

III JORNADA DE ACTUALIZACIÓN EN  
**URO-ONCOLOGÍA:**  
UPDATE 2026

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# Tratamientos intravesicales

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## DISCLOSURES

<b>Research support/PI</b>	Johnson & Johnson, Pfizer, Taris, BMS, Roche, Seagen, AstraZeneca, Combat Medical, Cepheid, Fidia, Astellas, UroGen, MSD, enGene, Tyra Bio
<b>Employee</b>	SERMAS (Servicio Madrileño de Salud)
<b>Consultant</b>	Johnson & Johnson, Pfizer, Merck, Roche, Taris, Combat Medical, AstraZeneca, MSD, BMS, enGene, Nanobots Therapeutics, Gebro, Photocure
<b>Stockholder</b>	CG Oncology, Johnson & Johnson, Pfizer, NEED Inc, Danae Urogenomics
<b>Speaker bureau</b>	Nucleix, MSD, Pfizer, Merck, BMS, AstraZeneca, Palex, Combat Medical, Johnson & Johnson, Recordati, Gebro
<b>Travel</b>	Pfizer, Recordati, Ipsen, Combat Medical, Alter, Salvat, Nucleix, AstraZeneca, Fidia, Johnson & Johnson
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<b>Others</b>	Co-founder of Danae Urogenomics

# Aprobaciones FDA y CRR (CIS)

**2020**

**FDA approves pembrolizumab for BCG-unresponsive, high-risk non-muscle invasive bladder cancer**

CRR 41%

**2022**

**FDA D.I.S.C.O. Burst Edition: FDA approval of Adstiladrin (nadofaragene firadenovec-vncg) for patients with high-risk Bacillus Calmette-Guérin unresponsive non-muscle invasive bladder cancer with carcinoma in situ with or without papillary tumors**

CRR 53.4%

**2024**

**FDA approves nogapendekin alfa inbakicept-pmln for BCG-unresponsive non-muscle invasive bladder cancer**

CRR 71%\*

\*Reinduction allowed

**2025**

**FDA approves gemcitabine intravesical system for non-muscle invasive bladder cancer**

CRR 82.4%

<i>Agent, mFU (mo)</i>	<b>AMONG RESPONDERS...</b>		<b>OVERALL</b>	
	<i>12 mo DoR</i>	<i>Median DoR (months)</i>	<i>Cystectomy rate</i>	<i>Upstaging to ≥MIBC</i>
<b>Pembrolizumab (36.4)</b>	46%	16.2	49%	12%
<b>Nadofaragene (20)</b>	24.3%	9.7	26%	12.5%
<b>BCG + N-803 (23.9)</b>	61.6%	26.6	15.6%	N/R
<b>TAR-200 (20.2)</b>	56.2%	25.8	21.2%	8.2%

## Grade ≥3 TRAEs

- Pembrolizumab = 13%
- Nadofaragene = 4%
- BCG + N-803 = 23%
- TAR-200 = 12.9%



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European Association of Urology



Platinum Priority – Bladder Cancer – Editor's Choice

Editorial by Girish S. Kulkarni, Marian S. Wettstein on pp. 545–546 of this issue

## Phase 2 Trial of Atezolizumab in Bacillus Calmette-Guérin-unresponsive High-risk Non-muscle-invasive Bladder Cancer: SWOG S1605

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## MoonRISe-3: Phase 3 Study of TAR-210 vs Intravesical Chemotherapy in Patients With BCG-treated, *FGFR*-altered Papillary-only HR NMIBC

### Key eligibility criteria

- Adults (aged  $\geq 18$  years)
- Histologically confirmed **papillary-only HR NMIBC**:
  - High-grade Ta
  - or–
  - Any T1 (no CIS)
  - Recurrent after BCG
  - or–
  - Intolerant of BCG
- ECOG performance status of  $\leq 2$
- Susceptible *FGFR* mutation or fusion by urine or tumor tissue testing

### Stratification factors

- T stage (high-grade Ta or any T1)
- Prior BCG treatment (BCG unresponsive, experienced, or intolerant)
- Choice of intravesical chemotherapy

1:1  
(N=220)

R

### TAR-210

(n $\approx$ 110)

Treatment cycles for 2 years

### Investigator's choice of single-agent intravesical chemotherapy

(n $\approx$ 110)

MMC or gemcitabine  
QW for 6 doses (induction) followed by Q4W  
for 1-2 years (maintenance)

### Primary end point

- Disease-free survival

### Key secondary end points

- Recurrence-free survival
- Time to next intervention
- Time to disease worsening
- Time to progression
- Overall survival
- Safety and tolerability

NCT06919965



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