AUA-2025 DAILY NEWS



AUA2025 Ramon Guiteras Keynote

The Future of Healthcare: How will Urology be Impacted?

Vin Gupta, MD

8:15-9:15 a.m. Plenary, Venetian Ballroom



Practice-Changing, Paradigm-Shifting Clinical Trials in **Urology**

11:15-11:45 a.m. 1-1:10 p.m. Plenary, Venetian Ballroom



Learning Lab

These important clinical trials are expected to influence practice.

Around the Horn: Female Urology

11:30 a.m.-12:30 p.m. AUA Square: Learning Lab



AUA Robotics Theater

Don't miss today's live narration of robotic procedure videos and a panel discussion.

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Prostate Procedures

10:30 a.m.-12:30 p.m. Booth #355



Flip the Script: Case Submissions

2-3·40 n m AUA Square: Learning Lab

Novel interventions show promise in bladder cancer

intravesical agents, cretostimogene grenadenorepvec and sustained-release intravesical gemcitabine, show significant clinical activity and excellent safety in non-muscle invasive bladder cancer (NMIBC). Both agents have been granted Breakthrough Therapy Designation by the U.S. Food and Drug Administration.

Cretostimogene grenadenorepvec, a highly immunogenic adenovirus, showed 75.5% complete response (CR) in cohort 3 of the phase 3 BOND-003 study of patients with BCGunresponsive NMIBC with carcinoma in situ.

TAR-200, an intravesical device for sustained gemcitabine delivery, showed 82.4% complete response in BCG-unresponsive NMIBC in SunRISe-1. Initial results for papillary-only MNIBC from the same trial showed 81.1% nine-month disease-free survival (DFS).

The three Practice-Changing. Paradigm-Shifting (P2) Clinical Trials in Urology were presented during the Saturday morning Plenary session.

"These data mark an important advancement for patients with this disease who are unwilling or unable to



Mark Tyson, MD, MPH



Joseph Jacob, MD, MCR

undergo radical cystectomy," said Mark Tyson, MD, MPH, associate professor of urology at Mayo Clinic Alix School of Medicine. "Importantly to patients (in BOND-003), 97% remain progression-free and 84.5% avoided cystectomy."

Cretostimogene is an oncolytic immunotherapy that selectively targets Rb-E2F pathway-altered cancers. Viral replication results in tumor lysis while sparing healthy tissue and primes a tumorspecific immune response in the tumor microenvironment.

Dr. Tyson noted that the dual mechanism of action is both highly effective and welltolerated. Nearly all patients, 97.3%, completed all protocoldefined treatments, and there were no treatment-related

discontinuations or Grade ≥3 treatment-related adverse events (TRAEs) or deaths. The most common adverse events (AEs) were bladder spasm, pollakiuria and urgency, all Grade 1 or 2.

Dr. Tyson said the first results from Cohort P in highgrade disease showed 90.5% recurrence-free survival with a consistent safety profile. More detailed results will be reported in the Learning Lab on Monday.

Patients with high-risk BCGunresponsive NMIBC currently have few options, at least in the U.S.: pembrolizumab, 41% CR; nadofaragene firadenovec, 51% CR; or nogapendekin alfa inbakicept + BCG, 62% CR.

"The overall CR for TAR-200 monotherapy was 82.5%. This is the highest CR rate reported to date," said Joseph Jacob, MD, MCR, associate professor of urology, SUNY Medical University. "These CRs were rapid, with a median onset of 2.8 months. The responses remain consistently high across all patient subgroups, including those with and without papillary disease."

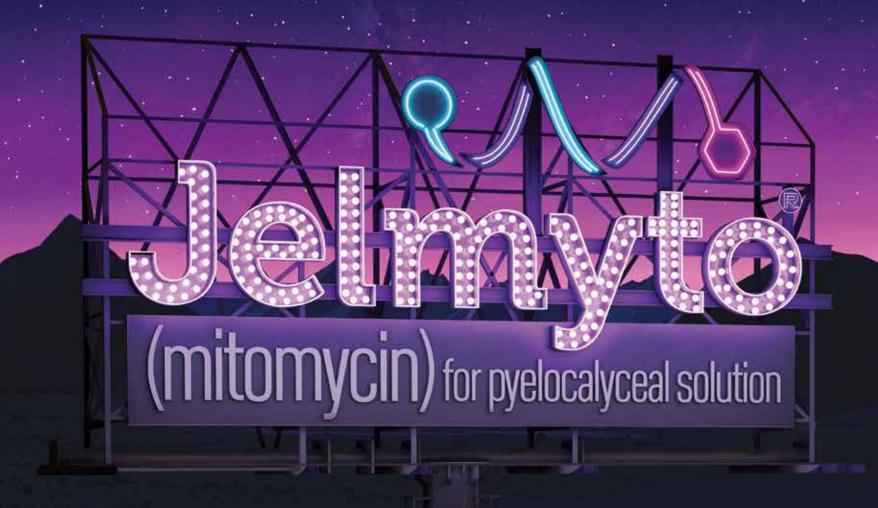
Quality of life was consistent throughout treatment, Dr. Jacob said. Office-based insertion via catheter was 99% successful, and most adverse events were Grade 1-2. Five patients had TRAEs, and three patients discontinued due to TRAEs.

TAR-200 is currently

NOVEL INTERVENTIONS

BCG-UNRESPONSIVE NMIBC 3 GERM CELL TUMOR BIOMARKERS 4 RENAL CELL CARCINOMA 6 AUA IN PICTURES 8 SCIENCE & TECHNOLOGY HALL 12-13 QUESTION OF THE DAY 14





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Saturday's debate surveyed the pros and cons of new bladder-sparing treatments for BCG-unresponsive non-muscle-invasive bladder cancer.

ew options are available to help patients with Bacillus Calmette-Guerin (BCG)-unresponsive non-muscle-invasive bladder cancer (NMIBC) avoid or delay radical cystectomy.

"With a full armamentarium of agents with multiple mechanisms of action, it's a game-changing era to preserve bladder and quality of life," said Tullika Garg, MD, MPH, FACS, associate professor in the department of urology at Geisinger Health System. Dr. Garg moderated Saturday's Plenary, "Controversies in Urology: Double Intravesical Chemotherapy Is Preferred Over New FDA-Approved

Agents for BCG Unresponsive NMIBC: The Price of Success."

To help you make informed treatment decisions, the session explored the pros and cons of double intravesical chemotherapy with Gemcitabine/Docetaxel (Gem/Doce) versus the new FDA-approved bladdersparing treatments for BCG-unresponsive NMIBC.

Vignesh Packiam, MD, associate professor of urology at Rutgers Cancer Institute of New Jersey, set the stage by defining BCG-unresponsive NMIBC. Patient must meet two out of three criteria: They must exhibit high-grade papillary (TaT1) NMIBC within six months of last BCG, high-grade carcinoma

in situ (CIS) NMIBC within 12 months of last BCG or high-grade T1 NMIBC recurrence at first (three months) evaluation after a single induction course of BCG. He presented data to build a persuasive case for Gem/Doce. "It's widely available, well-tolerated, highly efficacious and cost-effective. That's why it's a no-brainer to give this treatment for patients with unresponsive disease," Dr. Packiam said.

Shreyas S. Joshi, MD, MPH, assistant professor of urology at Emory University School of Medicine, presented the opening argument for the new FDA-approved agents, pembrolizumab (Keytruda), nadofaragene firadenovec (Adstiladrin) and nogapendekin alfa inbakicept-pmin (Anktiva), citing favorable data on prospective comprehensive outcomes reporting, side effects and long-term progression-free survival. "There's no silver bullet for treating BCG-unresponsive disease, but these new agents offer the highest level of data, plus they capitalize on the immune sensitivity of bladder cancer," he said.

William Huang, MD, urologic oncologist at NYU Langone Medical Center and the Perlmutter Cancer Institute, offered solid points for why Gem/Doce is still the preferred agent for NMIBC despite the explosion of new agents. From a cost standpoint alone, "Gem/Doce, at under \$10,000 per year, is 20 times less than all the other agents," he said.

"There is a cost for innovation," said Cheryl Lee, MD, chair of the department of urology at The Ohio State University. "The novel agents approved by the FDA are potentially creating multiple lines of therapy for patients with NMIBC, particularly with CIS, with 89% cystectomy avoidance at 24 months."

Which agent to choose? "All options incur costs in terms of financial, adverse events, treatment burden and clinical operations," Dr. Garg said. "We need algorithms to sequence agents."



The AUA Daily News is the official newspaper of AUA2025 and is published by Ascend Media.

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MicroRNA emerges as potential germ cell tumor biomarker

In stage I disease, miRNAs show promise for detecting relapse.



Aditya Bagrodia, MD

he current generation of biomarkers for germ cell tumors is underwhelming. As few as 60% of stage I patients have elevated biomarkers and about 5% of patients receive an orchiectomy for benign disease.

"Testis cancer is shrouded in uncertainty," said Aditya Bagrodia, MD, professor of urology at the University of California, San Diego School of Medicine. "Sensitive and specific biomarkers could allow for precise, individualized treatment recommendations. Circulating microRNA 371-1-3p holds the promise to be such a biomarker."

Dr. Bagrodia opened the first Plenary session on Saturday morning with a State-ofthe-Art lecture on "The State of Biomarkers in Germ Cell Tumors." MicroRNAs (miRNAs) are short, noncoding RNA sequences involved in epigenetic gene regulation. After release from cell nuclei, they modulate intracellular communication and are dysregulated in a variety of malignancies.

The first family of germ cell tumor-specific miRNAs not present in normal gonadal tissue were identified about 15 years ago, Dr. Bagrodia said. A continuing series of trials identified miRNAs in both seminoma and non-seminoma germ cell tumors. The largest trial to date, 874 patients, identified miRNA 371 in the pre-orchiectomy setting with an area under the curve of 96.6% for all comers.

"MicroRNA 371 has excellent performance and outperforms current conventional tumor markers to predict pathology in stage I disease, where there is the most ambiguity," Dr. Bagrodia reported. "Our current risk stratification is really insufficient for individualized patient counseling."

The data are less convincing for predicting the relapse of stage I disease. Longitudinal studies have not shown that early miRNA testing is reliably predictive of relapse following orchiectomy. But all patients who relapsed showed

detectable miRNA levels about two months before clinical evidence of relapse.

"I conclude in stage I disease, miRNAs are promising to detect relapse," Dr. Bagrodia said. "However, early post-surgery miRNAs may not predict relapse, and this is likely a sensitivity issue that can be technically overcome."

Clinical trials indicate utility for state II disease as well, he said, as miRNAs show sensitivity and specificity of 92% with an area under the curve of 93.4%. Positive predictive value, negative predictive value and accuracy all showed 92%.

More advanced disease

remains problematic. About half of patients show evidence of disease following post-treatment retroperitoneal lymph node dissection. Of these cancers, 5% are viable germ cell tumors and 45% are teratomas, and miRNA cannot detect teratomas.

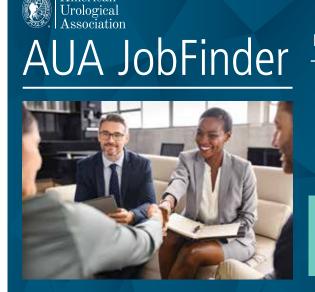
"The pre-orchiectomy setting is very promising with some sensitivity issues in stage I disease," Dr. Bagrodia said. "In stage II disease, miRNAs perform quite well. And in the post-therapy setting, we likely can pick up viable germ cell tumor, but the detection of teratoma remains outstanding. Further work regarding standardization, optimization and validation is required." •

Testis cancer is shrouded in uncertainty. Sensitive and specific biomarkers could allow for precise, individualized treatment recommendations. Circulating microRNA 371-1-3p holds the promise to be such a biomarker."

–Aditya Bagrodia, MD

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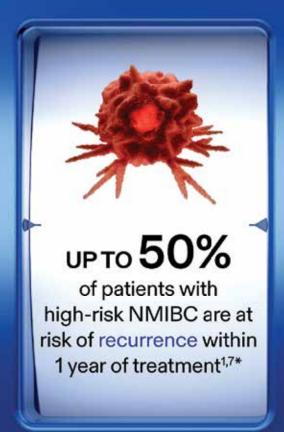
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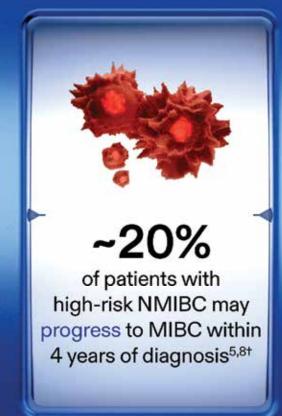


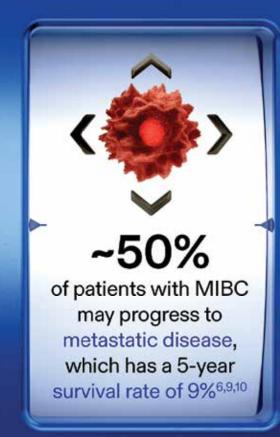
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How high are the stakes in high-risk NMIBC?

BCG monotherapy is essential to help protect against recurrence and progression, but many patients do not achieve lasting remission¹⁻⁶







Preventing recurrence and progression is critical in high-risk NMIBC



Scan to visit HighRiskNMIBC.com or visit the Pfizer booth to learn more about the stakes

*Based on a combined analysis of individual patient data from 7 EORTC clinical trials including 2,596 patients. All of the included studies evaluated patients post-TURBT, at which point they received variable treatments.

[†]Based on a systematic review of 19 clinical trials that included a total of 3,088 patients.⁸

long-term results in 1,054 patients. J Clin Oncol. 2001;19(3):666-675. doi:10.1200/jco.2001.19.3.666

BCG, bacillus Calmette-Guérin; EORTC, European Organisation for Research and Treatment of Cancer; MIBC, muscle-invasive bladder cancer; NMIBC, non-muscle-invasive bladder cancer; TURBT, transurethral resection of bladder tumor.

References: 1. Sylvester RJ, van der Meijden APM, Oosterlinck W, et al. Predicting recurrence and progression in individual patients with stage Ta T1 bladder cancer using EORTC risk tables: a combined analysis of 2596 patients from seven EORTC trials. Eur Urol. 2006;49(3):466-477. doi:10.1016/j.eururo.2005.12.031 2. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology. Bladder cancer. Version 5.2024. Published October 28, 2024. 3. Lamm DL, Morales A. A BCG success story: from prevention of tuberculosis to optimal bladder cancer treatment. Vaccine. 2021;39(50):7308-7318. doi:10.1016/j.vaccine.2021.08.026
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Michigan provider data offers direction for kidney cancer surveillance

Beyond AUA, NCCN and EAU guidelines, Michigan urologist data provides consensus for optimizing renal cancer surveillance.



Brian R. Lane, MD, PhD

ith appropriate follow-up after surgery for localized renal cell carcinoma (RCC), the majority of patients will die of other causes. Deaths after nephrectomy occur in 44% of patients more than two years

later. What is the best way to follow up and for how long?

During Saturday afternoon's State-of-the-Art Lecture, "Optimizing Follow-up Surveillance After Treatment of Localized Renal Cell Carcinoma," Brian R. Lane, MD, PhD, a urologist in the division of urology at Corewell Health West in Grand Rapids, Michigan, provided an overview of follow-up guidelines from the AUA, the National Comprehensive Cancer Network (NCCN) and the European Association of Urology (EAU) for patients with RCC based on risk stratification and noted the nuances.

"There are subtle differences among the guidelines in terms of types of testing and when. In the AUA guidelines, for example, high-risk patients are advised to have axial abdominal imaging every six months for five years, but 30% of recurrences occur outside of the five-year window," he said. Meanwhile, the literature isn't much help. It shows mixed opinions on existing followup guidelines. "Common themes include individualizing follow-up care based on cancer TNM classification stage and path features, patient age and comorbidities, and considering the type of treatment and likely site of recurrence," Dr. Lane

To shed light on how the guidelines and literature impact daily practice and how they can inform best practices for patients with RCC, Dr. Lane presented results from the Michigan Urological Survey Improvement Collaborative (MUSIC)-KIDNEY, a quality improvement initiative focused on improving urologic care for patients with localized renal masses throughout the state of Michigan.

MUSIC-KIDNEY, using modified Delphi methodology questionnaires, has collected data on more than 7,000 small renal mass cases from more than 260 high-volume urologists in Michigan from 46 high-volume practices (three outside of Michigan), with the goal of achieving consensus on how to perform better follow-up and reduce patients lost to follow-up. MUSIC-KIDNEY participants were presented with patient scenarios and asked questions, such as: "How often would you do follow-up abdominal imaging in this patient?" and "Does your frequency of imaging change in the second, third, fourth or fifth year of follow-up?"

"The Delphi methodology is designed to minimize the dominant voices so all voices can be heard," Dr. Lane said.

What emerged from the data is a provider roadmap for surveillance of T1 renal masses after kidney cancer surgery that's similar to AUA, NCCN and EAU guidelines, with the addition of specific recommendations for imaging and labs.

"Despite a bias toward 'individualized' follow-up plans, a consistent and unified surveillance strategy emerged through consideration of individual patient scenarios," Dr. Lane said. The roadmap isn't confined to the providers in the state of Michigan, of course. For more information about the MUSIC-KIDNEY roadmap and how it may benefit your practice, no matter where it is, visit musicurology.com.



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Linda Budzinski

The Patient Perspective program here at #AUA25 is so insightful. A terrific from patients on their experiences and thoughts on how to improve care.



@LindaBudz

opportunity for urologists to hear directly



Scott Lundy MD PhD HCLD @ScottLundyMDPhD

Andrew Barr presents the barbaric history of varicocele management over the last two millennia. I love stuff like this - gives all of our sterile (pun intended) scientific talks some much needed historical texture.

@CleClinicUro @AmerUrological

VOICES & VIEWS

Join the Conversation on Instagram, Facebook, and X. #AUA25



Corinna Hughes @CorinnaSHughes

Thank you, Meredith Donahue, APRN, for a fantastic overview of the AUA/ SUFU Microscopic Hematuria Guideline update— love the focus on both the foundation and the updates! #AUA25



Joanna Orzel, M.D. @JOrzel_MD

So much fun participating in the @AmerUrological global residents leadership retreat! great way to kick off #AUA25



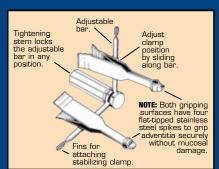
Amit Bhattu @amitbhattu

It is always great attending AUA meetings. #AUA25. I had the pleasure of catching up with my mentor @gonzomdphd @dsui_miami_uro. Great insights and discussions.



SydneyStrup @SydneyStrup

Great first day at the #AUA25 Loved presenting my poster on burnout and unhealthy coping mechanisms @AndrewHarris_MD! Looking forward to meeting new people and learning more these next couple of days





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In RCC, all T3 tumors are characterized by their invasiveness.¹

These tumors extend into structures within or adjacent to the kidney system, including the perirenal fat, the renal vein, the vena cava, or the pelvicalyceal system.^{1,a}

Patients with more invasive tumors are at a higher risk of their cancer returning.²

Identify patients in your practice who have T3 tumors so you can take appropriate action following nephrectomy.

How will you manage your next patient with an invasive T3 tumor?

^aT3 tumors do not extend beyond Gerota's fascia or into the ipsilateral adrenal gland. ¹ RCC = renal cell carcinoma.



References: 1. Edge SB, Greene FL, Byrd DR, et al, eds. Kidney. In: *AJCC Cancer Staging Manual*. 8th ed. Springer International Publishing; 2017:739–748. **2.** Sundaram M, Song Y, Rogerio JW, et al. Clinical and economic burdens of recurrence following nephrectomy for intermediate high- or high-risk renal cell carcinoma: a retrospective analysis of Surveillance, Epidemiology, and End Results-Medicare data. *J Manag Care Spec Pharm*. 2022;28(10):1149–1160. doi:10.18553/jmcp.2022.22133







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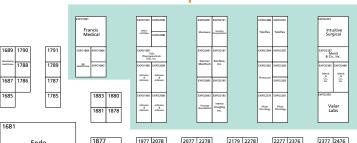
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Zimmer MedizinSystems

Felix Guerrero-Ramos, MD said Felix Guerrero-Ramos, MD, PhD, FEBU, coordinator of urologic oncology and After a median follow-up of bladder cancer at 12 de Octubre University Hospital in Madrid, Spain. "Only three patients had to undergo a

> Overall survival at nine months was 95.6% with no new safety signals, Dr.

radical cystectomy."

Guerrero-Ramos said. Most AEs were Grade 1-2 lower urinary tract symptoms and resolved rapidly.

A phase 3 SunRISe-5 study of TAR-200 vs. intravesical chemotherapy in a larger cohort is ongoing, he added. Additional information on TAR-200 will be available on Monday in the Learning Lab.

QUESTION OF THE DAY

What is a new/emerging urological treatment/technology you are most eager to learn about at AUA2025?

I am most excited this year to learn more about aquablation, a newer procedure for benign prostatic hyperplasia (BPH). It sounds like it's going to be excellent as a minimally invasive procedure, so I'm eager to learn more.



Elizabeth Blount, NP Birmingham, Alabama

I'm really excited to learn more about sacral neuromodulation in men in the post-prostatectomy space. I think it could really impact patients who are currently undertreated.



Adam Baumgarten, MD, MBA Birmingham, Alabama

I am looking forward to learning more about female sexual health. I think in the past, sexual health has been very male-focused, while female sexual health has been underserved and untreated for such a long time. So it's going to be fun to dive into that.

> Casey McCraw, MD Las Vegas, Nevada

as I would like to know about it, and I'm interested in learning more about how efficacious it might be-whether there is more blood loss and whether it's easy to get the tissue out.



Marvalyn Decambre, MD, MPH, MBA Livingston, New Jersey

Surgical approach. A lot of surgeons focus on the single-port robotic approach versus the multiport approach to robotic surgery ... especially for radical cystectomy. I think the trend for the urologist is that we not only focus on the surgery but also pay attention to long-term outcomes.

> Xiao Yang, MD Nanjing, China

Aquablation. I don't know as much

NOVEL INTERVENTIONS continued from page 1

under review by the FDA, he reported, and the manufacturer has launched a preapproval access program in the U.S.

The sustained-release gemcitabine device showed even more robust results in the first 24 patients in a cohort with high-risk papillary-only BCG-unresponsive NMIBC. Of the 650,000 bladder cancers diagnosed annually, 75% have NMIBC and half are high-risk.

12.8 months, the six-month DFS was 85.3%, and the ninemonth DFS was 81.5 %. DFS was consistently high across Ta and T1 disease.

"The median disease-free survival was not reached,"



1. ANKTIVA Package insert. ImmunityBio, Inc.; 2024.



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Indication and Important Safety Information

INDICATION AND USAGE ANKTIVA is an interleukin-15 (IL-15) receptor agonist indicated with Bacillus Calmette-Guerin (BCG) for the treatment of adult patients with BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors. **WARNINGS AND PRECAUTIONS** Risk of Metastatic Bladder Cancer with Delayed Cystectomy. Delaying cystectomy can lead to the development of muscle invasive or metastatic bladder cancer, which can be lethal. If patients with CIS do not have a complete response to treatment after a second induction course of ANKTIVA with BCG, reconsider cystectomy. **DOSAGE AND ADMINISTRATION** For Intravesical Use Only. Do not administer by subcutaneous or intravenous routes. Instill intravesically only after dilution. Total time from vial puncture to the completion of the intravesical instillation should not exceed 2 hours. **USE IN SPECIFIC POPULATIONS** Pregnancy: May cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception. ADVERSE REACTÍONS The most common (≥15%) adverse reactions, including laboratory test abnormalities, are increased creatinine, dysuria, hematuria, urinary frequency, micturition urgency, urinary tract infection, increased potassium, musculoskeletal pain, chills and pyrexia.

For more information about ANKTIVA, please see the Full Prescribing Information at www.anktiva.com.

You are encouraged to report negative side effects of prescription drugs to FDA. Visit www.FDA.gov/medwatch or call 1-800-332-1088. You may also contact ImmunityBio at 1-877-ANKTIVA (1-877-265-8482)





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