RECOMMENDED BY NICE[1]:
the perioperative IMFINZI NIAGARA regimen†

IMFINZI®
durvalumab
Injection for Intravenous Use 50 mg/mL

Redefining MIBC care together

Offer more eligible patients the potential of improved outcomes with the FIRST IO approved in the UK to achieve statistically significant EFS and OS improvement in MIBC vs neoadjuvant gem-cis.[2,3]

Therapeutic indication:[2]

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.

Despite current treatment options, **outcomes in MIBC remain poor** with ~50% of patients recurring within 3 years.[2]

Prior to the 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.[4]

NIAGARA* presented a **statistically significant improvement in EFS and OS** for the perioperative IMFINZI NIAGARA regimen† vs neoadjuvant gem-cis.[2,5]

- **EFS (Dual-primary endpoint);** HR 0.68 (95% CI, 0.56–0.82), p < 0.0001
- **pCR (Dual-primary endpoint);** Primary analysis: risk ratio, 1.30; 95% CI, 1.09 to 1.56- did not reach statistical significance; Descriptive reanalysis: risk ratio, 1.34; 95% CI, (1.13-1.60)- not powered to determine statistical significance.
- **OS (Key secondary endpoint);** HR 0.75 (95% CI, 0.59–0.93), p = 0.01

The addition of IMFINZI to neoadjuvant gem-cis **did not lead to a reduction** in the percentage of **patients who underwent RC.[2]**

The addition of **perioperative IMFINZI to neoadjuvant gem-cis was generally tolerable and manageable,** with **no new safety signals** and its safety profile was consistent with the known safety profiles of the individual components of the regimen[2,5]

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.[2]

In the NIAGARA arm, the most common adverse events of any cause were nausea, anaemia and constipation.[2]

As a uro-oncology team, offer more eligible MIBC patients the potential of improved outcomes with the perioperative IMFINZI NIAGARA regimen vs NAC†[,2]

† The perioperative IMFINZI NIAGARA regimen is defined as neoadjuvant IMFINZI + gem-cis followed by adjuvant IMFINZI as a single agent after RC.[2]

***NIAGARA was a phase 3, open-label, randomised trial.** Cisplatin- eligible patients with muscle-invasive bladder cancer (n=1063) 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 n=533), or to receive neoadjuvant gemcitabine–cisplatin followed by radical cystectomy alone (comparison group n= 530). 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. 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.[2]

GB-76784 | July 2026

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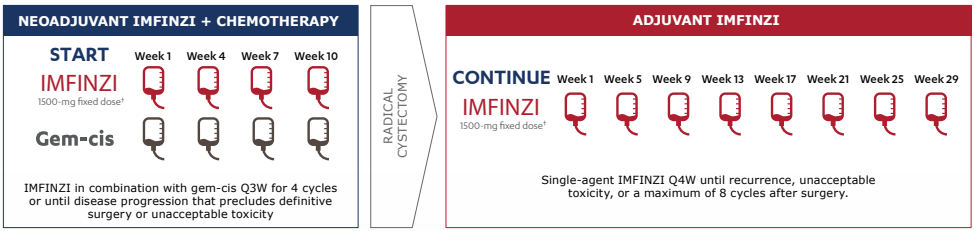
Give your eligible patients with MIBC the potential for improved outcomes vs NAC by offering IMFINZI + gem-cis from the start[2]



†Patients with a body weight of 30 kg or less must receive weight-based dosing of Imfinzi at 20 mg/kg.[3]

- PD-L1 testing is not required to start treatment with IMFINZI[2]

- Administer IMFINZI prior to chemotherapy on the same day.[3]
- Refer to the SmPC of appropriate chemotherapeutic agent for dosing alongside IMFINZI.
- IMFINZI is administered as a 60-minute IV infusion after dilution.[3]

- **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.[2,3]**

Please refer to the IMFINZI SmPC prior to prescribing for safety profile considerations to minimise the risks associated with its use, and for full prescribing information including dosing guidance and adverse drug reactions (ADRs).

Click or scan the QR code below for UK IMFINZI Prescribing Information

Adverse events should be reported. Reporting forms and information can be found at **https://yellowcard.mhra.gov.uk/** 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.**

Abbreviations:

MIBC, muscle-invasive bladder cancer; **gem-cis**, gemcitabine-cisplatin; **IO,** immuno-oncology; **EFS,** event-free survival; **OS,** overall survival; **HR,** hazard ratio; **CI,** confidence interval; **AE,** adverse events; **Q4W,** once every 4 weeks; **Q3W,** once every 3 weeks; **SmPC,** summary of product characteristics; **CrCl,** creatinine clearance; **IV,** intravenous; **RC,** radical cystectomy; **ADR,** adverse drug reactions; **NAC,** neoadjuvant chemotherapy.

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/chapter/1-Recommendation (Accessed: June 2026); **2.** Powles T, et al. N Engl J Med. 2024;391(19):1773-1786 (including Supplementary Appendix and Protocol); **3.** IMFINZI, Summary of Product Characteristics; **4.** 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: June 2026); **5.** Powles T, et al. Presented at ESMO; September 13-17, 2024.

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