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Nurse and Advanced Practice Provider Perspectives on Gemcitabine Intravesical System Treatment of High-Risk Non–Muscle-Invasive Bladder Cancer in the Urology Clinic

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Key Takeaway

Nurses and APPs play a critical role in coordination of care, patient education, and AE management during gemcitabine intravesical system therapy

Conclusions

The recent approval of gemcitabine intravesical system for the treatment of patients with BCG-unresponsive NMIBC with CIS, with or without papillary tumors, is supported by efficacy and safety data from the SunRISe-1 clinical trial

Cohort 2 (CIS ± papillary disease) had a high complete response rate of 82.4% and 52.9% of patients responded to treatment for at least 1 year. In Cohort 4 (papillary disease only) 85.3% and 70.2% of patients remained disease-free after 6 and 12 months, respectively

Gemcitabine intravesical system therapy was well tolerated in SunRISe-1, with most side effects being mild to moderate symptoms of the lower urinary tract that were managed symptomatically

Recommendations for management of AEs includes lower urinary tract symptom treatments, antibiotics, and adequate hydration

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Acknowledgments

We thank the patients who participated in the study, their families, and the investigators and clinical research staff from the study centers. We would also like to thank Beth Winkley, Mary Hoyt, Christine Feliu, Joseph Jacob, Neal Shore and members of the SunRise-1 team, Chris Cutie, and Katharine Stromberg, for their input during development of this abstract. Editorial support was provided by Elizabeth Garity of Ashfield MedComms, an Inizio company, and was funded by Johnson & Johnson.

Disclosures

S Daneshmand has received grants/research funding from Photocure; consulting/advisory fees from Ferring, Photocure, QED Therapeutics, and Taris; honoraria/speaker fees from Aduro Biotech, Allergan (immediate family member), Bristol Myers Squibb, Ferring, Janssen, Johnson & Johnson, Olympus, Photocure, Pacific Edge, and QED Therapeutics; travel reimbursement from Photocure; and has stock/other ownership interests in Taris. N Osimo has nothing to declare. C Zinar has received consulting/advisory fees from Janssen. LH Belkoff has received consulting/advisory fees from Immunity Bio, Janssen, and Marius. K Crowley, H Sweiti, S Hampras, and J Martin are employees of Janssen and have stock/other ownership interests in Janssen.

Introduction

- Non–muscle-invasive bladder cancer (NMIBC) accounts for **~70%** of all bladder cancer cases and **~50%** of patients with high-risk (HR) NMIBC experience disease recurrence or progression on Bacillus Calmette-Guérin (BCG)[1,2]
- The standard of care for these patients is radical cystectomy (RC), a life-altering surgery with a high degree of morbidity and significant impacts on quality of life[3,4]
- Current treatment options for BCG-unresponsive HR NMIBC carcinoma *in situ* (CIS) have limited complete response rates and response durability[5–7]
- For patients with BCG-unresponsive HR NMIBC with only papillary disease, there are no approved treatments

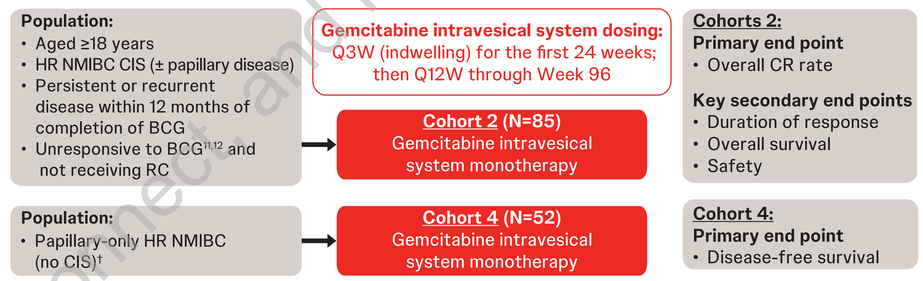
Gemcitabine intravesical system

- **Gemcitabine intravesical system was recently approved by the FDA for BCG-unresponsive NMIBC with CIS ± papillary disease**[8–10]
  - A first-in-class intravesical drug-releasing system designed to provide sustained delivery of gemcitabine in the bladder
  - Inserted during brief in-office procedure, without need for general anesthesia, by any trained healthcare professional using co-packaged urinary catheter and stylet
  - Delivers 225 mg gemcitabine directly into the bladder over a 3-week indwelling period
  - Inserted once every 3 weeks for up to 6 months (8 doses), followed by once every 12 weeks for up to 18 months (6 doses); removed after each 3-week indwelling period
  - Patients can return home immediately after the procedure and there is no need to hold bladder after insertion
- **Nurses and advanced practice providers** (APPs) play a crucial role in supporting patients receiving gemcitabine intravesical system treatment and managing adverse events (AEs)

Methods

- **SunRISe-1** (NCT04640623) is a Phase 2b study assessing gemcitabine intravesical system in patients with BCG-unresponsive HR NMIBC, ineligible for/refused RC (**Figure 1**)[9]
- Here we report:
  - Data in patients with CIS ± papillary disease (**Cohort 2**) and patients with papillary-only disease (**Cohort 4**)
  - Insights gathered from nurses and APPs with experience using gemcitabine intravesical system in the urology clinic during the SunRISe-1 trial

Figure 1: SunRISe-1 study schema*



The clinical data cutoff was March 31, 2025.
*Cohort 1 (TAR-200 + Cetrelimab [N=53]) and Cohort 3 (Cetrelimab monotherapy [N=28]) not presented here. †Patients with BCG-unresponsive papillary-only HR NMIBC (high-grade Ta, any T1) per protocol amendment.
BCG, Bacillus Calmette-Guérin; CIS, carcinoma *in situ*; CR, complete response; HR, high-risk; NMIBC, non–muscle-invasive bladder cancer; Q3W, every 3 weeks; Q12W, every 12 weeks; RC, radical cystectomy.

Results

Figure 2: SunRISe-1 Cohort 2 and 4 key efficacy results[9]

Cohort 2
(Gemcitabine intravesical system monotherapy in patients with CIS ± papillary disease)

82.4% of patients **achieved a complete response** (i.e., cancer was not detectable) following treatment

52.9% of patients who responded **were responsive to treatment** for at least **12 months**

The median time that cancer remained undetectable was **25.8 months**

Cohort 4
(Gemcitabine intravesical system monotherapy in patients with papillary disease only)

More than half of the participants did not have the cancer return

85.3% of patients were **disease-free after 6 months**

70.2% of patients were **disease-free after 12 months**

Proportions of patients who were **disease-free after 12 months** were **similar** for those with bladder cancer growing on the surface of the bladder lining (**Stage Ta**) and those with bladder cancer that has started to grow beneath the bladder lining and into the connective tissue (**Stage T1**)

CIS, carcinoma *in situ*.

- In **SunRISe-1 Cohort 2 and 4**, most side effects were **mild to moderate** symptoms of the lower urinary tract (Grade 1 or 2) that were **managed symptomatically** and of short duration (~3 weeks) (**Figure 3**)[9]
- There were **no deaths** that resulted from treatment in either cohort[9]

Figure 3: SunRISe-1 Cohort 2 and 4 common side effects (≥15%)[9]

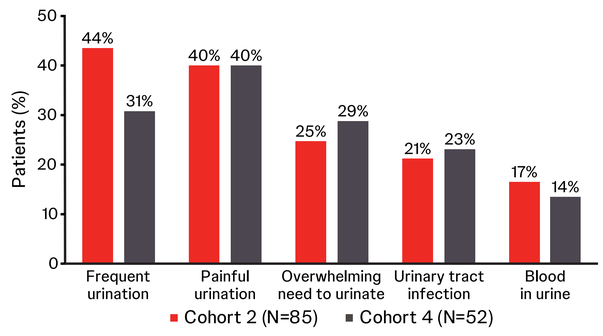
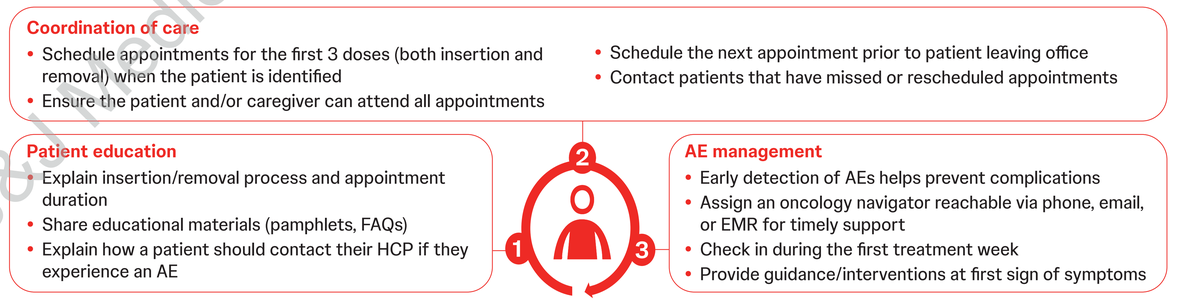
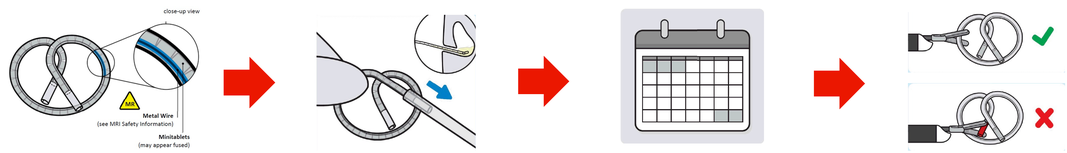


Figure 4: Nurses and APPs facilitate the patient experience through patient education, coordination of care and AE management



AE, adverse event; APP, advanced practice provider; EMR, electronic medical record; FAQs, frequently asked questions; HCP, healthcare professional.

Figure 5: Roles and clinical practice experiences of nurses and APPs in the gemcitabine intravesical system patient journey



Pre-procedure preparation
- Educate and prepare patients on what to expect, alleviate concerns on infection, impact on QoL
- Provide guidance on self-care
- Share educational materials (pamphlets, FAQs)
- Consultation with **nurses** and if required **APPs** and/or **urologists**

Gemcitabine intravesical system insertion
- Via a urinary catheter in a brief in-office procedure
- Can be performed by an **APP** after minimal training) or **urologist**
- **Nurses** help prepare patients, and address any questions

Follow-up
- Continue patient education, arrange follow-ups, and manage AEs
- **Nurses** report AEs, schedule appointments, consult with the patients and wider-care team
- **APPs** involved in AE management
- **Urologist** available for consultation if required

Gemcitabine intravesical system removal
- Via cystoscope and grasping forceps
- Can be performed by an **APP** after minimal training) or **urologist**
- **Nurses** help prepare patients, and address any questions

AE, adverse event; APP, advanced practice provider; FAQs, frequently asked questions; QoL, quality of life.

Figure 6: Gemcitabine intravesical system clinical management recommendations[13]

General
- Counsel on potential on lower urinary tract symptoms
- Screen for pre-existing lower urinary tract symptoms
- Consume ≥1500 mL of non-alcoholic, non-caffeinated liquid each day during treatment
- Use a heat pack to alleviate mild pain
- Advise on which over-the-counter pain medications patients can take

Lower urinary tract symptoms
dysuria/pain, overreactive bladder
- Avoid irritants such as spicy food and citrus
- Consider common treatments* for symptom management – if no clinical improvement within 72 hours consider removing gemcitabine intravesical system until resolution
- For **pain**, follow the WHO 3-step analgesic ladder[14]

Urinary tract infections
with/without fever
- Start appropriate antibiotics based on urinalysis and urine culture results – if no improvement within 72 hours consider removing gemcitabine intravesical system until resolution
- For cases of **urosepsis** consider removing gemcitabine intravesical system **once** clinically stable and restart treatment following resolution

Blood in urine (hematuria)
- Encourage adequate hydration
- Continue treatment for macroscopic cases but remove/delay for complicated cases or if no improvement, until resolution
- If persistent, perform cystoscopy to evaluate tumor
- Consider invasive intervention as clinically indicated for complicated cases

*e.g., Alpha-blocker, antispasmodics, phenazopyridine, NSAIDS, amitriptyline. NSAID, non-steroidal anti-inflammatory drug; WHO, World Health Organization.

References

1. Cassel A, et al. *World J Oncol*. 2019;10(3):123–131. 2. Sylvester RJ, et al. *Eur Urol*. 2006;49(3):466-5. 3. EAU Guidelines. Edn. presented at the EAU Annual Congress Madrid 2025. ISBN 978-94-92671-29-5. 4. AUA/SUO Guidelines. Available at: https://www.auanet.org/guidelines-and-quality/guidelines/bladder-cancer-non-muscle-invasive-guideline. 5. ADSTILADRIN® (nadofaragene firadenovec-vncg) [prescribing information]. Kastrup, Denmark: Ferring Pharmaceuticals; 2024. 6. ANKTIVA® (nogapendekin alfa inbakicept-pmln) [prescribing information]. Culver City, CA, USA: Altor BioScience; 2024. 7. KEYTRUDA® (pembrolizumab) [prescribing information]. Rahway, NJ, USA: Merck & Co., Inc.; 2024. 8. INLEXZO™ (Gemcitabine intravesical system) [US Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. 2025. 9. Daneshmand S, et al. *J Clin Oncol*. 2025 Jul 30 101200JCO2501651 doi: 10.1200/JCO-25-01651. 10. Instructions For Use INLEXZOTM (Gemcitabine intravesical system). Horsham, PA: Janssen Biotech, Inc. 2025. 11. Lerner SP, et al. *Urol Oncol*. 2009;27:155–159. 12. US Food and Drug Administration. Available at: https://www.fda.gov/media/101468/download. 13. Pradere B, et al. *Curr Opin Urol*. 2025:10.1097/MOU.0000000000001350. 14. World Health Organization Analgesic Ladder. Accessed September 15, 2025. https://professionals.wrha.mb.ca/old/professionals/files/PDTip_AnalgesicLadder.pdf.

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Presented by S Daneshmand at WSAUA 2025; Napa Valley, CA; November 2–6, 2025