IMFINZI®
durvalumab
Injection for Intravenous Use 50 mg/mL

IN CIS-ELIGIBLE MIBC

Consider the FIRST and ONLY FDA-approved IO-based perioperative treatment[1,2*]:

The NIAGARA Regimen[1†]

NEOADJUVANT
IMFINZI + gem-cis

RADICAL
CYSTECTOMY

ADJUVANT IMFINZI

Discover reasons to consider perioperative IMFINZI* + neoadjuvant gem-cis at IMFINZIhcp.com/mibc

Study design: The NIAGARA study was a randomized, open-label, multicenter, Phase III study in patients who were candidates for RC and had not received prior systemic chemotherapy or immune-mediated therapy for the treatment of NMIBC or MIBC. It was designed to evaluate the efficacy and safety of neoadjuvant IMFINZI in combination with gemcitabine and cisplatin followed by adjuvant IMFINZI as a single agent following RC. 1063 patients were randomized 1:1 to receive neoadjuvant IMFINZI (1500 mg) + gemcitabine (1000 mg/m^2) and cisplatin (70 mg/m^2) (n=533) Q3W for 4 cycles prior to surgery, followed by IMFINZI (1500 mg) Q4W as a single-agent adjuvant treatment, or neoadjuvant gemcitabine (1000 mg/m^2) and cisplatin (70 mg/m^2) (n=530) Q3W for 4 cycles prior to surgery without adjuvant treatment. Patients with borderline renal function received split-dose cisplatin (35 mg/m^2 on Days 1 and 8 of each cycle). All treatments were given until disease progression that precludes definitive surgery, recurrence, unacceptable toxicity, or a maximum of 8 cycles after surgery. The dual primary endpoints were pCR and EFS. OS was a key secondary endpoint.[1,3]

*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; EFS=event-free survival; gem-cis=gemcitabine-cisplatin; IO=immuno-oncology; MIBC=muscle-invasive bladder cancer; NMIBC=non–muscle-invasive bladder cancer; OS=overall survival; pCR=pathological complete response; Q3W=every 3 weeks; Q4W=every 4 weeks; RC=radical cystectomy.

In the treatment of cis-eligible MIBC

The **FIRST** and **ONLY** FDA-approved IO-based perioperative regimen* to significantly improve EFS† and OS in a curative MIBC setting[1,2]

EVENT-FREE SURVIVAL (dual primary endpoint)[1,3]

32%

REDUCTION IN RISK OF AN EVENT (progression, recurrence, death, or not undergoing RC)† with the NIAGARA Regimen‡ vs neoadjuvant gem-cis (HR=0.68 [95% CI, 0.56-0.82]; *P*<0.0001)

Median EFS was not reached with the NIAGARA Regimen‡ (95% CI, NR-NR) vs 46.1 months with neoadjuvant gem-cis (95% CI, 32.2-NR)

Median duration of follow-up: 42.3 months (range: 0.03-61.3).
The dual primary endpoints for the NIAGARA study were pCR assessed by BICR and EFS assessed by BICR or by CPR if a biopsy was needed for analysis of a suspected new lesion.

- EFS maturity is 39%[3]

OVERALL SURVIVAL (secondary endpoint)[1,3]

25%

REDUCTION IN RISK OF DEATH with the NIAGARA Regimen‡ vs neoadjuvant gem-cis (HR=0.75 [95% CI, 0.59-0.93]; *P*=0.01)

Median OS was not reached with the NIAGARA Regimen‡ (95% CI, NR-NR) nor with neoadjuvant gem-cis (95% CI, NR-NR)

Median duration of follow-up: 46.3 months (range: 0.03-64.7).
The key secondary endpoint was OS as assessed with an alpha-allocation approach, following EFS in the statistical hierarchy.

- OS maturity is 27%[3]

pCR RESULTS: PRIMARY ANALYSIS AND EXPLORATORY REANALYSIS[3]

- At the primary analysis (data cutoff: January 2022), 33.8% (n=180/533; 95% CI, 29.8-38.0) of patients treated with the NIAGARA Regimen‡ and 25.8% (n=137/530; 95% CI, 22.2-29.8) of patients treated with neoadjuvant gem-cis achieved a pCR
  - **pCR rates reported during the primary analysis did not reach statistical significance**
- At the reanalysis (data cutoff: April 2024), 37.3% (n=199/533; 95% CI, 33.2-41.6) of patients treated with the NIAGARA Regimen‡ and 27.5% (n=146/530; 95% CI, 23.8-31.6) of patients treated with neoadjuvant gem-cis achieved a pCR
  - The reanalysis included an additional 59 patients§
  - **This analysis was exploratory and not powered to determine statistical significance**

Treating your patients with the NIAGARA Regimen‡ may prolong survival[1,3]

*A perioperative regimen consists of both neoadjuvant and adjuvant treatment.[1]
†Event-free survival was defined as the time from randomization to first recurrence of disease post-RC, time to first documented progression in patients who were precluded from RC, time of expected surgery in patients who refused RC or failure to undergo RC due to residual disease, or death due to any cause, whichever occurs first.[3]
‡The NIAGARA Regimen is defined as neoadjuvant IMFINZI + gem-cis followed by adjuvant IMFINZI as a single agent after RC.[1]
§The descriptive reanalysis of pCR included the results of 59 evaluable samples that were omitted from the primary analysis because the date of central assessment (which occurred after January 14, 2022), rather than the date of surgery (which occurred before January 14, 2022), was used as the data cutoff date.[3]

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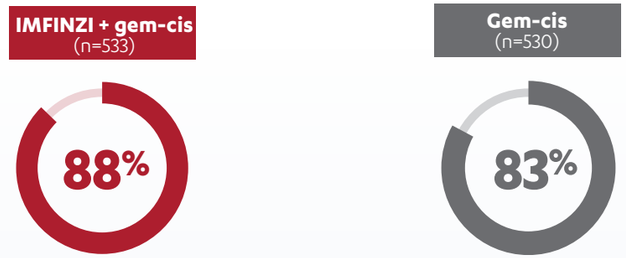
BICR=blinded independent central review; CI=confidence interval; CPR=central pathology review; HR=hazard ratio; NR=not reached.

Surgical data in the NIAGARA study

Time to RC following neoadjuvant treatment was similar between treatment arms: 39 days (range: 8-118) with IMFINZI + gem-cis and 38 days (range: 12-333) with gem-cis[3]

PERCENTAGE OF PATIENTS WHO UNDERWENT RC[1,3]



REASONS FOR NOT UNDERGOING OR COMPLETING RC[3]

	The NIAGARA Regimen‡ (n=533)	Neoadjuvant gem-cis (n=530)
Patients who did not undergo surgery–no. (%)	**63 (11.8%)**	84 (15.8%)
Patient decision	**6%**	6.8%
Unfit for surgery	**0.4%**	1.1%
Adverse event‖	**1.1%**	1.3%
Disease progression	**1.7%**	1.7%
Death	**0.9%**	1.5%
Study discontinuation	**0.6%**	2.3%
Investigator decision	**0.9%**	1.1%
Abandoned surgery (intra-operative)	**0.2%**	0%

Patient decision was the primary reason for not undergoing RC

- The percentage of patients with an AR¶ that prevented RC was the same across both treatment arms (0.2%)[1]
  - 1 patient experienced interstitial lung disease leading to cancellation of surgery in the IMFINZI + gem-cis arm[1]
- 1.7% (n=9) of patients in the IMFINZI + gem-cis arm and 1.1% (n=6) of patients in the gem-cis arm experienced a surgical delay# due to adverse events (AEs)[3]

‖Adverse event: Any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related.[4]
¶Adverse reaction: Any adverse event caused by a drug. Adverse reactions are a subset of all suspected adverse reactions where there is a reason to conclude that the drug caused the event.[4]
#Defined as occurring more than 56 days after the last dose of neoadjuvant treatment.[3]

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. 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.

AR=adverse reaction.

IMFINZI® durvalumab
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Discover the combined antitumor activity of an IO-based perioperative regimen[1,5]*

As observed in preclinical models

THE NIAGARA REGIMEN[1,6-9†]

NEOADJUVANT IMFINZI + CHEMOTHERAPY COMBINATION

CONTROL

Neoadjuvant chemotherapy:

- May reduce tumor size prior to surgery
- Provides upfront control by killing tumor cells—releasing neoantigens that may help induce an antitumor response

ENHANCE

Neoadjuvant IMFINZI:

Blocks PD-L1 to help inhibit immune suppression by the tumor and enhance T-cell activity

RADICAL CYSTECTOMY

ADJUVANT IMFINZI MONOTHERAPY

MAINTAIN

Blocking PD-L1 with **adjuvant IMFINZI** may help increase T-cell activation and maintain the antitumor immune response

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

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

NEOADJUVANT IMFINZI + CHEMOTHERAPY

START

IMFINZI ⊕ **gem-cis**

1500-mg fixed dose

Q3W FOR 4 CYCLES

RADICAL CYSTECTOMY

ADJUVANT IMFINZI

CONTINUE

IMFINZI

1500-mg fixed dose

Q4W FOR UP TO 8 CYCLES

- **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
- IMFINZI is administered as a 60-minute IV infusion after dilution[1]
- 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[1]
  - 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 cycle[1,3]
  - In the NIAGARA study, patients with borderline renal function received split-dose cisplatin (35 mg/m^2 on Days 1 and 8 of each neoadjuvant cycle)[1,3]
- Administer IMFINZI until disease progression that precludes definitive surgery, recurrence, unacceptable toxicity, or a maximum of 8 cycles after surgery[1]
- Biomarker testing is not required to start treatment with IMFINZI[1]

The NIAGARA Regimen† offers your cis-eligible MBIC patients another treatment approach[1,5]

*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]
IV=intravenous; PD-L1=programmed death-ligand 1.

In the treatment of cis-eligible MIBC

Cross-discipline collaboration may be beneficial to providing your patients an appropriate treatment plan

As your patients proceed through treatment, explore opportunities to engage across disciplines

IMFINZI is given in combination with gem-cis before RC and as a single agent after RC, requiring the respective capabilities of urologists and medical oncologists.[1,10]

Urologists and medical oncologists share responsibility and exchange leadership roles throughout the patient's treatment journey.[11]

Urologists work with medical oncologists to learn systemic therapy insights and imAE management in combination therapy.[11]

Urology-oncology collaboration may help your patients receive the most comprehensive care available[12]

IMPORTANT SAFETY INFORMATION (continued)

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.

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.

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imAE=immune-mediated adverse event.

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IMPORTANT SAFETY INFORMATION (continued)

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.

Complications of Allogeneic HSCT after IMFINZI (continued)

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.

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:

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IMFINZI®
durvalumab
Injection for Intravenous Use 50 mg/mL

THE NIAGARA REGIMEN*

(neoadjuvant IMFINZI + gem-cis followed by adjuvant IMFINZI)

The **FIRST** and **ONLY** perioperative IO-based regimen† to significantly improve survival[1,2]

IMFINZI® durvalumab
Injection for Intravenous Use 50 mg/mL

32% REDUCTION IN THE RISK OF AN EVENT[1,3]

(progression, recurrence, death, or not undergoing RC)‡ with the NIAGARA Regimen* vs neoadjuvant gem-cis (HR=0.68 [95% CI, 0.56-0.82]; *P*<0.0001). Median EFS was not reached with the NIAGARA Regimen* (95% CI, NR-NR) vs 46.1 months with neoadjuvant gem-cis (95% CI, 32.2-NR).

25% REDUCTION IN THE RISK OF DEATH[1,3]

with the NIAGARA Regimen* vs neoadjuvant gem-cis (HR=0.75 [95% CI, 0.59-0.93]; *P*=0.01).
Median OS was not reached with the NIAGARA Regimen* (95% CI, NR-NR) nor with neoadjuvant gem-cis (95% CI, NR-NR).

88% OF PATIENTS IN THE IMFINZI + GEM-CIS ARM UNDERWENT RC[3]

83.2% of patients who received neoadjuvant gem-cis underwent RC. In both arms, the most common reason for not undergoing RC was patient choice (6% of patients who received neoadjuvant IMFINZI + gem-cis and 6.8% of patients who received neoadjuvant gem-cis).

LOW DISCONTINUATION RATES DUE TO ARs[1]

In the neoadjuvant phase, 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).

In the adjuvant phase, 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).

*The NIAGARA Regimen is defined as neoadjuvant IMFINZI + gem-cis followed by adjuvant IMFINZI as a single agent after RC.[1]
†A perioperative regimen consists of both neoadjuvant and adjuvant treatment.[1]
‡Event-free survival was defined as the time from randomization to first recurrence of disease post-RC, time to first documented progression in patients who were precluded from RC, time of expected surgery in patients who refused RC or failure to undergo RC due to residual disease, or death due to any cause, whichever occurs first.[3]

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).

Safety and tolerability in the NIAGARA study

- The most common ARs (≥20% of patients; all grades), including laboratory abnormalities, overall in the study 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[1]
- In the neoadjuvant phase, serious ARs occurred in 24% of patients who received IMFINZI in combination with gem-cis (n=530); 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)[1]
- In the neoadjuvant phase, 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 before adjuvant treatment started[1]
- In the adjuvant phase, serious ARs occurred in 26% of patients who received IMFINZI (n=383); 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%)[1]
- In the adjuvant phase, 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)[1]

Discuss with your medical oncologist how the perioperative NIAGARA Regimen* may benefit your cis-eligible MIBC patients

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ALT=alanine aminotransferase; AST=aspartate aminotransferase.

AstraZeneca