NOW APPROVED IN RESECTABLE GC/GEJC

IMFINZI®
durvalumab
Injection for Intravenous Use 50 mg/mL

A PRACTICE-CHANGING ADVANCEMENT IN SURVIVAL:

THE MATTERHORN REGIMEN[1-3]*

The FIRST & ONLY perioperative IO-based regimen to significantly improve EFS† and OS vs perioperative FLOT alone[1-3]

EVENT-FREE SURVIVAL (primary endpoint)[1,2]

29% **REDUCTION IN RISK OF AN EVENT** (disease recurrence, progression, or death) with the MATTERHORN Regimen* vs perioperative FLOT alone (HR=0.71 [95% CI, 0.58-0.86]; *P*<0.001)

Median EFS with the MATTERHORN Regimen* was not reached (95% CI, 40.7-NE) vs 32.8 months (95% CI, 27.9-NE) with perioperative FLOT alone.

Median duration of follow-up: 31.5 months (IQR: 26.7-36.6).

OVERALL SURVIVAL (secondary endpoint)[1,3]

22% **REDUCTION IN RISK OF DEATH** with the MATTERHORN Regimen* vs perioperative FLOT alone (HR=0.78 [95% CI, 0.63-0.96]; *P*=0.021)

Median OS with the MATTERHORN Regimen* was not reached (95% CI, NE-NE) vs not reached (95% CI, NE-NE) with perioperative FLOT alone.

Median duration of follow-up was 43.0 months (range: 3.4-57.0) with the MATTERHORN Regimen* and 42.9 months (range: 0.0-56.5) with perioperative FLOT alone.

Discover reasons to consider the MATTERHORN Regimen* at IMFINZIhcp.com/MATTERHORN

Study design: The MATTERHORN study was a randomized, double-blind, placebo-controlled, global Phase III study of perioperative IMFINZI + FLOT followed by adjuvant monotherapy vs perioperative FLOT alone in patients with resectable gastric or gastroesophageal junction adenocarcinoma. 948 patients were randomized 1:1 to receive IMFINZI 1500 mg IV (n=474) or placebo (n=474) Q4W on Day 1 + FLOT Q4W on Days 1 and 15 for 2 cycles of neoadjuvant therapy before surgery and 2 cycles of adjuvant therapy after surgery, followed by IMFINZI 1500 mg IV or placebo Q4W for 10 additional cycles. Treatment was given until confirmed disease progression or recurrence, unacceptable toxicity, or until the completion of 12 cycles of adjuvant IMFINZI or at 1 year after the start of treatment. The primary endpoint was EFS. OS and pCR were key secondary endpoints.[1,2]

*The MATTERHORN Regimen is defined as neoadjuvant IMFINZI + FLOT followed by surgery, then adjuvant IMFINZI + FLOT followed by adjuvant IMFINZI monotherapy.[1]
†EFS was defined as the time from randomization to the following, according to RECIST v1.1 per BICR assessment and/or locally by pathology testing: Progression that precludes surgery or requires non-protocol therapy, local or distant recurrence or progression of disease, or death due to any cause.[2]

Indication:

IMFINZI in combination with fluorouracil, leucovorin, oxaliplatin and docetaxel (FLOT) as neoadjuvant and adjuvant treatment, followed by single agent IMFINZI, is indicated for the treatment of adult patients with resectable gastric or gastroesophageal junction adenocarcinoma (GC/GEJC).

IMPORTANT SAFETY INFORMATION

There are no contraindications for IMFINZI® (durvalumab).

Immune-Mediated Adverse Reactions

Important immune-mediated adverse reactions listed under Warnings and Precautions may not include all possible severe and fatal immune-mediated reactions. Immune-mediated adverse reactions, which may be severe or fatal, can occur in any organ system or tissue. Immune-mediated adverse reactions can occur at any time after starting treatment or after discontinuation. Monitor patients closely for symptoms and signs that may be clinical manifestations of underlying immune-mediated adverse reactions.

Please see additional Important Safety Information throughout and Full Prescribing Information including Medication Guide for IMFINZI.

BICR=blinded independent central review; CI=confidence interval; EFS=event-free survival; FLOT=fluorouracil, leucovorin, oxaliplatin, docetaxel; GC=gastric cancer; GEJC=gastroesophageal junction cancer; HR=hazard ratio; IO=immuno-oncology; IQR=interquartile range; IV=intravenous; NE=not estimable; OS=overall survival; pCR=pathological complete response; Q4W=every 4 weeks; RECIST=Response Evaluation Criteria in Solid Tumors.

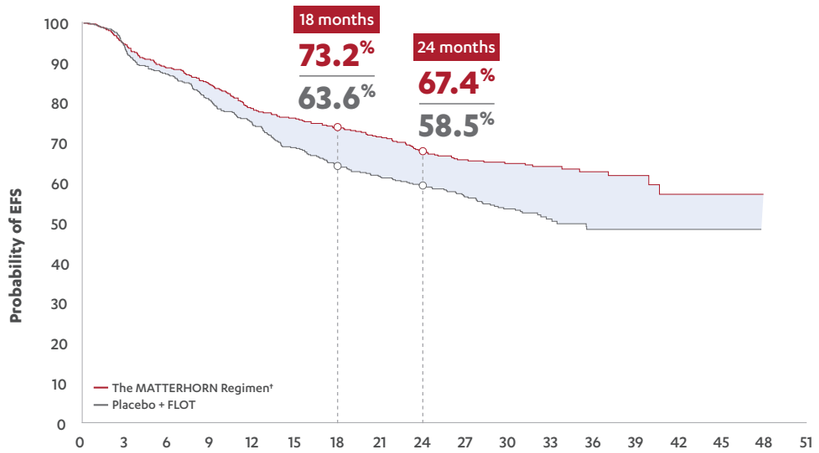
In resectable GC/GEJC

The **FIRST** & **ONLY** perioperative IO-based regimen to demonstrate superior EFS* vs perioperative FLOT alone[1,2]

EVENT-FREE SURVIVAL (primary endpoint)[1,2]

29% **REDUCTION IN RISK OF AN EVENT** (disease recurrence, progression, or death) with the MATTERHORN Regimen† vs perioperative FLOT alone (HR=0.71 [95% CI, 0.58-0.86]; *P*<0.001)

EVENT-FREE SURVIVAL (primary endpoint)[1,2]



Number at risk

The MATTERHORN Regimen†:	474	436	404	381	351	334	320	307	288	234	187	107	88	33	20	2	1	0
Placebo + FLOT:	474	429	392	360	329	302	278	264	249	202	160	89	65	26	21	2	1	0

As published in Janjigian YY, et al. 2025.
Median duration of follow-up: 31.5 months (IQR: 26.7-36.6).

- Median EFS with the MATTERHORN Regimen† was not reached (95% CI, 40.7-NE) vs 32.8 months (95% CI, 27.9-NE) with perioperative FLOT alone[1,2]
- **EFS rates at 18 and 24 months were exploratory and not powered to determine statistical significance[1,2]**

*EFS was defined as the time from randomization to the following, according to RECIST v1.1 per BICR assessment and/or locally by pathology testing: Progression that precludes surgery or requires non-protocol therapy, local or distant recurrence or progression of disease, or death due to any cause.[2]
†The MATTERHORN Regimen is defined as neoadjuvant IMFINZI + FLOT followed by surgery, then adjuvant IMFINZI + FLOT followed by adjuvant IMFINZI monotherapy.[1]

IMPORTANT SAFETY INFORMATION (continued)

Immune-Mediated Adverse Reactions (continued)

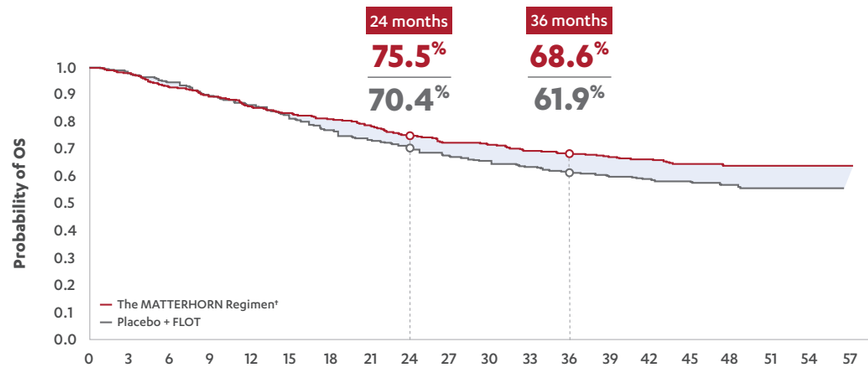
Evaluate liver enzymes, creatinine, and thyroid function at baseline and periodically during treatment. In cases of suspected immune-mediated adverse reactions, initiate appropriate workup to exclude alternative etiologies, including infection. Institute medical management promptly, including specialty consultation as appropriate. Withhold or permanently discontinue IMFINZI depending on severity. See USPI Dosing and Administration for specific details. In general, if IMFINZI requires interruption or discontinuation, administer systemic corticosteroid therapy (1 mg to 2 mg/kg/day prednisone or equivalent) until improvement to Grade 1 or less.

The **FIRST** & **ONLY** perioperative IO-based regimen to significantly improve OS vs perioperative FLOT alone[1,3]

OVERALL SURVIVAL (secondary endpoint)[1,3]

22% **REDUCTION IN RISK OF DEATH** with the MATTERHORN Regimen† vs perioperative FLOT alone (HR=0.78 [95% CI, 0.63-0.96]; *P*=0.021)

OVERALL SURVIVAL (secondary endpoint)[1,3]



Number at risk

The MATTERHORN Regimen†:	474	464	438	422	403	389	377	367	351	338	334	323	316	255	182	112	71	29	6	1	0
Placebo + FLOT:	474	457	439	414	395	374	355	338	324	310	298	293	278	221	167	99	61	23	7	0	0

Refer to Tabernero J, et al. 2025.
Median duration of follow-up was 43.0 months (range: 3.4-57.0) with the MATTERHORN Regimen† and 42.9 months (range: 0.0-56.5) with perioperative FLOT alone.

- Median OS with the MATTERHORN Regimen† was not reached (95% CI, NE-NE) vs not reached (95% CI, NE-NE) with perioperative FLOT alone[1,3]
- **OS rates at 24 months and 36 months were exploratory and not powered to determine statistical significance[1,3]**

IMPORTANT SAFETY INFORMATION (continued)

Immune-Mediated Adverse Reactions (continued)

Upon improvement to Grade 1 or less, initiate corticosteroid taper and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants in patients whose immune-mediated adverse reactions are not controlled with corticosteroid therapy.

Immune-Mediated Pneumonitis

IMFINZI can cause immune-mediated pneumonitis. The incidence of pneumonitis is higher in patients who have received prior thoracic radiation. In patients who did not receive recent prior radiation, the incidence of immune-mediated pneumonitis was 2.4% (34/1414), including fatal (<0.1%), and Grade 3-4 (0.4%) adverse reactions.

Please see additional Important Safety Information throughout and Full Prescribing Information including Medication Guide for IMFINZI.

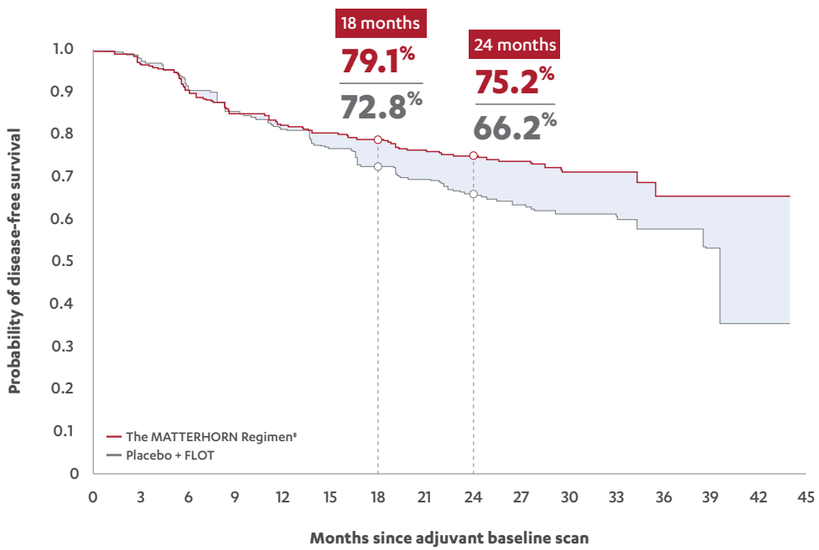
IMFINZI® durvalumab Injection for Intravenous Use 50 mg/mL

In resectable GC/GEJC

Disease-free survival in patients with R0 resection[2*]

R0 resection was achieved in ~92% of patients who completed surgery in each treatment arm[2†]

DFS IN THE R0 RESECTED ANALYSIS SET* (exploratory endpoint)[2]



Number at risk																
The MATTERHORN Regimen‡:	339	327	305	283	272	265	258	244	184	168	81	74	19	3	2	0
Placebo + FLOT:	323	315	293	275	262	245	230	217	157	142	72	56	23	4	2	0

As published in Janjigian YY, et al. 2025.

*Disease-free survival was assessed per RECIST v1.1 and defined as the time from adjuvant baseline scan until the first evidence of disease recurrence or death due to any cause, in patients with R0 resection and no evidence of disease at the adjuvant baseline scan.

†R0 resection rates were 91.5% (n=377/412) with the MATTERHORN Regimen‡ and 92.3% (n=369/400) with perioperative FLOT alone in patients who completed surgery.

- Median DFS was not reached (95% CI, NR-NR) with the MATTERHORN Regimen‡ and 39.8 months (95% CI, 38.7-NR) with perioperative FLOT alone (HR=0.70 [95% CI, 0.53-0.93])[4]
- **The DFS analysis, including DFS rates at 18 and 24 months, was exploratory and was not powered to determine statistical significance[2]**

NCCN CATEGORY 1, PREFERRED | NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Gastric Cancer and Esophageal and Esophagogastric Junction Cancers: Durvalumab (IMFINZI®) + FLOT as neoadjuvant and adjuvant treatment after surgery, followed by single-agent durvalumab, is the **ONLY Category 1, Preferred** perioperative immunotherapy-based treatment option for PD-L1 CPS ≥1 or TAP ≥1% resectable GC/GEJ adenocarcinoma.[5,6§‖]

‡The MATTERHORN Regimen is defined as neoadjuvant IMFINZI + FLOT followed by surgery, then adjuvant IMFINZI + FLOT followed by adjuvant IMFINZI monotherapy.[1]
§See the NCCN Guidelines® for detailed recommendations, including other preferred treatment options.
‖In the MATTERHORN trial, diffuse type gastric or gastroesophageal junction adenocarcinoma showed no EFS advantage when durvalumab was added to FLOT.[5,6]

IMPORTANT SAFETY INFORMATION (continued)

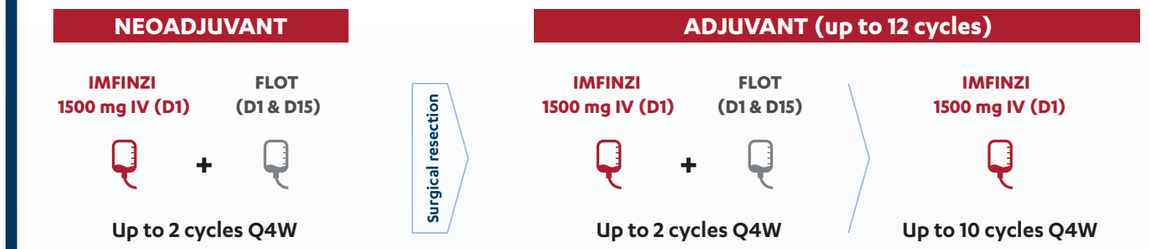
Immune-Mediated Pneumonitis (continued)

The frequency and severity of immune-mediated pneumonitis in patients who did not receive definitive chemoradiation prior to IMFINZI were similar in patients who received IMFINZI as a single agent or with ES-SCLC or BTC when given in combination with chemotherapy.

CPS=Combined Positive Score; D1=Day 1; D15=Day 15; DFS=disease-free survival; GEJ=gastroesophageal junction; NCCN=National Comprehensive Cancer Network® (NCCN®); NR=not reached; PD-L1=programmed death-ligand 1; TAP=Tumor Area Positivity.

The MATTERHORN Regimen‡: Perioperative IMFINZI + FLOT, followed by adjuvant IMFINZI monotherapy[1,2]

For patients with a body weight of ≥30 kg



In the MATTERHORN study, IMFINZI 1500 mg IV was administered on Day 1 and FLOT was administered as 5-fluorouracil 2600 mg/m², leucovorin 200 mg/m², oxaliplatin 85 mg/m², and docetaxel 50 mg/m² on Day 1 and Day 15 every 4 weeks (4 weeks=1 cycle). FLOT dose modifications, including dose reductions or delays for individual components, were allowed per FLOT modification protocols.[2]

Patients underwent surgery 4 to 8 weeks after the last dose of neoadjuvant therapy. Adjuvant therapy began 4 to 12 weeks post-surgery.[2]

- **For patients with a body weight of <30 kg[1]:**
  - **Neoadjuvant phase:** IMFINZI 20 mg/kg IV every 4 weeks with FLOT¶ for up to 2 cycles prior to surgery
  - **Adjuvant phase:** IMFINZI 20 mg/kg IV every 4 weeks with FLOT¶ for up to 2 cycles, followed by IMFINZI 20 mg/kg IV as a single agent every 4 weeks for up to 10 cycles, for a total of up to 12 cycles after surgery
- **Administer IMFINZI prior to chemotherapy on the same day.** Refer to the Prescribing Information for the agent(s) administered in combination with IMFINZI for recommended dosage information, as appropriate[1]
- **Neoadjuvant phase:** Administer IMFINZI + FLOT for up to 2 cycles or until disease progression that precludes definitive surgery or unacceptable toxicity[1]
- **Adjuvant phase:** Administer IMFINZI + FLOT for up to 2 cycles, then IMFINZI as a single agent for up to 10 cycles, or until disease progression, recurrence, unacceptable toxicity, or a maximum of 12 cycles after surgery[1]

IN THE MATTERHORN STUDY[2]

FLOT flexibility was allowed

Patients who received IMFINZI in combination with FLOT had the flexibility to continue IMFINZI, including as monotherapy, if FLOT or any FLOT component was **modified or discontinued#** for reasons other than disease progression or recurrence

¶FLOT chemotherapy is administered on Day 1 and Day 15 of each 4-week cycle.[1]
#Dose modifications of FLOT, including dose reduction, interruption, or discontinuation of any FLOT component, were allowed according to local standard clinical practice. For additional information, please refer to the Prescribing Information of each agent or the FLOT dosing modification guidance from the FLOT4 study (Al-Batran et al, 2019).[2]

IMPORTANT SAFETY INFORMATION (continued)

Immune-Mediated Colitis

IMFINZI can cause immune-mediated colitis that is frequently associated with diarrhea. Cytomegalovirus (CMV) infection/reactivation has been reported in patients with corticosteroid-refractory immune-mediated colitis. In cases of corticosteroid-refractory colitis, consider repeating infectious workup to exclude alternative etiologies. Immune-mediated colitis occurred in 2% (37/1889) of patients receiving IMFINZI, including Grade 4 (<0.1%) and Grade 3 (0.4%) adverse reactions.

Please see additional Important Safety Information throughout and Full Prescribing Information including Medication Guide for IMFINZI.

IMFINZI® durvalumab Injection for Intravenous Use 50 mg/mL

Immune-Mediated Hepatitis

IMFINZI can cause immune-mediated hepatitis. Immune-mediated hepatitis occurred in 2.8% (52/1889) of patients receiving IMFINZI, including fatal (0.2%), Grade 4 (0.3%) and Grade 3 (1.4%) adverse reactions.

Immune-Mediated Endocrinopathies

- ***Adrenal Insufficiency***: IMFINZI can cause primary or secondary adrenal insufficiency. For Grade 2 or higher adrenal insufficiency, initiate symptomatic treatment, including hormone replacement as clinically indicated. Immune-mediated adrenal insufficiency occurred in 0.5% (9/1889) of patients receiving IMFINZI, including Grade 3 (<0.1%) adverse reactions.
- ***Hypophysitis***: IMFINZI can cause immune-mediated hypophysitis. Hypophysitis can present with acute symptoms associated with mass effect such as headache, photophobia, or visual field cuts. Hypophysitis can cause hypopituitarism. Initiate symptomatic treatment including hormone replacement as clinically indicated. Grade 3 hypophysitis/hypopituitarism occurred in <0.1% (1/1889) of patients who received IMFINZI.
- ***Thyroid Disorders (Thyroiditis, Hyperthyroidism, and Hypothyroidism)***: IMFINZI can cause immune-mediated thyroid disorders. Thyroiditis can present with or without endocrinopathy. Hypothyroidism can follow hyperthyroidism. Initiate hormone replacement therapy for hypothyroidism or institute medical management of hyperthyroidism as clinically indicated.
  - ***Thyroiditis***: Immune-mediated thyroiditis occurred in 0.5% (9/1889) of patients receiving IMFINZI, including Grade 3 (<0.1%) adverse reactions.
  - ***Hyperthyroidism***: Immune-mediated hyperthyroidism occurred in 2.1% (39/1889) of patients receiving IMFINZI.
  - ***Hypothyroidism***: Immune-mediated hypothyroidism occurred in 8.3% (156/1889) of patients receiving IMFINZI, including Grade 3 (<0.1%) adverse reactions.
- ***Type 1 Diabetes Mellitus, which can present with diabetic ketoacidosis***: Monitor patients for hyperglycemia or other signs and symptoms of diabetes. Initiate treatment with insulin as clinically indicated. Grade 3 immune-mediated Type 1 diabetes mellitus occurred in <0.1% (1/1889) of patients receiving IMFINZI.

Immune-Mediated Nephritis with Renal Dysfunction

IMFINZI can cause immune-mediated nephritis. Immune-mediated nephritis occurred in 0.5% (10/1889) of patients receiving IMFINZI, including Grade 3 (<0.1%) adverse reactions.

Immune-Mediated Dermatology Reactions

IMFINZI can cause immune-mediated rash or dermatitis. Exfoliative dermatitis, including Stevens-Johnson Syndrome (SJS), drug rash with eosinophilia and systemic symptoms (DRESS), and toxic epidermal necrolysis (TEN), has occurred with PD-1/L-1 and CTLA-4 blocking antibodies. Topical emollients and/or topical corticosteroids may be adequate to treat mild to moderate non-exfoliative rashes. Immune-mediated rash or dermatitis occurred in 1.8% (34/1889) of patients receiving IMFINZI, including Grade 3 (0.4%) adverse reactions.

Other Immune-Mediated Adverse Reactions

The following clinically significant, immune-mediated adverse reactions occurred at an incidence of less than 1% each in patients who received IMFINZI or were reported with the use of other immune-checkpoint inhibitors.

- ***Cardiac/vascular***: Myocarditis, pericarditis, vasculitis.
- ***Nervous system***: Meningitis, encephalitis, myelitis and demyelination, myasthenic syndrome/myasthenia gravis (including exacerbation), Guillain-Barré syndrome, nerve paresis, autoimmune neuropathy.
- ***Ocular***: Uveitis, iritis, and other ocular inflammatory toxicities can occur. Some cases can be associated with retinal detachment. Various grades of visual impairment to include blindness can occur. If uveitis occurs in combination with other immune-mediated adverse reactions, consider a Vogt-Koyanagi-Harada-like syndrome, as this may require treatment with systemic steroids to reduce the risk of permanent vision loss.
- ***Gastrointestinal***: Pancreatitis including increases in serum amylase and lipase levels, gastritis, duodenitis.
- ***Musculoskeletal and connective tissue disorders***: Myositis/polymyositis, rhabdomyolysis and associated sequelae including renal failure, arthritis, polymyalgia rheumatic.
- ***Endocrine***: Hypoparathyroidism.
- ***Other (hematologic/immune)***: Hemolytic anemia, aplastic anemia, hemophagocytic lymphohistiocytosis, systemic inflammatory response syndrome, histiocytic necrotizing lymphadenitis (Kikuchi lymphadenitis), sarcoidosis, immune thrombocytopenia, solid organ transplant rejection, other transplant (including corneal graft) rejection.

Infusion-Related Reactions

IMFINZI can cause severe or life-threatening infusion-related reactions. Monitor for signs and symptoms of infusion-related reactions. Interrupt, slow the rate of, or permanently discontinue IMFINZI based on the severity. See USPI Dosing and Administration for specific details. For Grade 1 or 2 infusion-related reactions, consider using pre-medications with subsequent doses. Infusion-related reactions occurred in 2.2% (42/1889) of patients receiving IMFINZI, including Grade 3 (0.3%) adverse reactions.

Complications of Allogeneic HSCT after IMFINZI

Fatal and other serious complications can occur in patients who receive allogeneic hematopoietic stem cell transplantation (HSCT) before or after being treated with a PD-1/L-1 blocking antibody. Transplant-related complications include hyperacute graft-versus-host disease (GVHD), acute GVHD, chronic GVHD, hepatic veno-occlusive disease (VOD) after reduced intensity conditioning, and steroid-requiring febrile syndrome (without an identified infectious cause). These complications may occur despite intervening therapy between PD-1/L-1 blockade and allogeneic HSCT. Follow patients closely for evidence of transplant-related complications and intervene promptly. Consider the benefit versus risks of treatment with a PD-1/L-1 blocking antibody prior to or after an allogeneic HSCT.

Embryo-Fetal Toxicity

Based on its mechanism of action and data from animal studies, IMFINZI can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus.

Embryo-Fetal Toxicity (continued)

In females of reproductive potential, verify pregnancy status prior to initiating IMFINZI and advise them to use effective contraception during treatment with IMFINZI and for 3 months after the last dose of IMFINZI.

Lactation

There is no information regarding the presence of IMFINZI in human milk; however, because of the potential for serious adverse reactions in breastfed infants from IMFINZI, advise women not to breastfeed during treatment and for 3 months after the last dose.

Adverse Reactions

- In patients with resectable GC/GEJC, the most common adverse reactions in the overall study (occurring in ≥20% of patients) were diarrhea, nausea, peripheral neuropathy, fatigue, alopecia, decreased appetite, rash, abdominal pain, vomiting, musculoskeletal pain, pyrexia, and stomatitis.
- In patients with resectable GC/GEJC in the neoadjuvant phase of the MATTERHORN study receiving IMFINZI in combination with FLOT chemotherapy (n=475), permanent discontinuation of IMFINZI due to an adverse reaction occurred in 2.5% of patients. Serious adverse reactions occurred in 21% of patients; the most frequent (≥2%) serious adverse reaction was diarrhea (2.5%). Deaths occurred in 1.9% of patients; deaths ≥2 patients included septic shock (0.6%) and acute coronary syndrome (0.4%). Of the 475 patients in the IMFINZI + FLOT chemotherapy treatment arm and 469 patients in the placebo + FLOT chemotherapy treatment arm who received neoadjuvant treatment, 0.6% and 0.4% of patients, respectively, did not receive surgery due to adverse reactions, and 2.3% and 2.6% of patients, respectively, had a delay in surgery due to ARs.
- In patients with resectable GC/GEJC in the adjuvant phase of the MATTERHORN study receiving IMFINZI in combination with FLOT chemotherapy (n=365), permanent discontinuation of IMFINZI due to an adverse reaction occurred in 7% of patients. Serious adverse reactions occurred in 29% of patients; the most frequent (≥2%) serious adverse reaction was pneumonia (2.5%). Deaths occurred in 2.2% of patients; deaths ≥2 patients included gastrointestinal perforation (0.5%) and COVID-19 (0.5%).
- In patients with resectable GC/GEJC in the adjuvant phase of the MATTERHORN study receiving IMFINZI alone (n=345), permanent discontinuation of IMFINZI due to an adverse reaction occurred in 6% of patients. Serious adverse reactions occurred in 14% of patients. Deaths occurred in 1.7% of patients; deaths ≥2 patients included gastrointestinal perforation (0.6%) and COVID-19 (0.6%).

The safety and effectiveness of IMFINZI has not been established in pediatric patients.

You may report side effects related to AstraZeneca products.

REFERENCES: 1. IMFINZI® (durvalumab) [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2025. **2.** Janjigian YY, Al-Batran SE, Wainberg ZA, et al. Perioperative durvalumab in gastric and gastroesophageal junction cancer. *N Engl J Med*. 2025;393(3):217-230. **3.** Tabernero J, Al-Batran SE, Wainberg ZA, et al. Final overall survival and the association of pathological outcomes with event-free survival in MATTERHORN: a randomised, Phase 3 study of durvalumab plus 5-fluorouracil, leucovorin, oxaliplatin and docetaxel in resectable gastric / gastroesophageal junction adenocarcinoma. Presented at: 2025 ESMO Congress; October 17-21, 2025; Berlin, Germany. Session LBA81. **4.** Janjigian YY, Al-Batran SE, Wainberg ZA, et al. Event-free survival (EFS) in MATTERHORN: a randomized, phase 3 study of durvalumab plus 5-fluorouracil, leucovorin, oxaliplatin, and docetaxel chemotherapy (FLOT) in resectable gastric/gastroesophageal junction cancer (GC/GEJC). Presented at: ASCO Annual Meeting; May 30-June 3, 2025; Chicago, IL. **5.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Gastric Cancer V.3.2025. © National Comprehensive Cancer Network, Inc. 2025. All rights reserved. Accessed August 22, 2025. 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. **6.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Esophageal and Esophagogastric Junction Cancers V.4.2025. © National Comprehensive Cancer Network, Inc. 2025. All rights reserved. Accessed August 22, 2025. 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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In resectable GC/GEJC

THE MATTERHORN REGIMEN*

IMFINZI® durvalumab
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The FIRST & ONLY perioperative IO-based regimen to significantly improve EFS† and OS vs perioperative FLOT alone[1-3]

29% REDUCTION IN RISK OF AN EVENT[1,2]
(disease recurrence, progression, or death)

with the MATTERHORN Regimen* vs perioperative FLOT alone (HR=0.71 [95% CI, 0.58-0.86]; *P*<0.001).

Median EFS with the MATTERHORN Regimen* was not reached (95% CI, 40.7-NE) vs 32.8 months (95% CI, 27.9-NE) with perioperative FLOT alone.

22% REDUCTION IN RISK OF DEATH[1,3]

with the MATTERHORN Regimen* vs perioperative FLOT alone (HR=0.78 [95% CI, 0.63-0.96]; *P*=0.021).

Median OS with the MATTERHORN Regimen* was not reached (95% CI, NE-NE) vs not reached (95% CI, NE-NE) with perioperative FLOT alone.

FLOT FLEXIBILITY WAS ALLOWED[2]

Administer IMFINZI + FLOT for up to 2 cycles before and up to 2 cycles after surgery, followed by IMFINZI monotherapy for up to 10 cycles.

In the MATTERHORN study, patients who received IMFINZI in combination with FLOT had the flexibility to continue IMFINZI, including as monotherapy, if FLOT or any FLOT component was **modified or discontinued‡** for reasons other than disease progression or recurrence.

LOW DISCONTINUATION RATES DUE TO ARs[1]

2.5%, 7%, and 6% of patients discontinued IMFINZI in the neoadjuvant, adjuvant, and adjuvant monotherapy phases, respectively. Adverse reactions leading to permanent discontinuation of IMFINZI (≥2 patients) were nephritis (0.4%) in the neoadjuvant phase; hepatitis (1.1%), pneumonitis (1.1%), rash (0.8%), musculoskeletal pain (0.5%), and renal failure (0.5%) in the adjuvant phase; and hepatitis (0.9%), pneumonitis (0.9%), musculoskeletal pain (0.6%), and renal failure (0.6%) in the adjuvant monotherapy phase.

Safety and tolerability in the MATTERHORN study[1]

- The most common ARs (≥20% incidence) with the MATTERHORN Regimen* were diarrhea, nausea, peripheral neuropathy, fatigue, alopecia, decreased appetite, rash, abdominal pain, vomiting, musculoskeletal pain, pyrexia, and stomatitis
- **In patients in the neoadjuvant phase receiving IMFINZI + FLOT (n=475), serious ARs** occurred in 21% of patients; the most frequent (≥2%) serious AR was diarrhea (2.5%). **Deaths** occurred in 1.9% of patients. ARs that caused deaths (≥2 patients) were septic shock (0.6%) and acute coronary syndrome (0.4%). **Surgical delay/ no surgery:** 2.3% of patients receiving IMFINZI + FLOT and 2.6% of patients receiving placebo + FLOT (n=469) experienced a delay of surgery (defined as occurring more than 8 weeks after the last dose of neoadjuvant treatment) due to ARs; 0.6% and 0.4%, respectively, did not have surgery due to ARs
- **In patients in the adjuvant phase receiving IMFINZI + FLOT (n=365), serious ARs** occurred in 29% of patients; the most frequent (≥2%) serious AR was pneumonia (2.5%). **Deaths** occurred in 2.2% of patients. ARs that caused death (≥2 patients) were gastrointestinal perforation (0.5%) and COVID-19 (0.5%)
- **In patients in the adjuvant phase receiving IMFINZI monotherapy (n=345), serious ARs** occurred in 14% of patients. **Deaths** occurred in 1.7% of patients. ARs that caused death (≥2 patients) were gastrointestinal perforation (0.6%) and COVID-19 (0.6%)

*The MATTERHORN Regimen is defined as neoadjuvant IMFINZI + FLOT followed by surgery, then adjuvant IMFINZI + FLOT followed by adjuvant IMFINZI monotherapy.[1]
†EFS was defined as the time from randomization to the following, according to RECIST v1.1 per BICR assessment and/or locally by pathology testing: Progression that precludes surgery or requires non-protocol therapy, local or distant recurrence or progression of disease, or death due to any cause.[2]
‡Dose modifications of FLOT, including dose reduction, interruption, or discontinuation of any FLOT component, were allowed according to local standard clinical practice. For additional information, please refer to the Prescribing Information of each agent or the FLOT dosing modification guidance from the FLOT4 study (Al-Batran et al, 2019).[2]

Indication:

IMFINZI in combination with fluorouracil, leucovorin, oxaliplatin and docetaxel (FLOT) as neoadjuvant and adjuvant treatment, followed by single agent IMFINZI, is indicated for the treatment of adult patients with resectable gastric or gastroesophageal junction adenocarcinoma (GC/GEJC).

Please see Important Safety Information throughout and Full Prescribing Information including Medication Guide for IMFINZI.

ARs=adverse reactions.

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