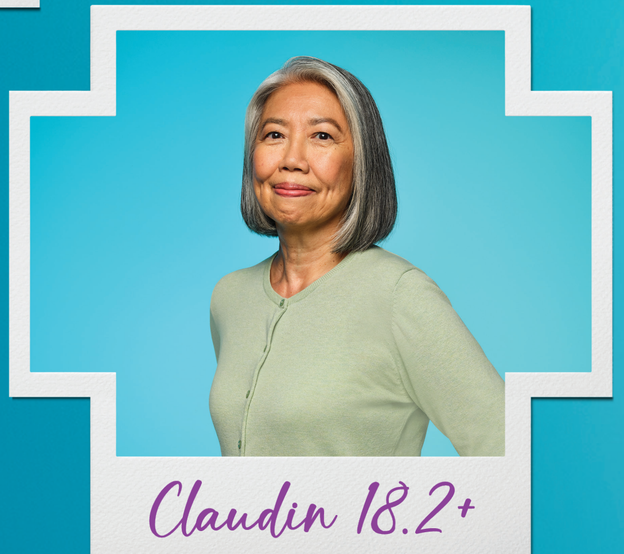
Hiking



Hypothetical case, not an actual patient.

Please see Important Safety Information on pages 14-15.

Claudin 18.2+



Claudin 18.2+

VYLOY is a first-in-class monoclonal antibody that specifically targets Claudin 18.2: a new and highly prevalent biomarker[1-7]

What is Claudin 18.2?

CLDN18.2 is typically confined within tight junctions of the healthy gastric mucosa. As tumours develop, it may be exposed and accessible to antibodies. CLDN18.2 is detectable via IHC.[8-10]

Testing for Claudin 18.2:

- IHC can be used to identify CLDN18.2 protein expression and positivity[2,3]
- Testing for CLDN18.2 can be implemented into your laboratory workflow alongside HER2 and other biomarkers[2,3,5,11]

BASED ON TWO GLOBAL PHASE 3 CLINICAL TRIALS, IT IS ESTIMATED THAT:

38% **OF PATIENTS** with advanced* gastric/GEJ cancer are CLDN18.2+,† which could make them candidates for VYLOY + chemotherapy[2-3‡]

To find those patients, start by testing for CLDN18.2 positivity at diagnosis with IHC

*Locally advanced unresectable or metastatic.[2,3]

†CLDN18.2+ (Claudin 18.2 positive) is defined as ≥75% of tumour cells demonstrating moderate to strong membranous staining by IHC.[2,3]

‡Data from 2 global randomised Phase 3 studies: SPOTLIGHT, which included 2,403 assessable patients, of which 922 were CLDN18.2 positive; and GLOW, which included 2,104 assessable patients, of which 808 were CLDN18.2 positive.[2,3]

CLDN18.2=Claudin 18.2; **HER2**=human epidermal growth factor receptor 2; **IHC**=immunohistochemistry; **G/GEJ**=gastric/gastro-oesophageal junction.

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In the SPOTLIGHT Phase 3 trial, VYLOY + mFOLFOX6 were evaluated against mFOLFOX6 alone[2]

SPOTLIGHT (N=565)

Patients with CLDN18.2-positive*, HER2-negative†, previously untreated‡ locally advanced unresectable or metastatic G/GEJ adenocarcinoma

Randomised 1:1

- **VYLOY + mFOLFOX6 (n=283)**[§]
- **PLACEBO + mFOLFOX6 (n=282)**[‖]

Treatment continued until disease progression, development of toxic effects, start of another anticancer treatment, or other discontinuation criteria were met, as specified in the protocol

PRIMARY ENDPOINT	KEY SECONDARY ENDPOINTS	SELECT SECONDARY ENDPOINTS
Progression-Free Survival (PFS)	Overall Survival (OS), Time to Confirmed Deterioration (TTCD)	Objective Response Rate (ORR), Duration of Response (DOR), Safety and Tolerability

*Tumour expresses CLDN18.2 in ≥75% of tumour cells demonstrating moderate to strong membranous staining as determined by central IHC testing.[2]

† HER2-negative tumour as determined by local or central testing on a gastric or GEJ tumour specimen.[2]

‡ No prior systemic chemotherapy.[2]

§ VYLOY was administered at a loading dose of 800 mg/m^2 IV on Cycle 1 Day 1 followed by 600 mg/m^2 IV every 3 weeks. Additionally, 12 treatments of mFOLFOX6 were administered over 4 cycles (42 days per cycle) on Days 1, 15, and 29. After 4 cycles of treatment, subjects continued to receive fluorouracil (5-FU) and folinic acid at the investigator's discretion until the subject met study treatment discontinuation criteria. Patients were allowed to continue treatment with VYLOY, 5-fluorouracil, and folinic acid (leucovorin or local equivalent) at the discretion of the investigator, until disease progression, development of toxic effects, start of another anticancer treatment, or other discontinuation criteria were met, as specified in the protocol.[2]

‖ Placebo was administered on Cycle 1 Day 1 and every 3 weeks thereafter. Additionally, 12 treatments of mFOLFOX6 were administered over 4 cycles (42 days per cycle) on Days 1, 15, and 29. After 12 mFOLFOX6 treatments, subjects continued to receive fluorouracil (5-FU) and folinic acid at the investigator's discretion until the subject met study treatment discontinuation criteria. Patients were allowed to continue treatment with VYLOY, 5-fluorouracil, and folinic acid (leucovorin or local equivalent) at the discretion of the investigator, until disease progression, development of toxic effects, start of another anticancer treatment, or other discontinuation criteria were met, as specified in the protocol.[2]

CLDN18.2=Claudin 18.2; **G/GEJ**=gastric/gastro-oesophageal junction; **HER2**=human epidermal growth factor receptor 2; **IHC**=immunohistochemistry; **IV**=intravenous.

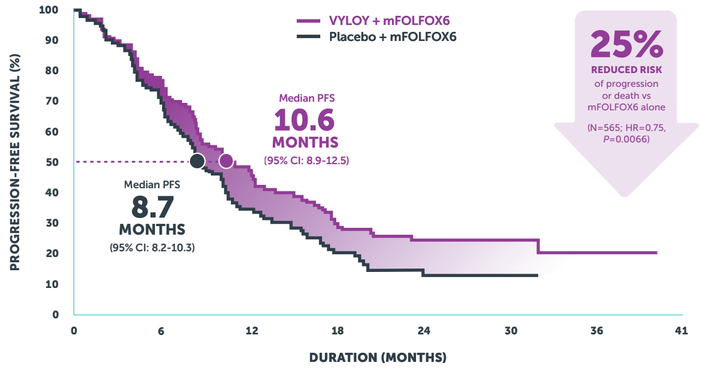
Please see Important Safety Information on pages 14-15.

In CLDN18.2+, HER2-, locally advanced unresectable or mG/GEJ cancer (vs placebo + mFOLFOX6)

VYLOY + mFOLFOX6 significantly improved progression-free survival (PFS)[2]

Median PFS was 10.6 months with VYLOY + mFOLFOX6 vs 8.7 months with mFOLFOX6 alone (HR=0.75 [95% CI: 0.60-0.94]; *P*=0.0066)[2]

PROGRESSION-FREE SURVIVAL (PRIMARY ENDPOINT)[2]*



PATIENTS AT RISK								
VYLOY + mFOLFOX6	283	187	78	33	12	7	2	0
Placebo + mFOLFOX6	282	168	56	19	8	2	0	0

*PFS was assessed per RECIST v1.1 by independent review committee.[2]

CI=confidence interval; **CLDN18.2**=Claudin 18.2; **HER2**=human epidermal growth factor receptor 2; **HR**=hazard ratio; **mG/GEJ**=metastatic gastric/gastro-oesophageal junction; **RECIST**=Response Evaluation Criteria in Solid Tumours.

Please see Important Safety Information on pages 14-15.

Sustained benefits in PFS were also seen at 12, 18, and 24 months (vs mFOLFOX6 alone)[2]

- **49% of patients** were still **progression free at 12 months** with VYLOY + mFOLFOX6 **vs 35%** with mFOLFOX6 alone
- **At 18 months: 31%** with VYLOY + mFOLFOX6 (**vs 21%** with mFOLFOX6 alone)
- **At 24 months: 24%** with VYLOY + mFOLFOX6 (**vs 15%** with mFOLFOX6 alone)

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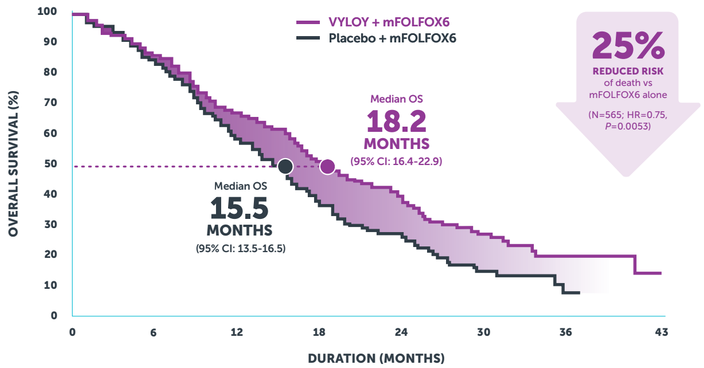
Overall survival (OS) significantly improved with first-line VYLOY + mFOLFOX6[2]

Median OS was 18.2 months with VYLOY + mFOLFOX6 vs 15.5 months with mFOLFOX6 alone (HR=0.75 [95% CI: 0.60-0.94]; *P*=0.0053)[2]

OVERALL SURVIVAL (SECONDARY ENDPOINT)[2]



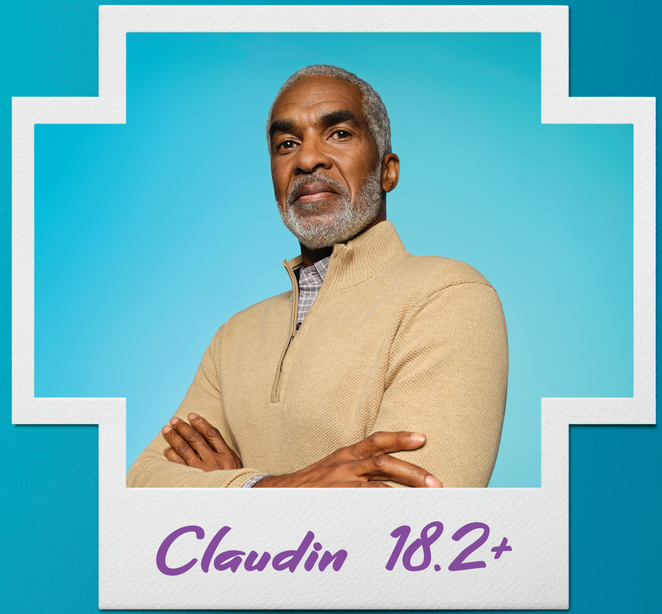
PATIENTS AT RISK								
VYLOY + mFOLFOX6	283	233	146	83	49	23	9	0
Placebo + mFOLFOX6	282	224	139	64	34	15	2	0

OS benefits were also sustained at 12, 18, and 24 months (vs mFOLFOX6 alone)[2]

- **68% of patients were still alive at 12 months** with VYLOY + mFOLFOX6 **vs 60%** with mFOLFOX6 alone
- **At 18 months: 51%** with VYLOY + mFOLFOX6 (**vs 38%** with mFOLFOX6 alone)
- **At 24 months: 39%** with VYLOY + mFOLFOX6 (**vs 28%** with mFOLFOX6 alone)

CI=confidence interval; **HR**=hazard ratio.

Please see Important Safety Information on pages 14-15.



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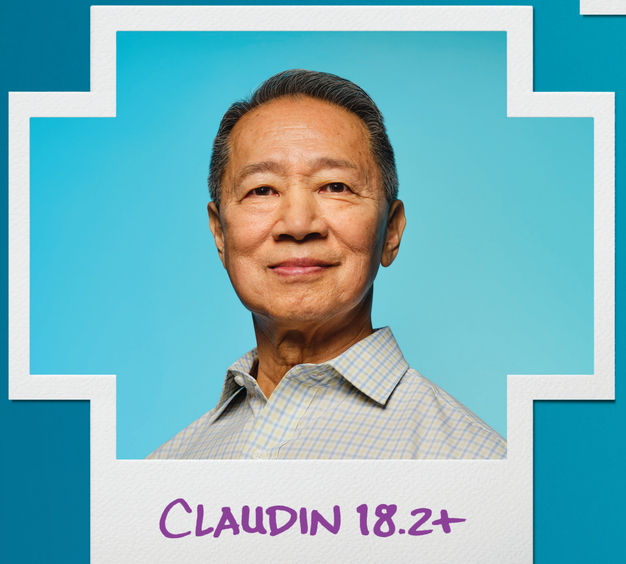

Start with VYLOY + chemotherapy* for a first-line treatment focused on CLDN18.2+, HER2-, advanced† G/GEJ cancer[1]

BASED ON TWO GLOBAL PHASE 3 CLINICAL TRIALS, IT IS ESTIMATED THAT:

38% OF PATIENTS with advanced† G/GEJ cancer are CLDN18.2+,‡ which could make them candidates for VYLOY + chemotherapy[2-3*§]

Test via IHC

TEST FOR CLDN18.2+ TUMOURS VIA IHC[2,3,5,11]:
Testing for CLDN18.2 can be run alongside HER2 and other biomarkers

18.2 month OS (median)

IMPROVED OVERALL SURVIVAL (OS)[2]:
Median OS was 18.2 months with VYLOY + mFOLFOX6 (vs 15.5 months with mFOLFOX6 alone, HR=0.75, *P*=0.0053)

10.6 month PFS (median)

IMPROVED PROGRESSION-FREE SURVIVAL (PFS)[2]:
Median PFS was 10.6 months with VYLOY + mFOLFOX6 (vs 8.7 months with mFOLFOX6 alone, HR=0.75, *P*=0.0066)

AEs

SAFETY PROFILE[2]:
Nausea (82%) and vomiting (67%) were the most frequently reported adverse events (AEs) with VYLOY + mFOLFOX6

TEST FOR CLDN18.2 AND BRING A NEW TREATMENT TARGET FOR ADVANCED‡ G/GEJ CANCER INTO FOCUS

*Fluoropyrimidine- and platinum-containing chemotherapy.[1]

† Locally advanced unresectable or metastatic.[1]

‡ CLDN18.2+ (Claudin 18.2 positive) is defined as ≥75% of tumour cells demonstrating moderate to strong membranous CLDN18 staining by IHC.[2,3]

§ Data from 2 global randomised Phase 3 studies; SPOTLIGHT, which included 2,403 assessable patients, of which 922 were CLDN18.2 positive; and GLOW, which included 2,104 assessable patients, of which 808 were CLDN18.2 positive.[2,3]

CLDN18.2=Claudin 18.2; **HER2**=human epidermal growth factor receptor 2; **HR**=hazard ratio; **G/GEJ**=gastric/gastro-oesophageal junction; **IHC**=immunohistochemistry.

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Important Safety Information

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Hypersensitivity reactions in patients treated with VYLOY in combination with fluoropyrimidine and platinum-containing chemotherapy during clinical studies were characterized by anaphylactic reaction or drug hypersensitivity. Monitor patients during and after infusion with VYLOY (at least 2 hours, or longer if clinically indicated) for hypersensitivity reactions with symptoms and signs that are highly suggestive of anaphylaxis (e.g., urticaria, repetitive cough, wheeze and throat tightness/change in voice). If an anaphylactic reaction occurs, administration of VYLOY should be immediately and permanently discontinued and appropriate medical therapy administered. For any Grade 3 or 4 hypersensitivity reaction or hypersensitivity reaction with features of anaphylaxis, administration of VYLOY should be immediately and permanently discontinued and appropriate medical therapy instituted based on the type of reaction. For any Grade 2 hypersensitivity reaction, interrupt the VYLOY infusion until Grade ≤1, then resume the infusion at a reduced infusion rate for the remaining infusion. Pre-medicate the patient with antihistamines for the next infusion, administer per the infusion rates in the VYLOY Singapore Approved Package Insert, and closely monitor the patient for symptoms and signs of a hypersensitivity reaction. The infusion rate may be gradually increased as tolerated.

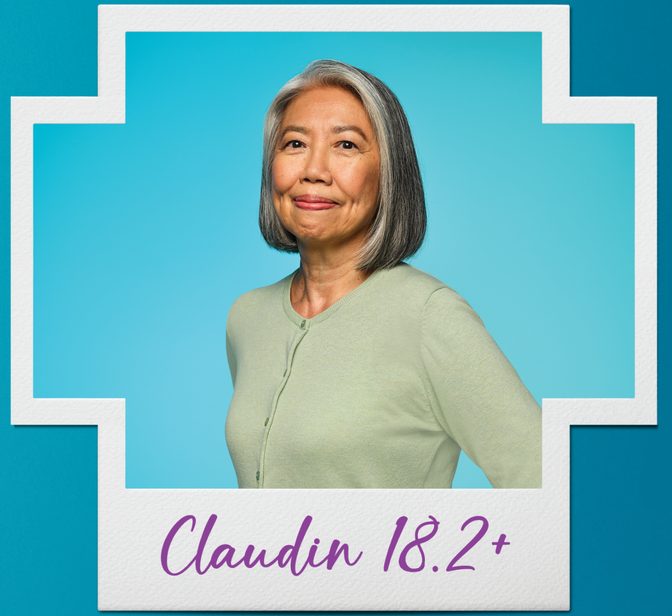
Infusion-related reaction (IRR) has occurred during clinical studies with Vyloy in combination with fluoropyrimidine and platinum-containing chemotherapy. Monitor patients for signs and symptoms of infusion-related reaction including nausea, vomiting, abdominal pain, salivary hypersecretion, pyrexia, chest discomfort, chills, back pain, cough and hypertension. These signs and symptoms are usually reversible with the interruption of the infusion. For Grade 3 or 4 IRRs, administration of Vyloy should be immediately and permanently discontinued and appropriate medical therapy instituted. For Grade 2 IRRs, interrupt the Vyloy infusion until Grade ≤1, then resume the infusion at a reduced infusion rate for the remaining infusion. Pre-medicate the patient with antihistamines for the next infusion, administer per the infusion rates in the VYLOY Singapore Approved Package Insert, and closely monitor the patient for symptoms and signs of an IRR. The infusion rate may be gradually increased as tolerated.

During clinical studies, **Nausea and vomiting** were the most frequently observed gastrointestinal (GI) adverse reactions with VYLOY in combination with fluoropyrimidine and platinum-containing chemotherapy treatment. Nausea and vomiting occurred more often during the first cycle of treatment but decreased in incidence with subsequent cycles of treatment. To prevent nausea and vomiting, pretreatment with a combination of antiemetics is recommended prior to each infusion of VYLOY. During and after infusion, patients should be monitored and managed using standard of care, including antiemetics or fluid replacement, as clinically indicated. For Grade 4 vomiting, permanently discontinue treatment with VYLOY. For Grade 2 or 3 nausea or vomiting, interrupt the VYLOY infusion until Grade ≤1, then resume at a reduced infusion rate for the remaining infusion. For the next infusion, administer per the infusion rates in Table 3, and closely monitor the patient for symptoms and signs of nausea or vomiting. The infusion rate may be gradually increased as tolerated.

Specific Populations

Lactation - Advice a lactating woman not to breastfeed during treatment with VYLOY.

Scan to view full VYLOY Singapore Package Insert



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Make VYLOY + mFOLFOX6 your first choice for first-line treatment of CLDN18.2+, HER2-, advanced* G/GEJ cancer[1]

*Locally advanced unresectable or metastatic.[1]

SELECT SAFETY INFORMATION

VYLOY has **WARNINGS AND PRECAUTIONS** for: **Hypersensitivity reactions** (Monitor patients during and for at least 2 hours after infusion with VYLOY. Interrupt, slow the rate of infusion or permanently discontinue VYLOY based on severity and type of reaction. Premedicate with antihistamines for subsequent infusions after a hypersensitivity reaction); **Infusion related reactions** (Monitor patients for signs and symptoms of an IRR. Interrupt, slow the rate of infusion or permanently discontinue VYLOY based on severity of the IRR. Premedicate with antihistamines for subsequent infusions after an IRR); **Nausea and vomiting** (Premedicate patients with antiemetics prior to each infusion. Interrupt, slow the rate of infusion or permanently discontinue VYLOY based on the severity of the nausea and/or vomiting. Manage patients during and after infusion with antiemetics or fluid replacement).

Please see Important Safety Information on pages 14-15.

REFERENCES: 1. VYLOY Singapore Approved Package Insert. **2.** Shitara K, Lordick F, Bang YJ, et al. Zolbetuximab plus mFOLFOX6 in patients with CLDN18.2-positive, HER2-negative, untreated, locally advanced unresectable or metastatic gastric or gastro-oesophageal junction adenocarcinoma (SPOTLIGHT): a multicentre, randomised, double-blind, phase 3 trial. Lancet 2023;401(10389):1655-1668. Errata in: Lancet. 2023;402(10398):290; Lancet. 2024;403(10421):30. **3.** Shah MA, Shitara K, Adani JA, et al. Zolbetuximab plus CAPOX in CLDN18.2-positive gastric or gastroesophageal junction adenocarcinoma: the randomized phase 3 GLOW trial. Nat Med 2023;29(8):2133-41. **4.** Van Cutsem E, Bang YJ, Feng-Yi F, et al. HER2 screening data from ToGA: targeting HER2 in gastric and gastroesophageal junction cancer. Gastric Cancer 2015;18(3):476-84. **5.** Fuchs CS, Özgüroğlu M, Bang YJ, et al. Pembrolizumab versus paclitaxel for previously treated PD-L1-positive advanced gastric or gastroesophageal junction cancer: 2-year update of the randomized, phase 3 KEYNOTE-061 trial. Gastric Cancer 2022;25(1):197-206. **6.** Schoemig-Markiefka B, Eschbach J, Scheel AH, et al. Optimized PD-L1 scoring of gastric cancer. Gastric Cancer. 2021;24(5):1115-22. **7.** Fuchs CS, Doi T, Jang RW, et al. Safety and efficacy of pembrolizumab monotherapy in patients with previously treated advanced gastric and gastroesophageal junction cancer: phase 2 clinical KEYNOTE-059 trial. JAMA Oncol 2018;4(5):e180013. Erratum in: JAMA Oncol 2019;5(4):579. **8.** Sahin U, Koslowski M, Dhaene K, et al. Claudin-18 splice variant 2 is a pan-cancer target suitable for therapeutic antibody development. Clin Cancer Res 2008;14(23):7624-34. **9.** Sahin U, Schuler M, Richly H, et al. A phase I dose escalation study of IMAB362 (zolbetuximab) in patients with advanced gastric and gastrooesophageal junction cancer. Eur J Cancer 2018;100:17-26. **10.** Lamouille S, Xu J, Derynck R. Molecular mechanisms of epithelial-mesenchymal transition. Nat Rev Mol Cell Biol 2014;15(3):178-96. **11.** Abrahao-Machado LF, Scapulatempo-Neto C. HER2 testing in gastric cancer: an update. World J Gastroenterol 2016;22(19):4619-25.

Scan to see more clinical trial results with VYLOY.

For healthcare professionals only.
Photos used in this document include models, not actual patients.

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