INTERNATIONAL BLADDER CANCER GROUP®

IBCG

International Bladder Cancer Group

Newsletter



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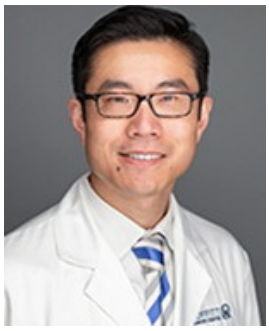
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EAU 2026: Intravesical Erdafitinib Drug-Releasing System Shows Promising Activity in FGFR-Altered Non–Muscle-Invasive Bladder Cancer



Roger LI, MD
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The final analysis of the first-in-human Phase 1 study evaluating the erdafitinib intravesical drug-releasing system (TAR-210) in patients with FGFR-altered non–muscle-invasive bladder cancer (NMIBC) was presented by Dr. Antoni Vilaseca at EAU 2026.

Recurrence and progression remain major challenges for patients with NMIBC. Many patients undergo repeated transurethral resections, intravesical therapies and rarely even radical cystectomy due to failure of available therapies. Fibroblast growth factor receptor (FGFR) alterations occur in approximately 70% of intermediate-risk and 30% of high-risk tumors. TAR-210 was developed to exploit this therapeutic opportunity. The device is designed for intravesical deployment and continuously release erdafitinib, a pan-FGFR inhibitor, over a three-month treatment cycle. By delivering the drug directly to the bladder, TAR-210 minimizes systemic exposure and associated toxicities observed with oral FGFR inhibitors.

In a multicenter, open-label Phase 1 trial, the investigators evaluated the safety, pharmacokinetics, and preliminary efficacy of TAR-210 in patients with NMIBC harboring select FGFR alterations. In Cohort 1, patients with recurrent, BCG-experienced high-risk papillary (high-grade Ta/T1) NMIBC who were either unwilling or ineligible to undergo radical cystectomy were enrolled following complete resection of their tumors. In Cohort 3, patients with recurrent intermediate-risk low grade NMIBC per the IBCG risk classification were enrolled prior to resection of visible tumors, allowing TAR-210 to be evaluated as an ablative therapy. Cohort 2 included BCG-experienced patients undergoing radical cystectomy, but was closed prematurely. The primary endpoint was safety. Secondary endpoints included recurrence-free survival (RFS) in Cohort 1 and complete response (CR) rate and duration of response in the Cohort 3.

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EAU 2026: Intravesical Erdafitinib Drug-Releasing System Shows Promising Activity in FGFR-Altered Non–Muscle-Invasive Bladder Cancer

As of the November 2025 data cutoff, 88 patients had received treatment (26 in Cohort 1 and 62 in Cohort 3), with median treatment durations approaching 12 months. The therapy was generally well tolerated. Most treatment-related adverse events consisted of low-grade lower urinary tract symptoms, including hematuria (32%) and dysuria (22%). Only 5% of patients experienced grade ≥3 treatment-related adverse events (pyelonephritis and severe hematuria), while treatment discontinuation due to toxicity occurred in 9%. Importantly, pharmacokinetic analyses demonstrated that plasma erdafitinib concentrations following TAR-210 administration were more than 40-fold lower than those observed with standard oral erdafitinib, supporting the concept of effective local drug delivery with substantially reduced systemic exposure.

Among patients with high-risk BCG-experienced papillary NMIBC, median recurrence-free survival was over 20 months, with an estimated 12-month recurrence-free survival of 83%. In patients with recurrent LG tumors who underwent TAR-210 ablation, 89% had complete tumor ablation. Among responders, median duration of complete response was 18 months.

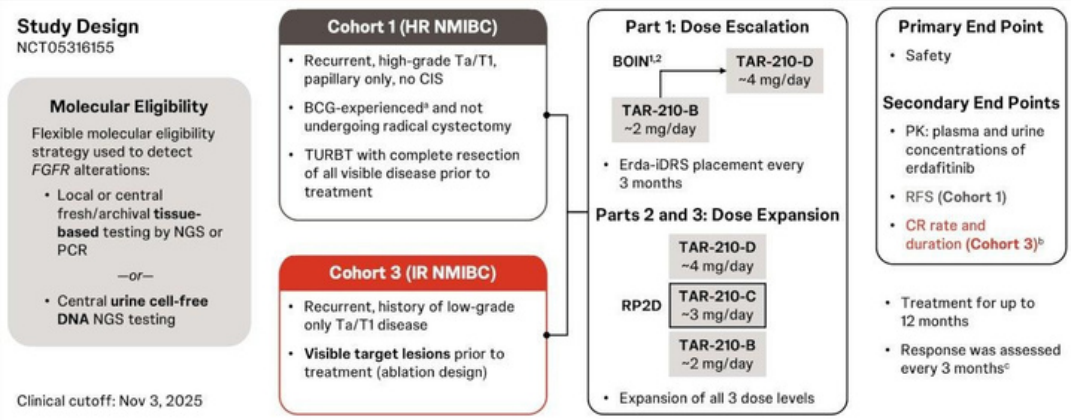
The Phase 1 study establishes proof of concept that local delivery of erdafitinib is feasible, well tolerated, and capable of achieving durable antitumor responses in FGFR-altered NMIBC. Building upon these encouraging early results, multiple registrational studies are now underway. In MoonRISe-1, efficacy of TAR-210 versus intravesical chemotherapy as adjuvant therapy for intermediate-risk NMIBC is being investigated. In parallel, MoonRISe-2 (Phase 2) is testing TAR-210 as primary ablative therapy in an expanded cohort of intermediate-risk NMIBC patients. Finally, MoonRISe-3 (Phase 3) tests TAR-210 versus intravesical chemotherapy following TURBT in papillary-only high-risk NMIBC.

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EAU 2026: Intravesical Erdafitinib Drug-Releasing System Shows Promising Activity in FGFR-Altered Non–Muscle-Invasive Bladder Cancer

Targeted therapy has transformed the management of advanced urothelial carcinoma, yet its application in localized disease has remained limited. TAR-210 represents an innovative approach that combines precision oncology with sustained intravesical drug delivery, potentially expanding treatment options for patients with molecularly defined NMIBC.

If the ongoing Phase 2 and Phase 3 trials confirm these early findings, intravesical FGFR inhibition could become an important addition to the treatment armamentarium, offering a personalized, bladder-preserving strategy for patients with FGFR-altered disease while minimizing systemic toxicity.



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ASCO 2026: Long-Term EV-302 Results Confirm Durable Survival Benefit with Enfortumab Vedotin Plus Pembrolizumab



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The phase III EV-302 trial has redefined the treatment landscape for patients with previously untreated locally advanced or metastatic urothelial carcinoma. At the 2026 ASCO Annual Meeting, investigators presented the final 3.5-year follow-up analysis, demonstrating that the survival advantage achieved with enfortumab vedotin plus pembrolizumab remains durable with extended follow-up.

With a median follow-up of 42.8 months, patients treated with the combination achieved a median overall survival (OS) of 33.6 months, compared with 15.9 months for those receiving platinum-based chemotherapy (hazard ratio [HR] 0.53). Notably, 44% of patients remained alive at 42 months, nearly double the 24.6% observed with chemotherapy, underscoring the unprecedented durability of benefit in the frontline metastatic setting.

The combination also continued to demonstrate superior antitumor activity. The overall response rate (ORR) was 67.5%, including a 30.4% complete response (CR) rate, compared with an ORR of 44.2% and CR rate of 14.5% with chemotherapy. Importantly, nearly half of responders receiving enfortumab vedotin plus pembrolizumab ultimately achieved a complete response, either as their initial best response or following an initial partial response, highlighting the capacity of this regimen to induce deep and durable remissions.

Long-term outcomes among patients achieving a complete response were particularly encouraging. Median overall survival has not yet been reached in patients treated with the combination who achieved a CR, and more than 80% remained alive at 42 months. Patients converting from a partial response to a complete response experienced similarly favorable outcomes, emphasizing that continued therapy may deepen responses over time.

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ASCO 2026: Long-Term EV-302 Results Confirm Durable Survival Benefit with Enfortumab Vedotin Plus Pembrolizumab

Despite improved frontline outcomes, approximately 40% of patients subsequently received systemic therapy following disease progression. Among those receiving platinum-based chemotherapy after progression on enfortumab vedotin plus pembrolizumab, response rates remained modest and median survival after initiation of subsequent chemotherapy was approximately 11 months, emphasizing the importance of maximizing benefit with first-line therapy.

Extended safety follow-up demonstrated no new safety concerns. The adverse event profile remained consistent with previous reports despite prolonged treatment exposure, with the greatest cumulative increase in peripheral sensory neuropathy, approaching 90% among patients treated beyond two years. While dose interruptions and reductions were common, particularly among patients receiving therapy beyond one year, these interventions allowed many patients to remain on treatment safely. Importantly, no cumulative or unexpected toxicities emerged during long-term follow-up.

The updated EV-302 results firmly establish enfortumab vedotin plus pembrolizumab as the standard first-line treatment for patients with advanced urothelial carcinoma. While the original publication demonstrated a transformative improvement in survival compared with platinum-based chemotherapy, the current analysis confirms that these benefits are maintained over more than three years of follow-up.

The findings from the extended followup further reinforce that achieving deep responses early in the disease course translates into durable survival benefits. Patients achieving CR tended to have fewer visceral metastases and more lymph-node only disease. As the therapeutic landscape continues to evolve, future studies will focus on identifying predictive biomarkers of response, optimizing sequencing strategies following progression, and determining whether treatment de-escalation may be appropriate for patients achieving sustained complete responses.

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At the Bladder Cancer Advocacy Network (BCAN), we are dedicated to turning today's research into tomorrow's breakthroughs for patients and their loved ones. Our mission is to accelerate the most promising discoveries in bladder cancer research, funding both emerging and established investigators who are pushing boundaries to develop lifesaving treatments and improve patient care.

BCAN
Bladder Cancer Advocacy Network

Discover more about BCAN's commitment to advancing research and how our grants are fueling innovation at **bcan.org/research**.



Join us for our **Walks to End Bladder Cancer** in the Spring of 2026. Our in-person and virtual walks raise spirits and raise funds to defeat bladder cancer. Please visit **bcanwalk.org**.

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Highlights from the 5th Annual AUA–IBCG Bladder Cancer Forum



Joseph Black, MD, PhD

The 5th annual AUA–IBCG Bladder Cancer Forum took place on May 17, 2026 during the American Urological Association Annual Meeting in Washington, D.C. Chaired by Dr. Ashish Kamat and Dr. Sarah Psutka, the forum featured seven spirited case-based debates focused on controversial issues impacting patient care in the modern era. Leading bladder cancer experts from around the world were invited to collaborate and present in this crossfire debate format.

Dr. Stephen Boorjian chaired the first debate centered on trimodal therapy (TMT) in muscle-invasive bladder cancer (MIBC). Dr. Kukreja highlighted that while TMT may preserve a patient's bladder, the toxicity secondary to TMT significantly impacts patients' quality of life. Dr. Kukreja also noted the financial toxicity of TMT and the morbidity of sa lvage cystectomy. In contrast, Dr. Leslie Ballas highlighted quality-of-life data to argue that patients should not be deterred from considering TMT. Dr. Ballas emphasized that in appropriately selected patients with good baseline bladder function, TMT is a viable option. Both debaters agreed that patients being offered TMT should be appropriately counseled on both functional and oncologic outcomes.

Dr. Tyson chaired the second debate, which focused on immunotherapy (IO) and BCG in the setting of high-risk NMIBC. The recent POTOMAC, CREST, and ALBAN trials set the foundation for this debate. Dr. Shore argued that the positive findings in CREST and POTOMAC, despite a negative ALBAN trial, provide evidence that IO can augment BCG efficacy. After acknowledging the potential side effects of IO, Dr. Shore argued that a one-size-fits-all approach is not appropriate and that an individualized treatment should be designed for each patient. Dr. Morgan Rouprêt countered this stance and noted that contemporary BCG studies yield strong outcomes and that the incremental benefit of immunotherapy appears limited in absolute terms. Dr. Rouprêt further highlighted that the conflicting trial results call for pause in recommending IO in this population. He further argued that predictive biomarkers are needed to better identify which patients will benefit from this therapy and that the addition of IO to BCG in this population is premature given current data.

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Highlights from the 5th Annual AUA–IBCG Bladder Cancer Forum



Sagar Patel , MD

Debate three, chaired by Dr. Vignesh Packiam, investigated the sequencing of treatments in BCG-unresponsive high-risk NMIBC in the setting of the rapid expansion of FDA-approved agents. Dr. Amanda Myers argued that Gem/Doce has favorable efficacy and lower financial toxicity. Thus, she purposed that Gem/Doce should be a primary starting point for this population. Dr. Bogdana Schmidt in contrast argued that BCG-unresponsive high-risk NMIBC is a heterogeneous entity and that there is no clear de facto first-line agent in this demographic. Underscoring the complexity and heterogeneity of this population, Dr. Schmidt emphasized the importance of improving biomarkers and better characterizing patients based on tumor-specific entities such as tumor mutational burden, genomic instability, TP53/FGFR3 biology, and immune exhaustion to better elucidate which patients will benefit from which modality.

Debate four, moderated by Dr. Mario Fernandez, addressed best practices in intermediate-risk (IR) NMIBC. Dr. Akshay Sood argued in favor of ablative approaches, noting that low-grade IR-NMIBC is characterized by high recurrence rates but low progression risk, suggesting that some patients are overtreated with repeated TURBT. Dr. Sood also highlighted data demonstrating the cost-effectiveness of in-office ablation. Dr. Joan Palou defended the continued role of TURBT followed by adjuvant intravesical therapy, emphasizing the heterogeneity of the IR-NMIBC population and the importance of proper risk stratification. Referencing the IBCG five-factor scoring system, Dr. Palou outlined how treatment intensity could be tailored.

Dr. Niyati Lobo chaired the fifth debate, which investigated the use of MRI with VI-RADS as standard practice. Dr. Carmen Mir highlighted the BladderPath Trial and growing body of literature demonstrating the utility of MRI in bladder cancer staging. Dr. Mir argued that MRI should be a standard part of modern bladder cancer management and can potentially be used to expedite care and defer TURBT in certain clinical situations. Dr. Hensley acknowledged the utility of MRI but highlighted that the diagnostic and therapeutic element of performing a complete TURBT underscores that MRI should not supplant TURBT. He argued that while promising, MRI is not currently able to replace conventional imaging with a TURBT for staging.

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Highlights from the 5th Annual AUA–IBCG Bladder Cancer Forum



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Dr. Shilpa Gupta chaired the sixth debate, which investigated the utility of using risk-adaptive strategies with systemic therapy in MIBC. Dr. Andrea Necchi argued that sandwich therapy is supported by the literature and represents the standard of care for patients with MIBC. He noted that there currently is no literature to support de-escalation of systemic therapy. Dr. Félix Guerrero-Ramos in contrast argued in favor of potential de-escalation based upon patient and disease factors. Specifically, he highlighted the utility of ctDNA as demonstrated in the IMvigor011 study, which served as the nidus for the concept of biomarker directed de-escalation. He concluded by highlighting ongoing studies to investigate the utility of ctDNA in guiding de-escalation.

Dr. Badrinath Konety chaired the seventh and final debate, which examined whether next-generation molecular markers are ready to replace legacy assays such as urine cytology and UroVysion FISH. Dr. Maurizio Brausi argued that urinary panels and urinary tumor DNA offer superior sensitivity and can reduce the need for cystoscopy, though he acknowledged that these tools should complement rather than replace traditional assays. Dr. Paolo Gontero countered that cytology uniquely detects high-grade disease, and that next-generation markers cannot discriminate tumor grade, and that their low positive predictive value risks driving excessive testing.

Throughout these seven energetic sessions, debaters highlighted the rapidly evolving landscape of NMIBC and MIBC management. Underscored during this forum was the need for patient and disease tailored care, advancement in biomarkers to better inform practice, and interdisciplinary care. As the bladder cancer landscape continues to evolve, continued global dialogue and collaborative research is needed to help translate these therapeutic advances into appropriate and meaningful clinical care.

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IBCG Meeting – Modena, Italy



Roger LI, MD
Moffit Cancer Center, FL

At the invitation of Professor Maruizio Brausi, the Scientific Advisory Board of the International Bladder Cancer Group convened in Modena, Italy to celebrate the group's 20th anniversary. The purpose of the meeting was not only to celebrate the achievements of the group over the last two decades, but also to look to the future. After recapping the history of the start of the IBCG, Prof. Kamat detailed efforts of the group over the years in education, patient engagement, leadership in guideline summarization and identification of gaps in knowledge. Most notable achievements include the Group's contribution to the definition of BCG unresponsive non-muscle invasive bladder cancer; stratification of intermediate risk non-muscle invasive bladder cancer; and defining what constitutes clinical complete response following neoadjuvant systemic therapy for patients with muscle invasive bladder cancer. The Group has also actively engaged patient advocacy groups such as the World Bladder Cancer Coalition, Bladder Cancer Advocacy Network as well as numerous patient advocates on many patient centric topics.

Looking to the future, the Advisory Board members discussed future aims in education and scientific collaboration. Transurethral resection of bladder tumors is the foundational procedure upon which sound bladder cancer care is built. However, levels of expertise vary and the quality of the surgery often falls short of clinical standards. The Group discussed various ways to disseminate sound surgical techniques to all who are interested, including formulating a checklist to standardize the capture and reporting of key elements of the procedure. Videos of index cases as well as common mistakes can be curated in a video library and accessed via the IBCG website. In addition, efforts on community education about the harms of tobacco smoking, and various other causes of bladder cancer were held.

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IBCG Meeting – Modena, Italy

Finally, discussion regarding deepening of the Group's research collaboration was also held. The Board Members agreed that collectively capturing real-world clinical data from patients treated with various types of therapies would be invaluable. Treatment efficacy, adverse events, and patient reported outcomes from the group's effort would collectively inform the field of real-world experiences with various treatments, complementing clinical trials data. In addition, systematic collection of biospecimens, including tissue, blood and urine, will enable translational research to better understand mechanisms of action and resistance. Lessons from past efforts were discussed, and the Group renewed its goal to formulate multi-institutional contracting to collectively tackle these questions. Professor Alfred Fred Witjes and Dr. Amir Horowitz enthusiastically volunteered to lead these efforts.

Throughout the meeting, Board Members shared fond memories both within and outside of the group. The conversation somehow always pivoted towards bladder cancer, what are the unmet needs, what questions remain and ideas to push the field forward for better treatments and better outcomes. Over the last two decades, the IBCG has played an integral role in education and research in bladder cancer. These efforts will be sure to continue in the decades to come.



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