NOW RECOMMENDED BY NICE[1]

The perioperative IMFINZI NIAGARA regimen*

IMFINZI®
durvalumab
Injection for Intravenous Use 50 mg/mL

A New Era in MIBC Care

Offer more eligible patients the potential of improved outcomes with the perioperative IMFINZI NIAGARA regimen* – the FIRST and ONLY IO treatment approved in the UK to show a statistically significant improvement in both EFS and OS vs NAC in MIBC.[2,3]

Therapeutic indication:

IMFINZI in combination with gemcitabine and cisplatin as neoadjuvant treatment, followed by IMFINZI as monotherapy adjuvant treatment after radical cystectomy, is indicated for the treatment of adults with resectable MIBC.[2]

*The perioperative IMFINZI NIAGARA regimen is defined as neoadjuvant IMFINZI + gem-cis followed by adjuvant IMFINZI as a single agent after RC.[3]

MIBC, muscle-invasive bladder cancer; IO, immuno-oncology; EFS, event-free survival; OS, overall survival; NAC, neoadjuvant chemotherapy; NICE, National Institute for Health and Care Excellence.

References: 1. NICE (2026) Durvalumab with gemcitabine and cisplatin for neoadjuvant treatment then alone for adjuvant treatment of muscle-invasive bladder cancer. Available at: https://www.nice.org.uk/guidance/ta1138/resources/durvalumab-with-gemcitabine-and-cisplatin-for-neoadjuvant-treatment-then-alone-for-adjuvant-treatment-of-muscleinvasive-bladder-cancer-pdf-2973530578195141 (Accessed: April 2026); 2. IMFINZI, Summary of Product Characteristics; 3. Powles T, et al. N Engl J Med. 2024;391(19):1773-1786 (including Supplementary Appendix and Protocol).

GB-74298 | April 2026

AstraZeneca

32%

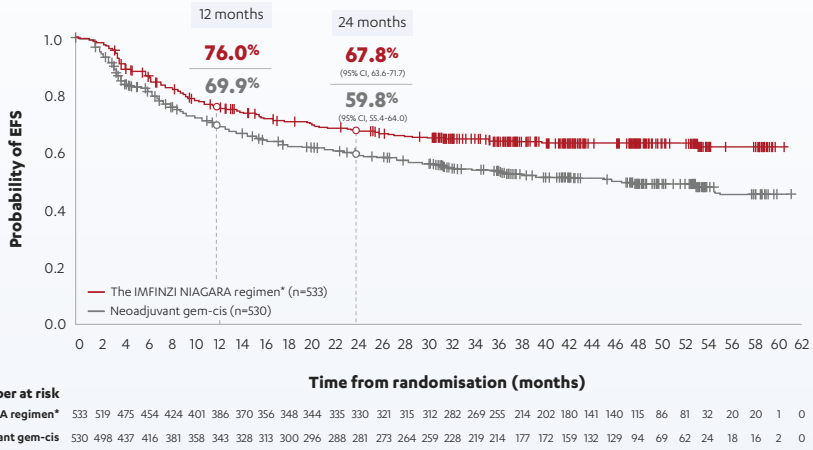
(ARR 8% at 24 months)

The perioperative IMFINZI NIAGARA regimen* was associated with a 32% statistically significant reduction in the risk of an EFS event vs neoadjuvant gem-cis[1]

EVENT-FREE SURVIVAL (DUAL PRIMARY ENDPOINT)[1,2†]

	IMFINZI NIAGARA regimen (n=533)	Neoadjuvant gem-cis (n=530)
Number of events, n (%)	187 (35.1)	246 (46.4)
Median EFS (95% CI), months	NR (NR-NR)	46.1 (32.2-NR)
HR (95% CI)	**0.68 (0.56-0.82)**	
p-value	<0.0001	

Median duration of follow-up: 42.3 months (range, 0.03–61.3)



Number at risk

The IMFINZI NIAGARA regimen*	533	519	475	454	424	401	386	370	356	348	344	335	330	321	315	312	282	269	255	214	202	180	141	140	115	86	81	32	20	20	1	0
Neoadjuvant gem-cis	530	498	437	416	381	358	343	328	313	300	296	288	281	273	264	259	228	219	214	177	172	159	132	129	94	69	62	24	18	16	2	0

NIAGARA was a phase 3, open-label, randomised trial:

Cisplatin- eligible patients with muscle-invasive bladder cancer were assigned, in a 1:1 ratio, to receive neoadjuvant durvalumab plus gemcitabine–cisplatin every 3 weeks for four cycles, followed by radical cystectomy and adjuvant durvalumab every 4 weeks for eight cycles (durvalumab group), or to receive neoadjuvant gemcitabine–cisplatin followed by radical cystectomy alone (comparison group). Event-free survival and pathological complete response were dual primary endpoints. Overall survival was the key secondary end point. Patients with borderline renal function (CrCl ≥40 mL/min to <60 mL/min) received split-dose cisplatin.[1]

† Event-free survival was defined as the time from randomisation 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.[1]

*The perioperative IMFINZI NIAGARA regimen is defined as neoadjuvant IMFINZI + gem-cis followed by adjuvant IMFINZI as a single agent after RC[1]

EFS, event-free survival; CI, confidence interval; NR, not reached; HR, hazard ratio; gem-cis, gemcitabine-cisplatin; RC, radical cystectomy.

Reference: 1. Powles T, et al. N Engl J Med. 2024;391(19):1773-1786 (including Supplementary Appendix and Protocol). **2.** Powles T, et al. Presented at ESMO; September 13-17, 2024; Barcelona, Spain. Abs LBA5.

pCR RESULTS (DUAL PRIMARY ENDPOINT)[1]

Primary analysis (DCO: January 2022)

- **33.8%** (n=180/533; 95% CI, 29.8-38.0) of patients treated with the perioperative IMFINZI NIAGARA regimen* achieved a pCR vs **25.8%** (n=137/530; 95% CI, 22.2-29.8) of patients treated with neoadjuvant gem-cis
- **pCR rates reported during the primary analysis did not reach statistical significance**

Exploratory re-analysis (DCO: April 2024)

- **37.3%** (n=199/533; 95% CI, 33.2-41.6) of patients treated with the perioperative IMFINZI NIAGARA regimen* achieved a pCR vs **27.5%** (n=146/530; 95% CI, 23.8-31.6) of patients treated with neoadjuvant gem-cis
- The reanalysis included an additional 59 patients that were not included in the primary analysis‡
- **This analysis was exploratory and not powered to determine statistical significance**

The perioperative IMFINZI NIAGARA regimen* is the first and only IO therapy in MIBC to achieve a statistically significant OS improvement vs neoadjuvant gem-cis[1]

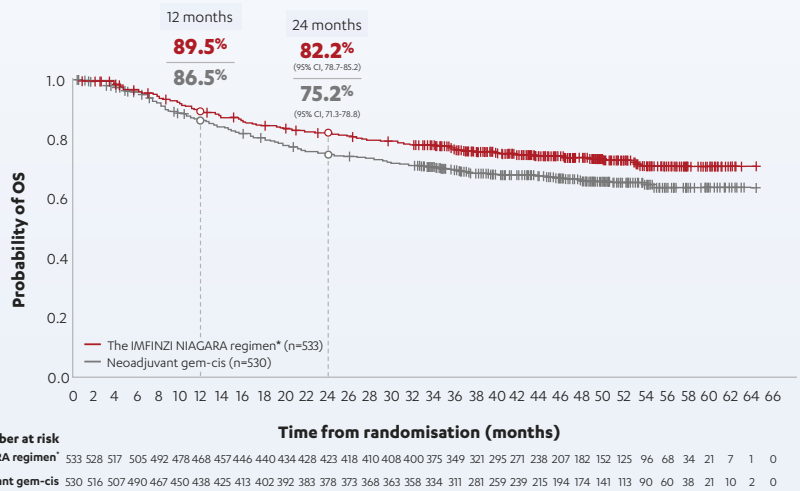
25%
(ARR 7% at 24 months)

The perioperative IMFINZI NIAGARA regimen* was associated with a 25% statistically significant reduction in the risk of death vs neoadjuvant gem-cis[1]

OVERALL SURVIVAL (SECONDARY ENDPOINT)[1,2†]

	IMFINZI NIAGARA regimen (n=533)	Neoadjuvant gem-cis (n=530)
Number of deaths, n (%)	136 (25.5)	169 (31.9)
Median OS (95% CI), months	NR (NR-NR)	NR (NR-NR)
HR (95% CI)	**0.75 (0.59–0.93)**	
p-value	0.01	

Median duration of follow-up: 46.3 months (range: 0.03-64.7)



*The perioperative IMFINZI NIAGARA regimen is defined as neoadjuvant IMFINZI + gem-cis followed by adjuvant IMFINZI as a single agent after RC[1]

† The key secondary endpoint was OS as assessed with an alpha-allocation approach, following EFS in the statistical hierarchy.[1]

‡The descriptive reanalysis of pCR corrected an earlier oversight in the primary analysis where 59 evaluable samples were mistakenly omitted from the primary analysis. This occurred because the data cut-off was based on the date of the central assessment (which occurred after January 14, 2022), rather than the date of surgery (which occurred before January 14, 2022) which led to the exclusion of samples that should have been included.[1]

DCO, data cut-off; CI, confidence interval; gem-cis, gemcitabine–cisplatin; IO, immuno-oncology; OS, overall survival; HR, hazard ratio; NR, not reached.

Reference: 1. Powles T, et al. N Engl J Med. 2024;391(19):1773-1786 (including Supplementary Appendix and Protocol); **2.** Powles T, et al. Presented at ESMO; September 13-17, 2024; Barcelona, Spain. Abs LBA5.

The addition of IMFINZI to NAC did not negatively impact the rate or timing of RC vs neoadjuvant gem-cis[1]

A HIGHER PROPORTION OF PATIENTS COMPLETED RC WITH THE PERIOPERATIVE IMFINZI NIAGARA REGIMEN* VS NEOADJUVANT GEM-CIS:[1]

88% in the perioperative IMFINZI NIAGARA regimen* arm (n=533)

83% in the neoadjuvant gem-cis arm (n=530)

MEDIAN TIME TO RC FOLLOWING NEOADJUVANT TREATMENT WAS SIMILAR BETWEEN TREATMENT ARMS[1]

39 days (range, 8-118) for the perioperative IMFINZI NIAGARA regimen* arm (n=533)

38 days (range, 12-333) for the neoadjuvant gem-cis arm (n=530)

*The perioperative IMFINZI NIAGARA regimen is defined as neoadjuvant IMFINZI + gem-cis followed by adjuvant IMFINZI as a single agent after RC.[1]
RC, radical cystectomy; NAC, neoadjuvant chemotherapy; gem-cis, gemcitabine-cisplatin.

Reference: 1. Powles T, et al. N Engl J Med. 2024;391(19):1773-1786 (including Supplementary Appendix and Protocol).

Addition of perioperative IMFINZI to NAC was generally tolerable and manageable, with no new safety signals[1,2]

THE SAFETY PROFILE OF THE PERIOPERATIVE IMFINZI NIAGARA REGIMEN* WAS STUDIED IN >500 CIS-ELIGIBLE MIBC PATIENTS[1]

- The safety profile of the perioperative IMFINZI NIAGARA regimen* was **consistent with the known safety profiles of the individual components** of the regimen[1]
- imAEs were reported in 21% (111/530; grade 3/4, 3%) of patients in the IMFINZI NIAGARA arm and 3% (16/526; grade 3/4 0.2%) of patients in the neoadjuvant gem-cis arm.[2]
- **imAEs are special warnings for use with IMFINZI. Please refer to the SmPC for further information on special warnings, safety profile and adverse events.**

SURGERY CANCELLATION DUE TO AES WAS COMPARABLE BETWEEN BOTH ARMS[1]

- AEs leading to cancellation of RC: 1.1% and 1.3% in the IMFINZI NIAGARA and neoadjuvant gem-cis arms respectively
- AEs leading to delayed RC: 1.7% and 1.1% in the IMFINZI NIAGARA and neoadjuvant gem-cis arms respectively

AE DISCONTINUATION RATES BETWEEN ARMS WERE COMPARABLE IN THE NEOADJUVANT PHASE AND RELATIVELY INFREQUENT IN THE IMFINZI ADJUVANT PHASE[1]

- 14.9% of patients (79/530) discontinued neoadjuvant treatment‡ due to AEs in the IMFINZI NIAGARA regimen* arm, with 9.4% (50/530) discontinuing neoadjuvant IMFINZI.‖
- 15.2% of patients (80/526) discontinued neoadjuvant gem-cis due to AEs in the neoadjuvant gem-cis arm.
- 7.8% of patients (30/383) discontinued adjuvant IMFINZI due to AEs.¶ No Adjuvant treatment was received in the gem-cis arm.

*The perioperative IMFINZI NIAGARA regimen is defined as neoadjuvant IMFINZI + gem-cis followed by adjuvant IMFINZI as a single agent after RC[1]

‡Refers to IMFINZI/gemcitabine/cisplatin and does not include surgery.[1]

‖Neoadjuvant phase - includes all patients who received at least one dose of neoadjuvant treatment.[1]

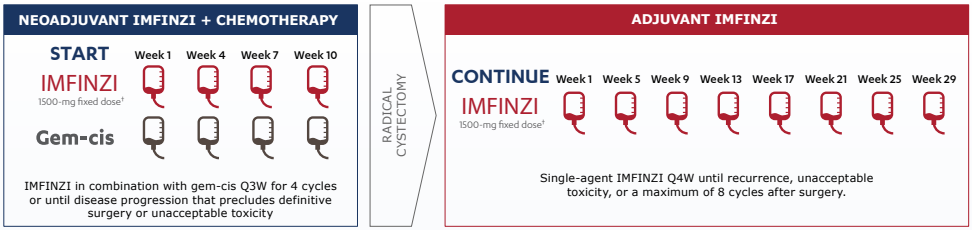
¶ Adjuvant phase - Includes all patients who received at least one dose of IMFINZI as adjuvant treatment in the IMFINZI NIAGARA group and all patients who had at least 1 visit in the adjuvant phase in the neoadjuvant gem-cis group.[1]

NAC, neoadjuvant chemotherapy; MIBC, muscle-invasive bladder cancer; RC, radical cystectomy; gem-cis, gemcitabine-cisplatin; AE, adverse event; imAE, immune mediated adverse event.

Reference: 1. Powles T, et al. N Engl J Med. 2024;391(19):1773-1786 (including Supplementary Appendix and Protocol); **2.** Galsky MD, et al. Presented at ASCO GU Cancers Symposium; February 13-15, 2025; San Francisco, CA. Abs659.

Give your eligible patients with MIBC the potential for improved outcomes vs NAC by offering IMFINZI from the start*[1]

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



- PD-L1 testing is not required to start treatment with IMFINZI[1]

- MIBC patients with a body weight of ≤30 kg must receive weight-based dosing of IMFINZI at 20 mg/kg.[2]
- Administer IMFINZI prior to chemotherapy on the same day.[2]
- Refer to the SmPC for appropriate chemotherapeutic agent for dosing alongside IMFINZI.
- IMFINZI is administered as a 60-minute IV infusion after dilution.[2]

- **Patients with borderline renal function (CrCl ≥40 mL/min/1.73 m² to <60 mL/min/1.73 m²) received split-dose cisplatin 35 mg/m² on days 1 and 8 of each neoadjuvant cycle in the NIAGARA trial.[1,2]**

A holistic uro-oncology care team approach is essential to unlocking the full potential of the perioperative IMFINZI NIAGARA regimen* for eligible patients with MIBC in the UK.

*The perioperative IMFINZI NIAGARA regimen is defined as neoadjuvant IMFINZI + gem-cis followed by adjuvant IMFINZI as a single agent after RC[1]

MIBC, muscle-invasive bladder cancer; gem-cis, gemcitabine-cisplatin; Q4W, once every 4 weeks; Q3W, once every 3 weeks; SmPC, summary of product characteristics; IV, intravenous; CrCl, creatinine clearance; NAC, neoadjuvant chemotherapy.

Reference: 1. Powles T, et al. N Engl J Med. 2024;391(19):1773-1786 (including Supplementary Appendix and Protocol); **2.** IMFINZI, Summary of Product Characteristics.

Time for a NEW ERA IN MIBC with the perioperative IMFINZI NIAGARA regimen*

– the FIRST and ONLY IO approved in the UK with statistically significant improvements in EFS and OS vs neoadjuvant gem-cis in cis-eligible resectable MIBC[1,2]

- Despite current treatment options, **outcomes in MIBC remain poor** with 50% of patients recurring within 3 years.[1]
- Prior to the new NICE recommendation, available IO therapies for MIBC were **restricted to the adjuvant setting in PD-L1 positive patients** at a high risk of recurrence after surgery.[3]

- NIAGARA demonstrated a **statistically significant improvement in EFS and OS** vs neoadjuvant gem-cis in resectable MIBC[1]
- The addition of IMFINZI to neoadjuvant gem-cis did not negatively impact time to surgery or rate of surgery[1]

- The addition of perioperative IMFINZI to neoadjuvant gem-cis was **generally tolerable and manageable, with no new safety signals**[1,4]
- Discontinuation of IMFINZI due to AEs in the neoadjuvant and adjuvant phases, and AEs impacting surgery, were within expected ranges[1]

*The perioperative IMFINZI NIAGARA regimen is defined as neoadjuvant IMFINZI + gem-cis followed by adjuvant IMFINZI as a single agent after RC[1]
MIBC, muscle-invasive bladder cancer; IO, immuno-oncology; EFS, event-free survival; OS, overall survival; AE, adverse events; RC, radical cystectomy; gem-cis, gemcitabine-cisplatin

References: 1. Powles T, et al. N Engl J Med. 2024;391(19):1773-1786 (including Supplementary Appendix and Protocol); **2.** IMFINZI, Summary of Product Characteristics; **3.** NICE (2022) Nivolumab for adjuvant treatment of invasive urothelial cancer at high risk of recurrence. Available at: https://www.nice.org.uk/guidance/ta817 (Accessed: April 2026); **4.** Powles T, et al. Presented at ESMO; September 13-17, 2024.

As a uro-oncology team, offer your eligible MIBC patients the potential of improved outcomes vs NAC with the perioperative IMFINZI NIAGARA regimen*[1]

CURRENT CLINICAL GUIDANCE FOR MIBC MANAGEMENT

- UK and EU clinical guidelines including EAU, ESMO and NICE recommend offering radical cystectomy or bladder preserving approaches, such as trimodal bladder preserving treatments (TMT), as curative treatment options for eligible patients.[2-4]
- These guidelines also emphasise the importance of multidisciplinary care and shared decision-making between the patient and relevant specialists, including urologists and medical oncologists.[2-4]

Click or scan the QR code below for UK IMFINZI (durvalumab) prescribing information

Adverse events should be reported. Reporting forms and information can be found at **http://www.mhra.gov.uk/yellowcard** or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to AstraZeneca by visiting **https://contactazmedical.astrazeneca.com/** or by calling **0800 783 0033**

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

IO, immuno-oncology; EAU, European Association of Urology; ESMO, European Society for Medical Oncology; NICE, National Institute for Health and Care Excellence; TMT, trimodal bladder preserving treatments; NAC, neoadjuvant chemotherapy.

References: 1. Powles T, et al. N Engl J Med. 2024;391(19):1773-1786 (including Supplementary Appendix and Protocol); **2.** EAU (2025) Muscle-invasive and Metastatic Bladder Cancer, disease management. Available at: https://uroweb.org/guidelines/muscle-invasive-and-metastatic-bladder-cancer/chapter/disease-management (Accessed: April 2026); **3.** Powles T, et al. Annals of Oncology. 2022; 33 (3); 244 – 258; **4.** NICE (2015) Bladder cancer: diagnosis and management. Available at: https://www.nice.org.uk/guidance/ng2/chapter/Recommendations (Accessed: April 2026).