The first and only regimen indicated for resectable muscle-invasive bladder cancer in neoadjuvant combination therapy followed by adjuvant monotherapy[1,2]*

PrIMFINZI® durvalumab

NEW INDICATION
PrIMFINZI® (durvalumab) is indicated for the treatment of patients with resectable muscle invasive bladder cancer (MIBC) in combination with gemcitabine and cisplatin as neoadjuvant treatment, followed by adjuvant IMFINZI monotherapy treatment after radical cystectomy.

In resectable MIBC patients eligible for cisplatin

REACH FOR IMFINZI®

Based on the NIAGARA trial
(neoadjuvant IMFINZI® + gemcitabine + cisplatin followed by adjuvant IMFINZI® after radical cystectomy)

NIAGARA: A large Phase III study in resectable MIBC with 1063 patients eligible for cisplatin[1]

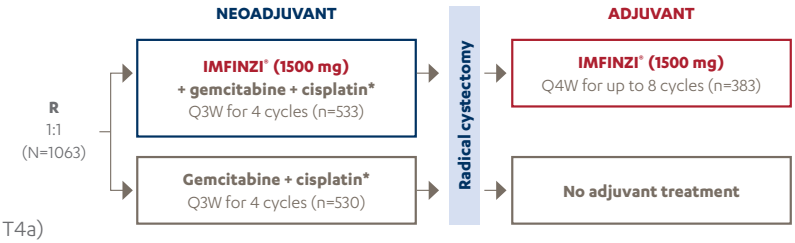
NIAGARA STUDY DESIGN: PHASE III, MULTICENTRE, OPEN-LABEL STUDY

Key inclusion criteria:[1,3]

- Cis-eligible resectable MIBC (T2-T4a, N0 or N1, and M0)
- No prior systemic chemotherapy or immune-mediated therapy for MIBC
- Candidates for radical cystectomy
- Weight >30 kg
- CrCl ≥40 mL/min

Randomization was stratified by:

- Clinical tumour stage (T2N0 vs >T2N0, including T2N1, T3, and T4a)
- PD-L1 status (high vs. low/negative expression)
- Adequate renal function (borderline [CrCl ≥40 mL/min to <60 mL/min] vs. adequate [≥60 mL/min])



Adapted from Product Monograph[1]

Key inclusion criteria:[1]

- Stage IIIb disease, pure non-urothelial or any small cell histology
- Primary non-bladder cancer of the urothelium
- Active or prior documented autoimmune disease, active tuberculosis or hepatitis B or C or HIV infection
- Cardiovascular conditions (e.g., myocardial infarction within 6 months, Class III/IV heart failure)
- ECOG performance status ≥2
- Recent use of live attenuated vaccine (within 30 days of the first dose) or immunosuppressive medication (within 14 days, with exceptions for corticosteroids)

Primary endpoint:[1]

- Event-free survival (EFS) by BICR‡

Secondary endpoint:[1]

- Overall survival (OS)

Other endpoint:[1]

- Proportion of patients who underwent radical cystectomy

ECOG=Eastern Cooperative Oncology Group; PD-L1=programmed death-ligand 1; PS=performance status; Q3W=every 3 weeks; Q4W=every 4 weeks; R=randomized.

* Comparative clinical significance unknown.

† Day 1: cisplatin 70 mg/m2, gemcitabine 1000 mg/m2; Day 8: gemcitabine 1000 mg/m2 every 21 days for 4 cycles.

‡ Defined as the time from randomization to progressive disease that precluded radical cystectomy, the first recurrence of disease after radical cystectomy, the expected date of surgery (in patients who did not undergo radical cystectomy), or death from any cause.[3]

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IMFINZI®: demonstrated safety profile

Most commonly reported adverse events (any Grade; occurring in ≥10% of patients) in the NIAGARA study[1]

Pr IMFINZI® durvalumab

	IMFINZI® + gemcitabine + cisplatin (n=530)		Gemcitabine + cisplatin (n=526)	
Adverse drug reaction	**Any Grade n (%)**	**Grade 3-4 n (%)**	**Any Grade n (%)**	**Grade 3-4 n (%)**
Blood and lymphatic system disorders				
Neutropenia	214 (40.4)	113 (21.3)	237 (45.1)	123 (23.4)
Anemia	205 (38.7)	73 (13.8)	213 (40.5)	79 (15.0)
Thrombocytopenia	91 (17.2)	25 (4.7)	91 (17.3)	31 (5.9)
Leukopenia	58 (10.9)	11 (2.1)	71 (13.5)	11 (2.1)
Febrile neutropenia	11 (2.1)	10 (1.9)	11 (2.1)	11 (2.1)
Respiratory thoracic and mediastinal disorders				
Cough/ Productive Cough	43 (8.1)	0	30 (5.7)	0
Pneumonitis*	9 (1.7)	0	3 (0.6)	0
Dysphonia	8 (1.5)	0	8 (1.5)	0
Hepatobiliary disorders				
Aspartate aminotransferase increased or alanine aminotransferase increased†	55 (10.4)	10 (1.9)	48 (9.1)	6 (1.1)
Gastrointestinal disorders				
Nausea	284 (53.6)	8 (1.5)	255 (48.5)	5 (1.0)
Constipation	205 (38.7)	4 (0.8)	203 (38.6)	4 (0.8)
Diarrhea	109 (20.6)	8 (1.5)	74 (14.1)	2 (0.4)
Abdominal pain‡	107 (20.2)	5 (0.9)	71 (13.5)	5 (1.0)
Vomiting	102 (19.2)	5 (0.9)	97 (18.4)	1 (0.2)
Stomatitis	34 (6.4)	0	30 (5.7)	0
Colitis§	7 (1.3)	1 (0.2)	1 (0.2)	0
Endocrine disorders				
Hypothyroidism¶	67 (12.6)	2 (0.4)	12 (2.3)	0
Hyperthyroidism**	33 (6.2)	0	12 (2.3)	0
Nervous system disorders				
Neuropathy peripheral	66 (12.5)	1 (0.2)	59 (11.2)	0
Renal and urinary disorders				
Blood creatinine increased	98 (18.5)	12 (2.3)	77 (14.6)	4 (0.8)
Dysuria	28 (5.3)	0	19 (3.6)	0
Nephritis††	6 (1.1)	2 (0.4)	2 (0.4)	0

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	IMFINZI® + gemcitabine + cisplatin (n=530)		Gemcitabine + cisplatin (n=526)	
Adverse drug reaction	**Any Grade n (%)**	**Grade 3-4 n (%)**	**Any Grade n (%)**	**Grade 3-4 n (%)**
Skin and subcutaneous tissue disorders				
Rash‡‡	111 (20.9)	5 (0.9)	51 (9.7)	3 (0.6)
Pruritus	80 (15.1)	0	38 (7.2)	0
Alopecia	49 (9.2)	2 (0.4)	57 (10.8)	0
General disorders and administration site conditions				
Fatigue§§	273 (51.5)	12 (2.3)	257 (48.9)	16 (3.0)
Pyrexia	110 (20.8)	1 (0.2)	87 (16.5)	0
Oedema peripheral¶¶	47 (8.9)	1 (0.2)	52 (9.9)	0
Infections and infestations				
Upper respiratory tract infections***	28 (5.3)	0	27 (5.1)	1 (0.2)
Pneumonia†††	22 (4.2)	8 (1.5)	13 (2.5)	6 (1.1)
Dental and oral soft tissue infections‡‡‡	6 (1.1)	0	3 (0.6)	1 (0.2)
Musculoskeletal and connective tissue disorders				
Myalgia	32 (6.0)	0	13 (2.5)	0
Injury, poisoning and procedural complications				
Infusion-related reaction§§§	7 (1.3)	0	2 (0.4)	0
Metabolism and nutrition disorders				
Decreased appetite	141 (26.6)	3 (0.6)	131 (24.9)	3 (0.6)

Adapted from Product Monograph[1]

– Serious adverse events occurred in 61.5% of patients in the IMFINZI® + gemcitabine and cisplatin arm and 54.6% of patients in the chemotherapy arm[1]

- Serious embolic adverse events were reported at a frequency of ≥3% higher in patients in the IMFINZI® + gemcitabine and cisplatin arm compared to the gemcitabine and cisplatin control arm (4.7% vs. 1%, respectively)
- Other serious adverse events reported at a higher frequency in patients in the IMFINZI® + gemcitabine and cisplatin arm compared to the gemcitabine and cisplatin control arm were prostate cancer (6.6% vs. 5.1%), urosepsis (3.8% vs. 1.9%), hydronephrosis (2.8% vs. 1.5%) and pneumonia (2.3% vs. 1.0%)

* Includes immune-mediated lung disease and pneumonitis.
† Includes alanine aminotransferase increased, aspartate aminotransferase increased, and hepatic enzyme increased.
‡ Includes abdominal pain, abdominal pain lower, abdominal pain upper, and flank pain.
§ Includes colitis, enterocolitis, and immune-mediated enterocolitis.
¶ Includes blood thyroid stimulating hormone increased and hypothyroidism.
** Includes blood thyroid stimulating hormone decreased and hyperthyroidism.
†† Includes nephritis and immune-mediated nephritis.
‡‡ Includes eczema, erythema, rash, rash erythematous, rash maculo-papular, rash papular, rash pruritic, and rash pustular.
§§ Includes asthenia and fatigue.
¶¶ Includes oedema peripheral and peripheral swelling.
*** Includes laryngitis, nasopharyngitis, pharyngitis, rhinitis, sinusitis, tonsillitis, and upper respiratory tract infection.
††† Includes pneumonia, pneumonia bacterial, and pneumonia klebsiella.
‡‡‡ Includes gingivitis, pulpitis dental, tooth abscess, and tooth infection.
§§§ Includes infusion related reactions and urticaria.

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Perioperative IMFINZI®* + neoadjuvant gemcitabine + cisplatin: Demonstrated a statistically significant and clinically meaningful improvement in EFS and OS[1]

Pr IMFINZI® durvalumab

RESULTS FROM THE NIAGARA STUDY (preplanned interim analysis; data cutoff: April 29, 2024)

Event-free survival (primary endpoint)†

32% ↓ REDUCTION IN RISK OF AN EVENT†
with the NIAGARA Regimen (IMFINZI + gemcitabine + cisplatin)* (187/533) vs neoadjuvant gem-cis (246/530)
(HR=0.68 [95% CI, 0.56-0.82]; *P*<0.001).[1,3]

Median OS was not reached with the NIAGARA Regimen* (95% CI, NR-NR) nor with neoadjuvant gem-cis (95% CI, NR-NR)[1]
Median duration of follow-up: 46.3 months (range: 0.03-64.7).[3]
2-sided *P* value; the boundary for declaring statistical significance was 0.0412.[1]

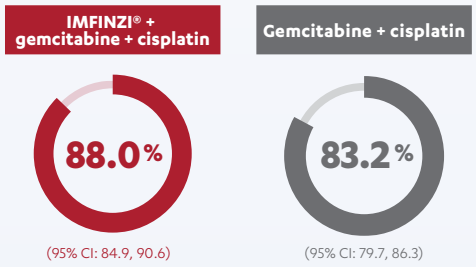
Overall survival (key secondary endpoint)

25% ↓ REDUCTION IN RISK OF DEATH
with the NIAGARA Regimen (IMFINZI + gemcitabine + cisplatin)* (136/533) vs neoadjuvant gem-cis (169/530)
(HR=0.75 [95% CI, 0.59-0.93]; *P*=0.011).[1,3,§]

Median EFS was not reached with the NIAGARA Regimen* (95% CI, NR-NR) vs 46.1 months (95% CI, 32.2-NR) with neoadjuvant gem-cis[1]
Median duration of follow-up: 42.3 months (range: 0.03-61.3).[3]
2-sided *P* value; the boundary for declaring statistical significance was 0.0154.[1]

Surgical data in the NIAGARA study (other endpoint)[1]

PERCENTAGE OF PATIENTS WHO UNDERWENT RADICAL CYSTECTOMY



The proportion of patients who underwent radical cystectomy was higher in the IMFINZI® + gemcitabine + cisplatin arm vs. the gemcitabine + cisplatin control arm[1]

IMFINZI® is indicated for the treatment of patients with resectable muscle invasive bladder cancer (MIBC) in combination with gemcitabine and cisplatin as neoadjuvant treatment, followed by adjuvant IMFINZI® monotherapy treatment after radical cystectomy.

Gem-cis: gemcitabine and cisplatin.
*Refers to neoadjuvant IMFINZI® + gemcitabine + cisplatin followed by adjuvant IMFINZI® after radical cystectomy.
† Defined as the time from randomization to progressive disease that precluded radical cystectomy, the first recurrence of disease after radical cystectomy, the expected date of surgery (in patients who did not undergo radical cystectomy), or death from any cause.[3]

Clinical use:
The safety and efficacy of IMFINZI® in patients younger than 18 years of age have not been established. Therefore, Health Canada has not authorized an indication for pediatric use.
No overall differences in safety or efficacy were reported between elderly patients (≥65 years of age) and younger patients (<65 years of age).

Most serious warnings and precautions:
Immune-mediated adverse reactions: IMFINZI® as monotherapy or in combination with other products can cause severe and fatal immune-mediated adverse reactions, including enterocolitis, intestinal perforation, hepatitis, dermatitis, Stevens-Johnson syndrome, endocrinopathy, pneumonitis, interstitial lung disease, myocarditis, neuropathy, encephalitis, myasthenia gravis, as well as toxicities in other organ systems. Immune-mediated adverse reactions have occurred at higher frequencies when IMFINZI® is administered as a combination therapy with tremelimumab compared with IMFINZI® as monotherapy.

Other relevant warnings and precautions:
- Administer under the supervision of healthcare practitioners experienced in the treatment of cancer
- Serious embolic events in combination with gemcitabine and cisplatin
- Driving and operating machinery
- Immune-mediated adverse reactions; continuous monitoring required
- Infections
- Infusion-related reactions
- Monitoring and laboratory tests
- Fertility
- Pregnant and breast-feeding women

For more information:
Please consult the IMFINZI® Product Monograph at https://www.content.astrazeneca.com/ca/en/00620641015302/ePI.html for important information relating to adverse reactions, drug interactions, and dosing, which have not been discussed in this piece. The Product Monograph is also available by calling us at 1-800-668-6000.

References:
1. IMFINZI® Product Monograph. AstraZeneca Canada Inc. July 17, 2025
2. Data on file. AstraZeneca Canada Inc.
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.

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