IMFINZI®
durvalumab
Injection for Intravenous Use 50 mg/mL

Dosing and safety with perioperative IMFINZI* + neoadjuvant gem-cis in cis-eligible MIBC

IMFINZI in combination with gem-cis as neoadjuvant treatment, followed by single-agent IMFINZI as adjuvant treatment following RC, is indicated for the treatment of adult patients with MIBC.

Learn how the NIAGARA Regimen† may fit into your practice at IMFINZIhcp.com/mibc

*A perioperative regimen consists of both neoadjuvant and adjuvant treatment.[1]

†The NIAGARA Regimen is defined as neoadjuvant IMFINZI + gem-cis followed by adjuvant IMFINZI as a single agent after RC.[1]

Indication:

IMFINZI in combination with gemcitabine and cisplatin as neoadjuvant treatment, followed by single-agent IMFINZI as adjuvant treatment following radical cystectomy, is indicated for the treatment of adult patients with muscle-invasive bladder cancer (MIBC).

IMPORTANT SAFETY INFORMATION

There are no contraindications for IMFINZI® (durvalumab).

Severe and Fatal 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.

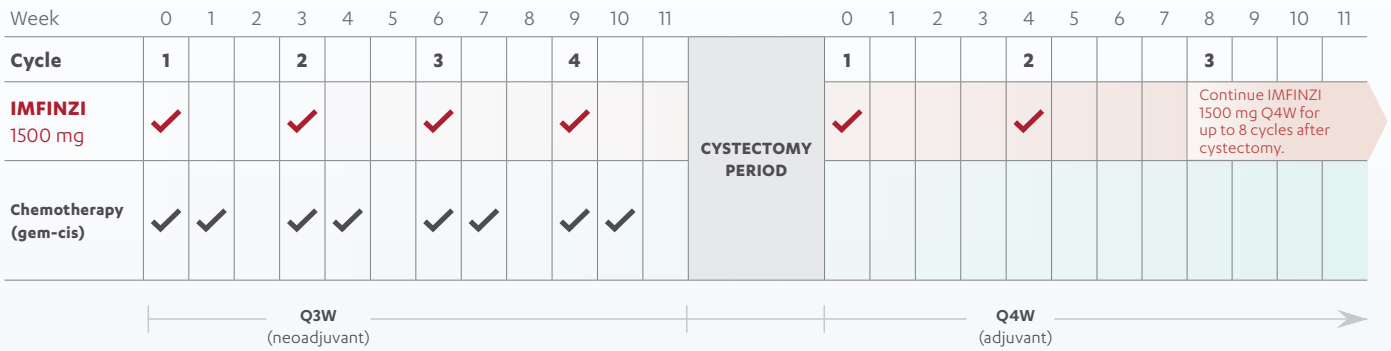
Please see additional Important Safety Information throughout and Full Prescribing Information including Medication Guide for IMFINZI.

Cis-eligible=cisplatin-eligible; gem-cis=gemcitabine-cisplatin; MIBC=muscle-invasive bladder cancer; RC=radical cystectomy.

PERIOPERATIVE IMFINZI* + neoadjuvant gem-cis: The **FIRST** and **ONLY** FDA-approved regimen to combine perioperative IO with neoadjuvant gem-cis[1,2]

Start with neoadjuvant IMFINZI + gem-cis, then continue with adjuvant IMFINZI monotherapy following RC[1]

For patients with a body weight of ≥30 kg[1,3]



Administer IMFINZI until disease progression that precludes definitive surgery, recurrence, unacceptable toxicity, or a maximum of 8 cycles after surgery.

Administer IMFINZI prior to chemotherapy on the same day. Refer to the Prescribing Information for the agent administered in combination with IMFINZI for recommended dosage information, as appropriate.

- **For patients with a body weight of <30 kg[1]:**
  - **Neoadjuvant:** IMFINZI 20 mg/kg in combination with gem-cis Q3W for 4 cycles prior to surgery
  - **Adjuvant:** IMFINZI 20 mg/kg Q4W for up to 8 cycles as a single agent after surgery
- In the NIAGARA study:
  - **Patients received** neoadjuvant gem-cis on Day 1 (cisplatin 70 mg/m^2, gemcitabine 1000 mg/m^2) and Day 8 (gemcitabine 1000 mg/m^2), every 21 days for 4 cycles[1,3]
  - **Patients with borderline renal function received** split-dose cisplatin (35 mg/m^2 on Days 1 and 8 of each neoadjuvant cycle[1,3]
- IMFINZI is administered as a 60-minute IV infusion after dilution[1]
- Biomarker testing is not required to start treatment with IMFINZI[1]

Systemic treatment completion rates in the NIAGARA study[3]

- 78.7% (n=417/530) of patients who started **neoadjuvant** IMFINZI + gem-cis and 74% (n=389/526) of patients who started neoadjuvant gem-cis completed all 4 cycles
- 75.2% (n=288/383) of patients who started **adjuvant** IMFINZI completed all 8 cycles

The NIAGARA Regimen† offers your patients another treatment approach[1]

*A perioperative regimen consists of both neoadjuvant and adjuvant treatment.[1]
†The NIAGARA Regimen is defined as neoadjuvant IMFINZI + gem-cis followed by adjuvant IMFINZI as a single agent after RC.[1]

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

IO=immuno-oncology; IV=intravenous; Q3W=every 3 weeks; Q4W=every 4 weeks.

Safety of IMFINZI was studied in >500 cis-eligible MIBC patients[1]

ADVERSE REACTIONS OCCURRING IN ≥10% OF PATIENTS IN THE NIAGARA STUDY[1]

Adverse reaction	All grades (%)‡	Grade 3-4 (%)‡	All grades (%)‡	Grade 3-4 (%)‡
	The NIAGARA Regimen† (n=530)		Neoadjuvant gem-cis (n=526)	
Gastrointestinal disorders				
Nausea	**54**	**1.5**	48	1
Constipation	**39**	**0.8**	39	0.8
Diarrhea	**21**	**1.5**	14	0.4
Vomiting§	**20**	**0.9**	19	0.2
Abdominal pain§	**20**	**0.9**	13	1
General disorders and administration site conditions				
Fatigue§	**52**	**2.3**	49	3
Pyrexia§	**22**	**0.4**	17	0
Edema§	**13**	**0.4**	13	0
Metabolism and nutrition disorders				
Decreased appetite	**27**	**0.6**	25	0.6
Skin and subcutaneous tissue disorders				
Rash§	**23**	**1.3**	12	0.6
Pruritus	**15**	**0**	7	0
Nervous system disorders				
Peripheral neuropathy§	**16**	**0.2**	14	0
Headache§	**11**	**0**	11	0
Dizziness§	**11**	**0**	10	0.2
Endocrine disorders				
Hypothyroidism§	**13**	**0.4**	2.3	0
Vascular disorders				
Hypertension§	**12**	**4.5**	9	2.9
Hemorrhage§	**11**	**0.9**	10	2.1

‡Graded according to NCI CTCAE version 5.0.
§Includes multiple similar terms.

- The most common laboratory abnormalities (≥20% of all patients, all grades) overall in the study were decreased hemoglobin (88%), decreased neutrophils (76%), increased blood creatinine (63%), decreased sodium (54%), increased ALT (53%), decreased calcium (52%), decreased platelets (52%), increased potassium (51%), decreased lymphocytes (44%), increased AST (42%), decreased magnesium (38%), and increased alkaline phosphate (26%)[1]
- **For patients treated with IMFINZI + gem-cis in the neoadjuvant phase (n=530)[1]:**
  - Serious ARs were reported in 24% of patients. The most frequent serious ARs (≥1%) were pulmonary embolism (1.9%), febrile neutropenia (1.5%), acute kidney injury, thrombocytopenia, urinary tract infection, and pneumonia (1.3% each)
  - Fatal ARs occurred in 1.1% of patients, including sepsis, myocardial infarction, and pulmonary embolism (0.2% each). One fatal AR of pneumonia (0.2%) was reported in the post-RC phase prior to adjuvant treatment
  - 9% of patients discontinued IMFINZI due to an AR. The most frequent ARs (≥0.5%) leading to permanent discontinuation of IMFINZI were increased blood creatinine (0.9%), neutropenia, acute kidney injury, asthenia, and fatigue (0.6% each)
- **For patients treated with IMFINZI in the adjuvant phase (n=383)[1]:**
  - Serious ARs were reported in 26% of patients. The most frequent serious ARs (≥1%) were urinary tract infection (7%), acute kidney injury (3.7%), hydronephrosis (2.1%), pyelonephritis (2.1%), urosepsis (1.8%), and sepsis (1.6%)
  - Fatal ARs occurred in 1.8% of patients, including COVID-19, severe acute respiratory syndrome, cardiopulmonary failure, gastrointestinal hemorrhage, and chronic hepatic failure (0.3% each)
  - 5% of patients discontinued IMFINZI due to an AR. The most frequent ARs (≥0.5%) leading to permanent discontinuation of IMFINZI were nephritis (0.8%), fatigue, diarrhea, decreased appetite, and pneumonitis (0.5% each)

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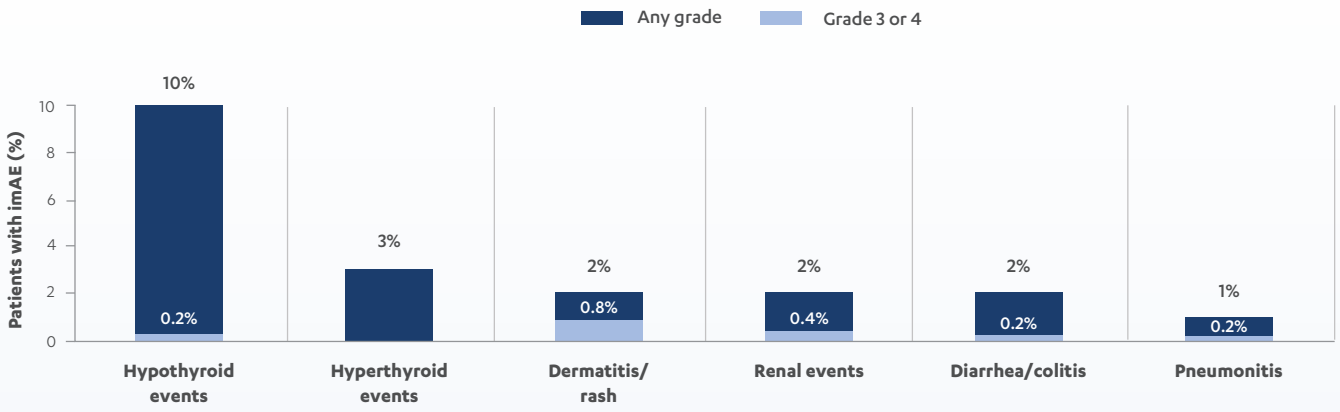
ALT=alanine aminotransferase; ARs=adverse reactions; AST=aspartate aminotransferase; NCI CTCAE=National Cancer Institute Common Terminology Criteria for Adverse Events.

imAEs* with the NIAGARA Regimen†

- **Immune-mediated adverse reactions, which may be severe or fatal, can occur in any organ system or tissue,** including the following: Immune-mediated pneumonitis, immune-mediated colitis, immune-mediated hepatitis, immune-mediated endocrinopathies, immune-mediated dermatologic adverse reactions, immune-mediated nephritis and renal dysfunction, solid organ transplant rejection, and immune-mediated pancreatitis[1]

imAEs OCCURRING IN ≥1% OF PATIENTS IN THE NIAGARA REGIMEN† ARM IN THE OVERALL STUDY PERIOD[4‡]



- imAEs were reported in 21% (n=111/530) of patients with the NIAGARA Regimen† and in 3% (n=16/526) of patients treated with neoadjuvant gem-cis[4]
  - Grade 3/4 imAEs were reported in 3% of patients with the NIAGARA Regimen† and in 0.2% (n=1/526) of patients treated with neoadjuvant gem-cis
- 41% (n=45/111) of patients treated with the NIAGARA Regimen† and 44% (n=7/16) of patients treated with neoadjuvant gem-cis had all imAEs resolve[4§]
- Data cutoff was April 29, 2024[4]

*AEs of special interest that were consistent with an immune-mediated mechanism of action with no clear alternative cause and resulted in the use of systemic glucocorticoids, other immunosuppressants, or endocrine therapy.[4]
†The NIAGARA Regimen is defined as neoadjuvant IMFINZI + gem-cis followed by adjuvant IMFINZI as a single agent after RC.[1]
‡The overall study period includes AEs that occurred between the first dose of study treatment, and whichever occurred first: (1) 90 days after the last dose of treatment, surgery, or last adjuvant visit; (2) date of first dose of subsequent anti-cancer therapy; or (3) data cutoff date.[4]
§Resolved includes outcomes of recovered/resolved and recovered/resolved with sequelae.[4]

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

AEs=adverse events; imAEs=immune-mediated adverse events.

Treatment modifications for IMFINZI: General guidance[1]

- No dose reduction of IMFINZI is recommended
- Withhold IMFINZI for severe (Grade 3) imARs
- Permanently discontinue IMFINZI for life-threatening (Grade 4) imARs
- Permanently discontinue IMFINZI for recurrent severe (Grade 3) imARs that require systemic immunosuppressive treatment, or an inability to reduce corticosteroid dose to ≤10 mg of prednisone or equivalent per day within 12 weeks of initiating corticosteroids

RECOMMENDED DOSAGE MODIFICATIONS FOR ADVERSE REACTIONS[1]

Adverse reaction	Severity‖	Treatment modification
Immune-mediated adverse reactions		
Pneumonitis	Grade 2	Withhold¶
	Grade 3 or 4	Permanently discontinue
Colitis	Grade 2 or 3	Withhold¶
	Grade 4	Permanently discontinue
Intestinal perforation	Any grade	Permanently discontinue
Hepatitis with no tumor involvement of the liver	AST or ALT increases to >3 and up to 8 × ULN or total bilirubin increases to >1.5 and up to 3 × ULN	Withhold¶
	AST or ALT increases to >8 × ULN or total bilirubin increases to >3 × ULN	Permanently discontinue
Hepatitis with tumor involvement of the liver#	AST or ALT is >1 and up to 3 × ULN at baseline and increases to >5 and up to 10 × ULN or AST or ALT is >3 and up to 5 × ULN at baseline and increases to >8 and up to 10 × ULN	Withhold¶
	AST or ALT increases to >10 × ULN or total bilirubin increases to >3 × ULN	Permanently discontinue
Endocrinopathies	Grade 3 or 4	Withhold until clinically stable or permanently discontinue depending on severity
Nephritis with renal dysfunction	Grade 2 or 3 increased blood creatinine	Withhold¶
	Grade 4 increased blood creatinine	Permanently discontinue
Exfoliative dermatologic conditions	Suspected SJS, TEN, or DRESS	Withhold¶
	Confirmed SJS, TEN, or DRESS	Permanently discontinue
Myocarditis	Grade 2, 3, or 4	Permanently discontinue
Neurological toxicities	Grade 2	Withhold¶
	Grade 3 or 4	Permanently discontinue
Other adverse reactions		
Infusion-related reactions	Grade 1 or 2	Interrupt or slow the rate of infusion
	Grade 3 or 4	Permanently discontinue

‖Based on NCI CTCAE, version 4.03.
¶Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper. Permanently discontinue if no complete or partial resolution within 12 weeks of initiating corticosteroids or an inability to reduce corticosteroid dose to 10 mg of prednisone or less per day (or equivalent) within 12 weeks of initiating corticosteroids.
#If AST and ALT are less than or equal to ULN at baseline in patients with liver involvement, withhold or permanently discontinue IMFINZI based on recommendations for hepatitis with no liver involvement.

IMPORTANT SAFETY INFORMATION (continued)

Severe and Fatal 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.

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DRESS=Drug Rash with Eosinophilia and Systemic Symptoms; imARs=immune-mediated adverse reactions; SJS=Stevens-Johnson Syndrome; TEN=toxic epidermal necrolysis; ULN=upper limit of normal.

Check patients for imARs at each visit[1]

Monitoring your patients who are being treated with IMFINZI at every infusion and office visit can aid in early identification and interventions for imARs. This is important to help ensure the safety of your patients as they continue treatment.

Consult with the care team right away if patients present any new or worsening signs or symptoms, including the below.

Pulmonary

- Cough
- Shortness of breath
- Chest pain

Gastrointestinal

- Diarrhea (loose stools) or more frequent bowel movements than usual
- Stools that are black, tarry, sticky, or have blood or mucus
- Severe abdominal pain or tenderness

Hepatic

- Yellowing of the skin or whites of the eyes
- Severe nausea or vomiting
- Pain on the right side of the abdomen
- Dark urine (tea colored)
- Bleeding or bruising more easily than normal

Endocrine

- Headaches that will not go away or unusual headaches
- Eye sensitivity to light
- Eye problems
- Rapid heartbeat
- Increased sweating
- Extreme tiredness
- Weight gain or weight loss
- Feeling more hungry or thirsty than usual
- Urinating more often than usual
- Hair loss
- Feeling cold
- Constipation
- Voice gets deeper
- Dizziness or fainting
- Changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness

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

Early identification and intervention may help manage imARs[1]

Renal

- Decrease in amount of urine
- Blood in urine
- Swelling of ankles
- Loss of appetite

Pancreatic

- Pain in the upper abdomen
- Severe nausea or vomiting
- Loss of appetite

Skin

- Rash
- Itching
- Skin blistering or peeling
- Painful sores or ulcers in mouth or nose, throat, or genital area
- Fever or flu-like symptoms
- Swollen lymph nodes

Other organs and tissues

- Chest pain, irregular heartbeats, shortness of breath, or swelling of ankles
- Confusion, sleepiness, memory problems, changes in mood or behavior, stiff neck, balance problems
- Tingling, numbness or weakness of the arms or legs
- Double vision, blurry vision, sensitivity to light, eye pain, changes in eyesight
- Persistent or severe muscle pain or weakness, muscle cramps, joint pain, joint stiffness or swelling
- Low red blood cells, bruising

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Preparation[1]

Visually inspect drug product for particulate matter and discoloration prior to administration, whenever solution and container permit. Discard the vial if the solution is cloudy, discolored, or visible particles are observed

Do not shake the vial

Withdraw the required volume from the vial(s) of IMFINZI and transfer into an IV bag containing 0.9% Sodium Chloride Injection, USP or 5% Dextrose Injection, USP. Mix diluted solution by gentle inversion. Do not shake the solution. The final concentration of the diluted solution should be between 1 mg/mL and 15 mg/mL

Discard partially used or empty vials of IMFINZI

Administration[1]

Administer infusion solution intravenously over 60 minutes through an IV line containing a sterile, low-protein binding 0.2 or 0.22 micron in-line filter

Use separate infusion bags and filters for each drug product. Do not co-administer other drugs through the same infusion line

IMPORTANT SAFETY INFORMATION (continued)

Severe and Fatal Immune-Mediated Adverse Reactions (continued)

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. 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. 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.

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

Storage[1]

- IMFINZI does not contain a preservative
- Administer infusion solution immediately once prepared. If the infusion solution is not administered immediately and needs to be stored, the time from preparation until the completion of the infusion should not exceed:

28 days in a refrigerator at 2°C to 8°C (36°F to 46°F)

8 hours at room temperature up to 25°C (77°F)

Do not freeze

Do not shake

Dosage forms and strengths[1]

Injection: 120 mg/2.4 mL (50 mg/mL) and 500 mg/10 mL (50 mg/mL) clear to opalescent, colorless to slightly yellow solution in a single-dose vial

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.

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.

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Immune-Mediated Endocrinopathies (continued)

- ***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. 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.

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

- The most common adverse reactions, including laboratory abnormalities, in the overall study (occurring in ≥20% of patients) were decreased hemoglobin, decreased neutrophils, increased blood creatinine, decreased sodium, nausea, increased ALT, decreased calcium, decreased platelets, fatigue, increased potassium, decreased lymphocytes, increased AST, constipation, decreased magnesium, decreased appetite, increased alkaline phosphate, rash, pyrexia, diarrhea, vomiting and abdominal pain.
- In patients with MIBC in the neoadjuvant phase of the NIAGARA study receiving IMFINZI in combination with gemcitabine and cisplatin (n=530), permanent discontinuation of IMFINZI due to an adverse reaction occurred in 9% of patients. Serious adverse reactions occurred in 24% of patients; the most frequent (≥1%) serious adverse reactions were pulmonary embolism (1.9%), febrile neutropenia (1.5%), acute kidney injury (1.3%), thrombocytopenia (1.3%), urinary tract infection (1.3%), and pneumonia (1.3%). Fatal adverse reactions occurred in 1.1% of patients including sepsis, myocardial infarction, and pulmonary embolism (0.2% each). One fatal adverse reaction of pneumonia was reported in 1 (0.2%) patient in the post-surgery phase before adjuvant treatment started. Of the 530 patients in the IMFINZI treatment arm and 526 patients in the chemotherapy treatment arm who received neoadjuvant treatment, 1 (0.2%) patient in each treatment arm did not receive surgery due to adverse reactions. The adverse reaction that led to cancellation of surgery in the IMFINZI treatment arm was interstitial lung disease.
- In patients with MIBC in the adjuvant phase of the NIAGARA study receiving IMFINZI as a single agent (n=383), permanent discontinuation of adjuvant IMFINZI due to an adverse reaction occurred in 5% of patients. Serious adverse reactions occurred in 26% of patients. The most frequent serious adverse reactions (occurring in ≥1% of patients) were urinary tract infection (7%), acute kidney injury (3.7%), hydronephrosis (2.1%), pyelonephritis (2.1%), urosepsis (1.8%) and sepsis (1.6%). Fatal adverse reactions occurred in 1.8% of patients, including COVID-19, severe acute respiratory syndrome, cardiopulmonary failure, gastrointestinal hemorrhage, and chronic hepatic failure (0.3% each).

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.** US Food and Drug Administration. Oncology (cancer)/hematologic malignancies approval notifications. Updated March 28, 2025. Accessed March 28, 2025. https://www.fda.gov/drugs/resources-information-approved-drugs/oncology-cancerhematologic-malignancies-approval-notifications **3.** Powles T, Catto JWF, Galsky MD, et al. Perioperative durvalumab with neoadjuvant chemotherapy in operable bladder cancer. *N Engl J Med*. 2024;391(19):1773-1786. **4.** Galsky M, van der Heijden MS, Catto JWF, et al. Additional efficacy and safety outcomes and an exploratory analysis of the impact of pCR on long-term outcomes from NIAGARA. Presented at: 2025 ASCO GU Cancers Symposium; February 13-15, 2025; San Francisco, CA. Session 659.

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In cis-eligible MIBC

The NIAGARA Regimen*: Give your patients IO from the start

Key takeaways from the NIAGARA study:

1. **Start with neoadjuvant IMFINZI + gem-cis, then continue with adjuvant IMFINZI monotherapy following RC[1]**

   Administer neoadjuvant IMFINZI (1500 mg) + gem-cis† Q3W for 4 cycles, followed by adjuvant IMFINZI monotherapy (1500 mg) Q4W for up to 8 cycles after RC.

2. **Biomarker testing is not required to start treatment with IMFINZI[1]**

3. **The safety of the NIAGARA Regimen* was studied in >500 patients[1]**

4. **imAEs were reported in 21% (n=111/530) of patients with the NIAGARA Regimen* and in 3% (n=16/526) of patients treated with neoadjuvant gem-cis[4]**

   41% (n=45/111) of patients treated with the NIAGARA Regimen* and 44% (n=7/16) of patients treated with neoadjuvant gem-cis had all imAEs resolve‡.

Discover how the largest Phase III cis-eligible MIBC study may change your treatment approach[1-3] at IMFINZIhcp.com/mibc

*The NIAGARA Regimen is defined as neoadjuvant IMFINZI + gem-cis followed by adjuvant IMFINZI as a single agent after RC.[1]
†Day 1: Cisplatin 70 mg/m^2, gemcitabine 1000 mg/m^2; Day 8: gemcitabine 1000 mg/m^2; every 21 days for 4 cycles.[1,3]
‡Resolved includes outcomes of recovered/resolved and recovered/resolved with sequelae.[4]

Indication:

IMFINZI in combination with gemcitabine and cisplatin as neoadjuvant treatment, followed by single-agent IMFINZI as adjuvant treatment following radical cystectomy, is indicated for the treatment of adult patients with muscle-invasive bladder cancer (MIBC).

IMPORTANT SAFETY INFORMATION

There are no contraindications for IMFINZI® (durvalumab).

Severe and Fatal 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.

AstraZeneca