Year in Review: Clinical Investigator Perspectives on the Most Relevant New Datasets and Advances in Oncology

Non-Muscle-Invasive and Muscle-Invasive Urothelial Bladder Cancer

A CME/MOC-Accredited Live Webinar

Tuesday, May 5, 2026

5:00 PM – 6:00 PM ET

Faculty

Ashish M Kamat, MD, MBBS

Thomas Powles, MBBS, MRCP, MD

Moderator

Neil Love, MD

RTP Year in Review 2026

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Professor of Urologic Oncology (Surgery)
Wayne B Duddlesten Professor of Cancer Research
Department of Urology, Division of Surgery
The University of Texas
MD Anderson Cancer Center
Houston, Texas

Thomas Powles, MBBS, MRCP, MD
Director of Barts Cancer Institute
Queen Mary University of London
London, United Kingdom

MODERATOR
Neil Love, MD
Research To Practice
Miami, Florida

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Patents	CyPRIT (Cytokine Predictors of Response to Intravesical Therapy) — Joint patent with MD Anderson Cancer Center # 00043705
Research Funding	Arquer Diagnostics, enGene, Ferring Pharmaceuticals Photocure, Seagen Inc
Nonrelevant Financial Relationships	American Urological Association (AUA), *European Urology Oncology,* International Bladder Cancer Group (IBCG), *Journal of Urology*, Patient-Centered Outcomes Research Institute (PCORI), SWOG, UroToday, World Bladder Cancer Patient Coalition

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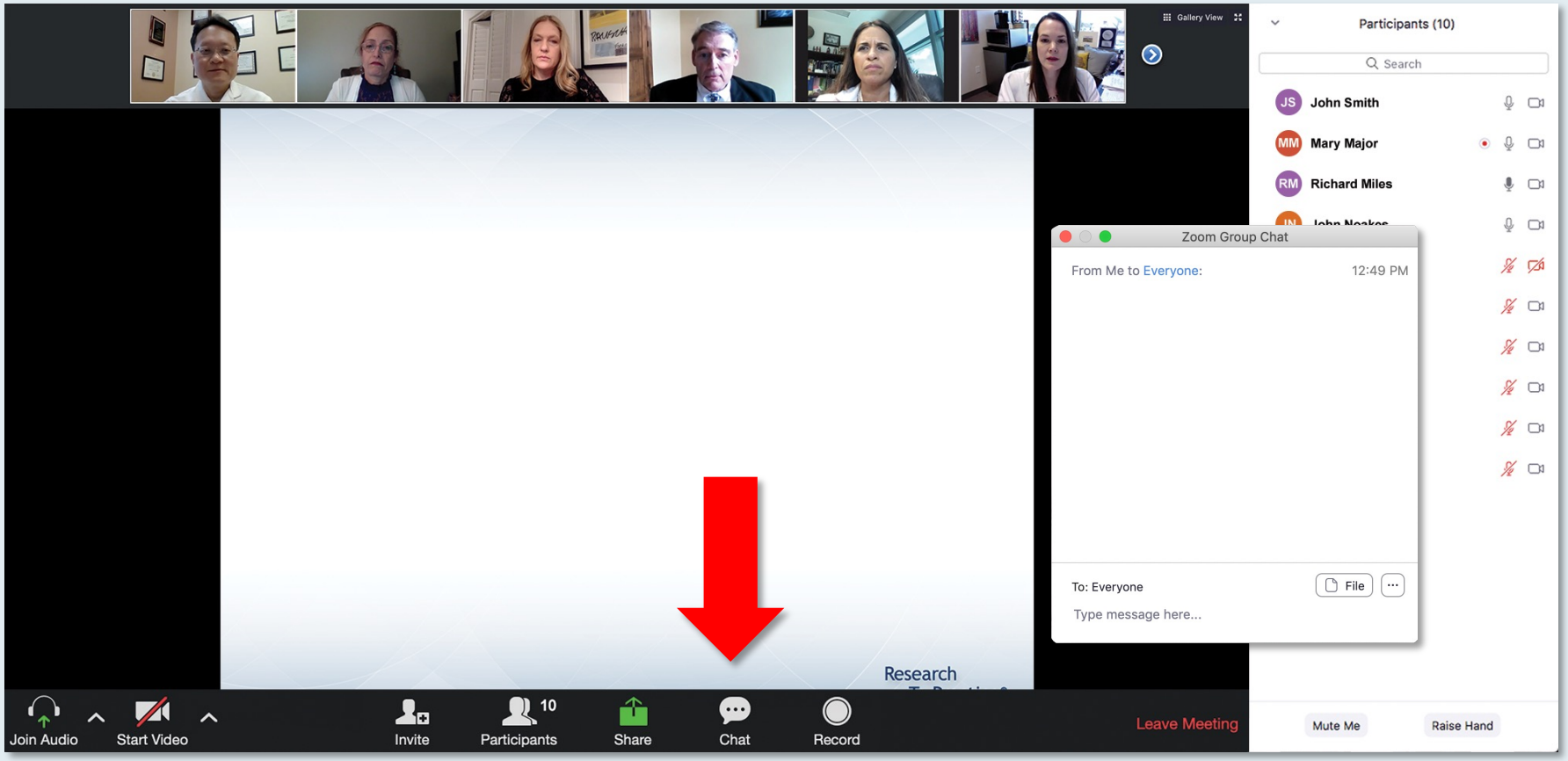

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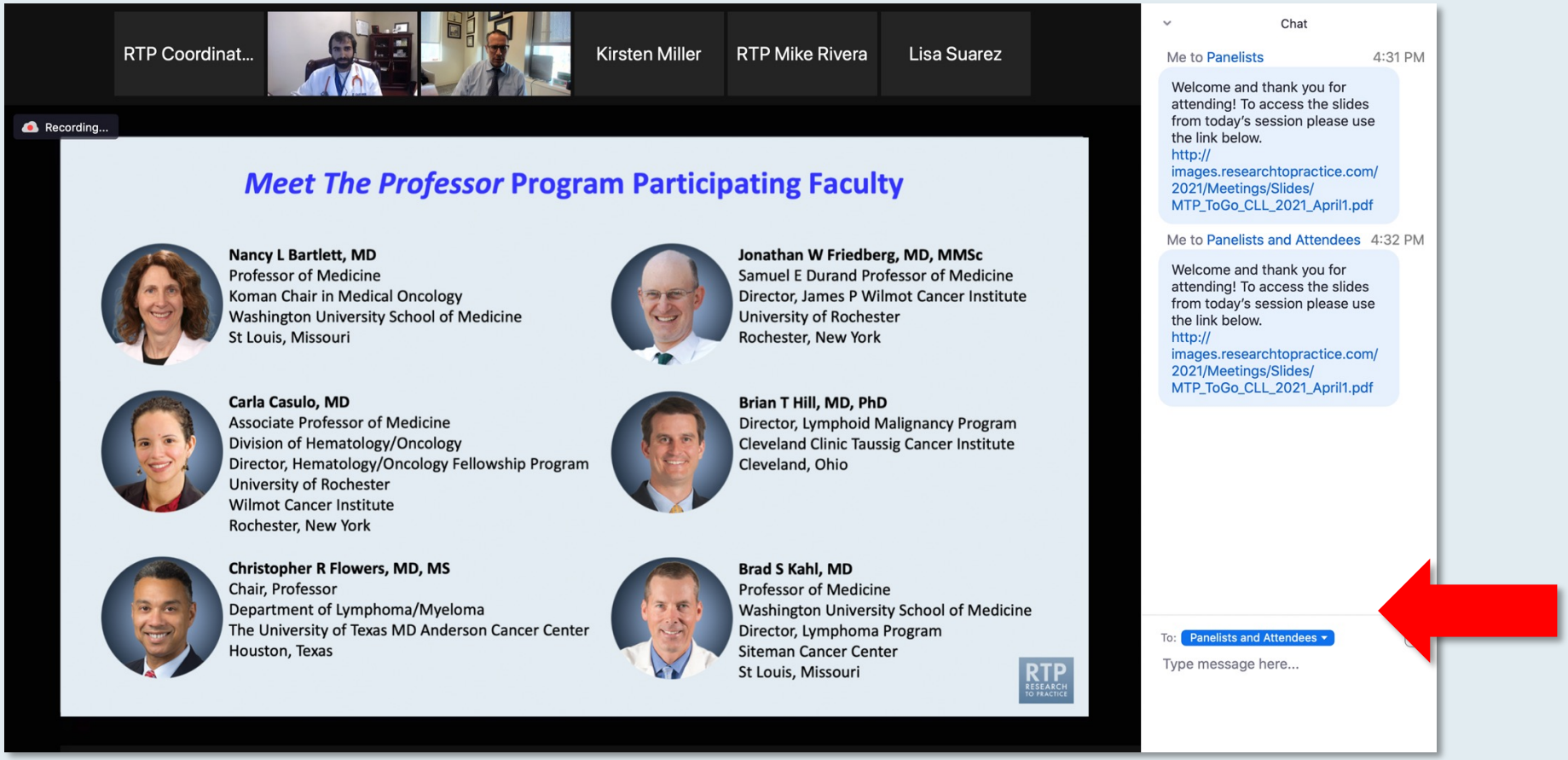

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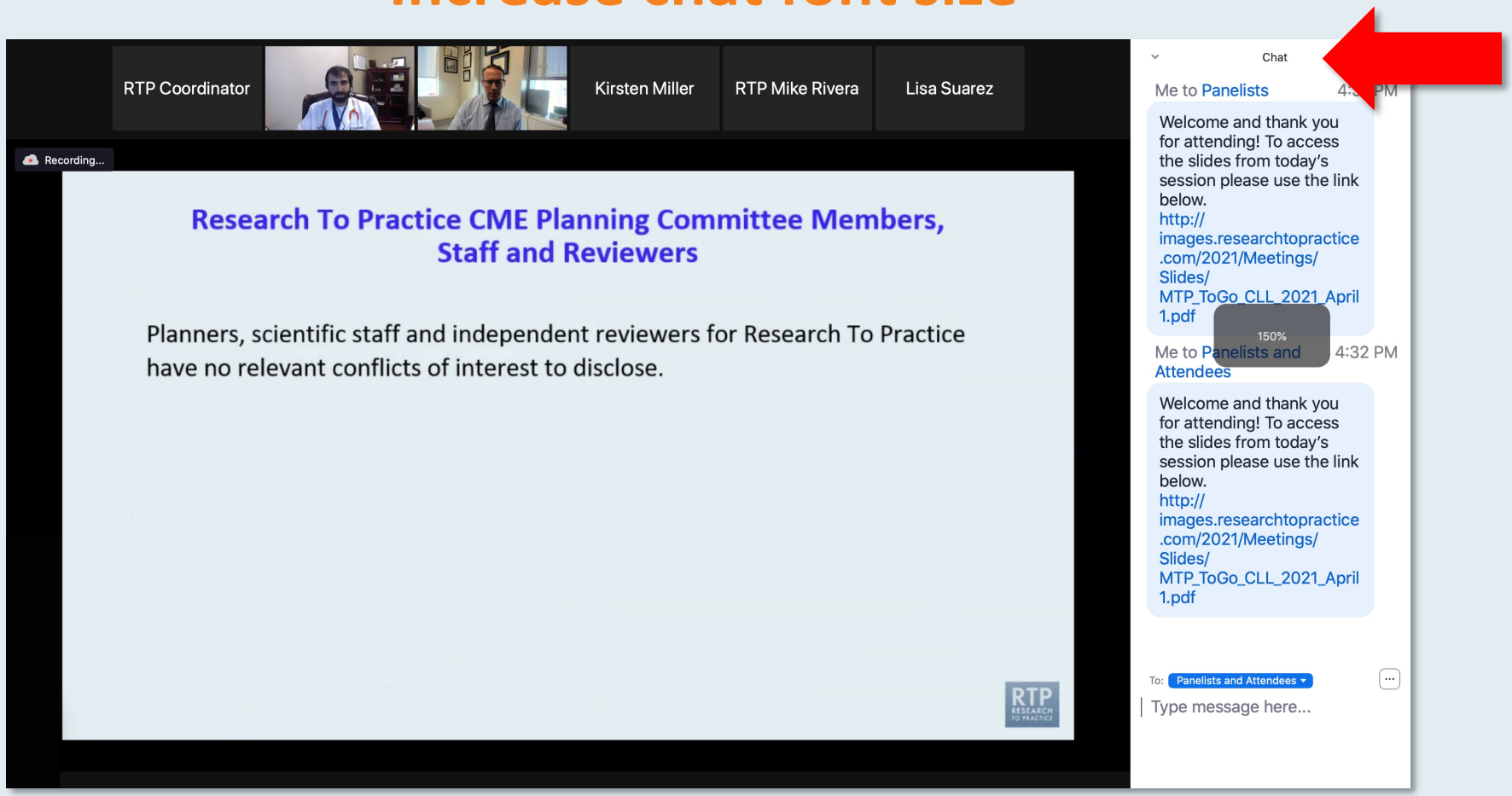

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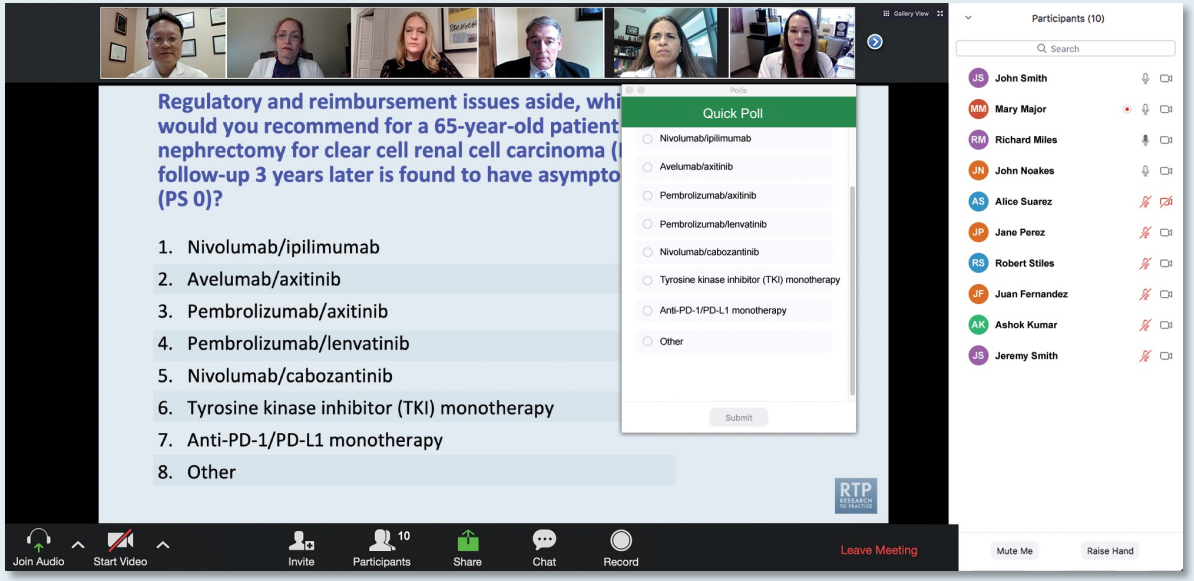

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INTRODUCTION: Life After Radical Cystectomy

MODULE 1: Muscle-Invasive Bladder Cancer — Prof Powles

MODULE 2: Non-Muscle-Invasive Bladder Cancer — Dr Kamat

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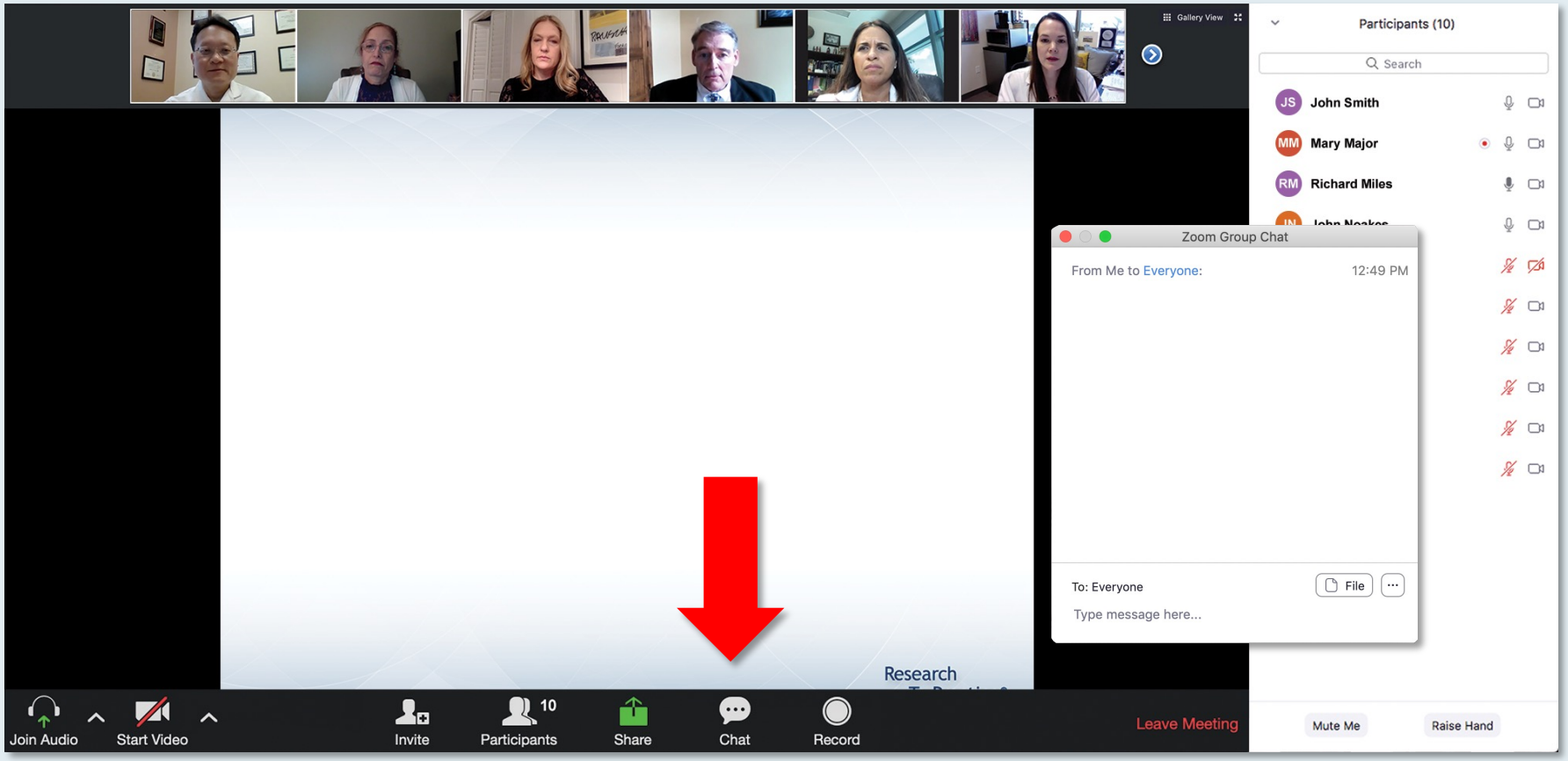

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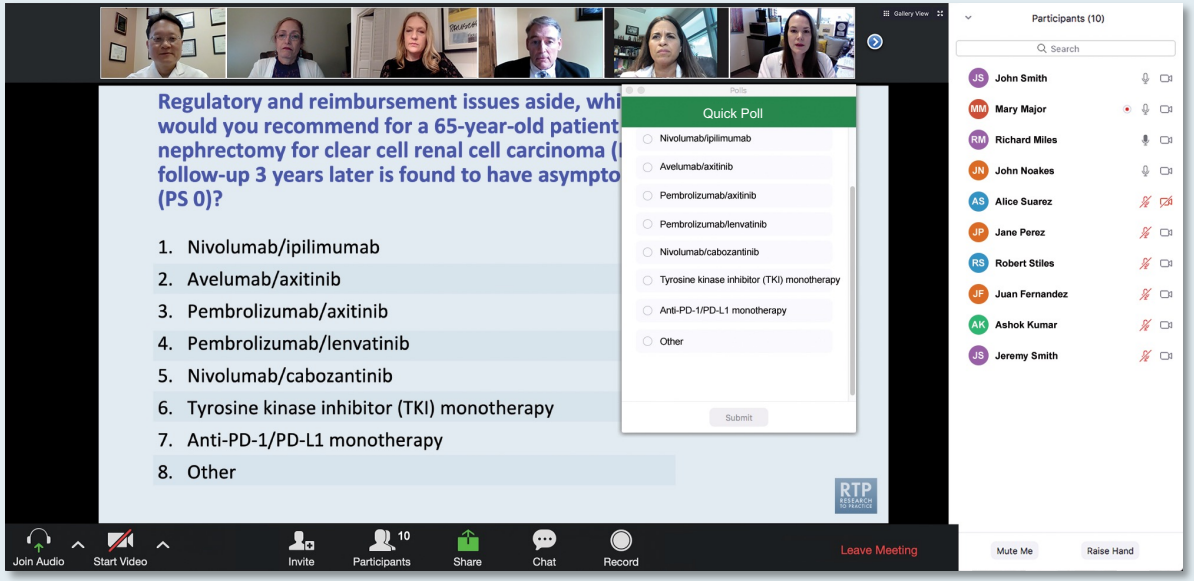

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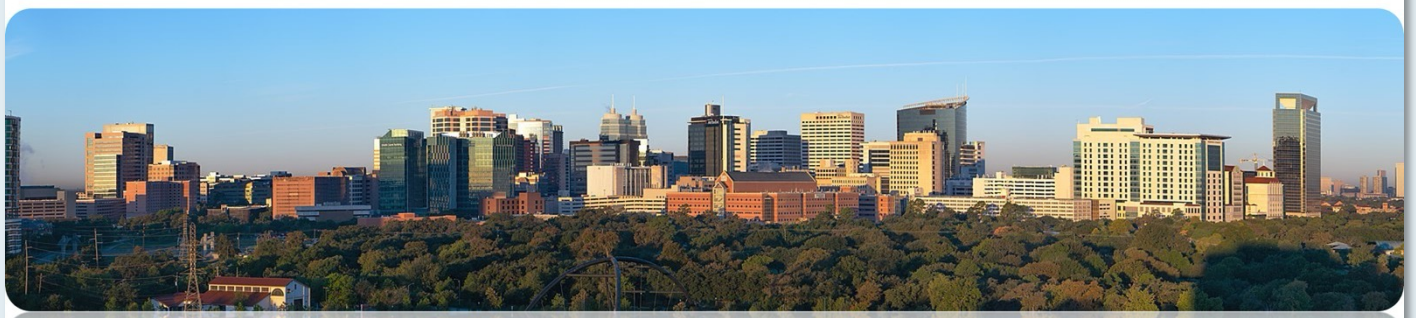
Director of Barts Cancer Institute
Queen Mary University of London
London, United Kingdom



Year in Review - NMIBC

Ashish M. Kamat, MD, MBBS

Professor of Urologic Oncology
Wayne B. Duddlesten Professor of Cancer Research
Director, Bladder Cancer Research
President, International Bladder Cancer Group (IBCG)

Key Datasets

Ashish Kamat, MD, MBBS

- Shore ND et al. Sasanlimab plus BCG in BCG-naive, high-risk non-muscle invasive bladder cancer: The randomized phase 3 CREST trial. *Nat Med* 2025;31(8):2806-14.
- De Santis M et al. Durvalumab in combination with BCG for BCG-naive, high-risk, non-muscle-invasive bladder cancer (POTOMAC): Final analysis of a randomised, open-label, phase 3 trial. *Lancet* 2025;406(10516):2221-34.
- Rouprêt M et al. ALBAN (GETUG-AFU 37): A phase III, randomized, open-label international trial of intravenous atezolizumab and intravesical bacillus Calmette-Guerin (BCG) versus BCG alone in BCG-naive high-risk, non-muscle-invasive bladder cancer (NMIBC). *Ann Oncol* 2026;37(1):44-52.
- Hayne D et al. Mitomycin plus BCG as adjuvant intravesical therapy for high-risk, non–muscle-invasive bladder cancer: A randomized phase 3 trial (ANZUP 1301). ASCO 2025;Abstract LBA4504.
- Daneshmand S et al. TAR-200 for bacillus Calmette-Guerin-unresponsive high-risk non-muscle-invasive bladder cancer: Results from the phase IIb SunRISe-1 study. *J Clin Oncol* 2025;43(33):3578-88.

Key Datasets

Ashish Kamat, MD, MBBS (continued)

- Jacob JM et al. TAR-200 monotherapy in patients with bacillus Calmette-Guérin-unresponsive high-risk non–muscle-invasive bladder cancer carcinoma in situ: 1-year durability and patient-reported outcomes from SUNRISE-1. AUA 2025.
- Guerrero-Ramos F et al. TAR-200 monotherapy in patients with bacillus Calmette-Guérin–unresponsive papillary disease–only high-risk non–muscle-invasive bladder cancer: First results from cohort 4 of SUNRISE-1. AUA 2025.
- Daneshmand S et al. Erdafitinib in patients with high- and intermediate-risk non-muscle-invasive bladder cancer: Final analysis of THOR-2 Study. *Eur Urol* 2026;89(2):165-73.
- Chang SS et al. Prolonged progression-free survival, disease-free survival, and cystectomy avoidance with IL-15 receptor lymphocyte-stimulating agent NAI plus bacillus Calmette-Guerin in bacillus Calmette-Guerin-unresponsive papillary-only nonmuscle-invasive bladder cancer. *J Urol* 2026;215(1):44-56.
- Wang B et al. Real-world experience with a commercial circulating tumor dna assay in non-muscle-invasive bladder cancer. *Eur Urol Oncol* 2025 August;8(4):883-7.

Key Datasets

Thomas Powles, MBBS, MRCP, MD

- Meeks JJ et al. The first report of disease-free survival analyses from the NIAGARA trial of perioperative durvalumab plus neoadjuvant chemotherapy in muscle-invasive bladder cancer. AUA 2025;Abstract PD37-09.
- Powles T et al. Circulating tumor DNA (ctDNA) in patients with muscle-invasive bladder cancer (MIBC) who received perioperative durvalumab (D) in NIAGARA. ASCO 2025;Abstract 4503.
- Van der Heijden MS et al. Urinary tumor DNA (utDNA) and circulating tumor DNA (ctDNA) in patients (pts) with muscle-invasive bladder cancer (MIBC) who received perioperative durvalumab (D) in NIAGARA. Genitourinary Cancers Symposium 2026;Abstract 636.
- Vulsteke C et al. Perioperative enfortumab vedotin and pembrolizumab in bladder cancer. *N Engl J Med* 2026 April 2;394(13):1257-69.
- Galsky M et al. Neoadjuvant and adjuvant enfortumab vedotin (EV) plus pembrolizumab (pembro) for participants with muscle-invasive bladder cancer (MIBC) who are eligible for cisplatin: Randomized, open-label, phase 3 KEYNOTE-B15 study. Genitourinary Cancers Symposium 2026;Abstract LBA630.

Key Datasets

Thomas Powles, MBBS, MRCP, MD (continued)

- Powles TB et al. ctDNA-Guided adjuvant atezolizumab in muscle-invasive bladder cancer. *N Engl J Med* 2025;393(24):2395-408.
- Bellmunt J et al. Circulating tumor (ct)DNA-guided adjuvant atezolizumab (atezo) in muscle-invasive bladder cancer (MIBC): Exploratory analysis of ctDNA dynamics in the IMvigor011 trial. Genitourinary Cancers Symposium 2026;Abstract 633.
- Ghatalia P et al. Circulating tumor DNA (ctDNA) to guide response-adapted bladder preservation in muscle invasive bladder cancer (MIBC): Integrated analysis of the RETAIN trials. Genitourinary Cancers Symposium 2026;Abstract LBA632.
- Mellema JJ et al. Ipilimumab and nivolumab followed by chemoradiotherapy as bladder-sparing treatment in muscle-invasive bladder cancer: A phase 2 trial. *Nat Med* 2026;[Online ahead of print].
- Galsky MD et al. Adjuvant nivolumab versus placebo for high-risk muscle-invasive urothelial carcinoma: 5-year efficacy and ctDNA results from CheckMate 274. *Ann Oncol* 2026;37(1):69-78.

Year in Review:
Non-Muscle-Invasive and Muscle-Invasive Bladder Cancer

INTRODUCTION: Life After Radical Cystectomy

MODULE 1: Muscle-Invasive Bladder Cancer — Prof Powles

MODULE 2: Non-Muscle-Invasive Bladder Cancer — Dr Kamat

RTP Year in Review 2026

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INTRODUCTION: Life After Radical Cystectomy

MODULE 1: Muscle-Invasive Bladder Cancer — Prof Powles

- IMvigor011, CheckMate 274
- NIAGARA ctDNA analysis
- Perioperative enfortumab vedotin with pembrolizumab
- Bladder-sparing approaches

MODULE 2: Non-Muscle-Invasive Bladder Cancer — Dr Kamat

Select Key Datasets
IMvigor011, CheckMate 274

- Powles TB et al. ctDNA-guided adjuvant atezolizumab in muscle-invasive bladder cancer. *N Engl J Med* 2025;393(24):2395-408.
- Bellmunt J et al. Circulating tumor (ct)DNA-guided adjuvant atezolizumab (atezo) in muscle-invasive bladder cancer (MIBC): Exploratory analysis of ctDNA dynamics in the IMvigor011 trial. Genitourinary Cancers Symposium 2026;Abstract 633.
- Galsky MD et al. Adjuvant nivolumab versus placebo for high-risk muscle-invasive urothelial carcinoma: 5-year efficacy and ctDNA results from CheckMate 274. *Ann Oncol* 2026;37(1):69-78.

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 DECEMBER 18/25, 2025 VOL. 393 NO. 24

ctDNA-Guided Adjuvant Atezolizumab in Muscle-Invasive Bladder Cancer

T. Powles,[1] A.G. Kann,[2] D. Castellano,[3] M. Gross-Goupil,[4] H. Nishiyama,[5] S. Bracarda,[6] J.
L. Makaroff,[8,9] S. Jiang,[10] J.H. Ku,[11] S.H. Park,[12] O. Reig Torras,[13] D. Ye,[14] M. Maruzzo,
R. Morales-Barrera,[18] E.F. Giunta,[19] J.L. Lee,[20] G. Tortora,[21,22] Y. Ürün,[23] L. Dolowy,[24] D. E
F. Grando,[27] W. Zou,[28] Z.J. Assaf,[28] J. Vuky,[28] V. Degaonkar,[6,28] E.E. Steinberg,[28] J. Bellmunt,[2
for the IMvigor011 Investigators*

Abstract 633

ASCO Genitourinary Cancers Symposium

Circulating tumor (ct)DNA-guided adjuvant atezolizumab (atezo) in muscle-invasive bladder cancer (MIBC): Exploratory analysis of ctDNA dynamics in the IMvigor011 trial.

Thomas Powles[1], Jessica Grindheim[2], Mesut Yılmaz[3], Grigorios Rallis[4], Mahmut Gümüş[5], Consuelo Buttigliero[6], Teresa Bonfill[7], Franco Nolè[8], Ho Kyung Seo[9], Michaela Matoušková[10], Iwona Skoneczna[11], Wim Demey[12], Patrizia Giannatempo[13], Sylvie Rottey[14], Damien Pouessel[15], Syed A. Hussain[16], Elizabeth E. Steinberg[2], Richard Price[2], Yohann Loriot[17], Joaquim Bellmunt[18]

[1]Barts Cancer Institute, National Institute for Health Research Biomedical Research Centre, Queen Mary University of London, London, UK; [2]Genentech, Inc., South San Francisco, CA, USA; [3]Department of Medical Oncology, Bakırköy Dr. Sadi Konuk Training and Research Hospital, Istanbul, Türkiye; [4]2nd Department of Medical Oncology, Theageneio Cancer Center, Thessaloniki, Greece; [5]Istanbul Medeniyet University Goztepe Training and Research Hospital, Istanbul, Türkiye; [6]Department of Oncology, University of Turin, San Luigi Gonzaga Hospital, Turin, Italy; [7]Hospital Universitari Parc Taulí, Sabadell, Spain; [8]Medical Oncology Division of Urogenital and Head & Neck Tumours, IEO, European Institute of Oncology IRCCS, Milan, Italy; [9]Department of Urology, Center for Urologic Cancer, Hospital/Division of Tumor Immunology, Research Institute, National Cancer Center, Goyang, Republic of Korea; [10]Urocentrum Praha, Prague, Czech Republic; [11]Maria Skłodowska-Curie Memorial Cancer Centre, Warsaw, Poland; [12]Department of Medical Oncology, Algemeen Ziekenhuis Klina, Brasschaat, Belgium; [13]Fondazione IRCCS Istituto Nazionale dei Tumori, Milano, Italy; [14]Department of Medical Oncology, Ghent University Hospital, Ghent, Belgium; [15]University of Toulouse, Oncopole Claudius Regaud, IUCT-Oncopole, Department of Medical Oncology, Toulouse, France; [16]Department of Oncology and Metabolism, Academic Unit of Oncology, University of Sheffield, Sheffield, UK; [17]Gustave Roussy, Université Paris-Saclay, Département de Médecine, DITEP, Villejuif, France; [18]Dana-Farber Cancer Institute and Harvard University, Boston, MA, USA.

2026;37(1):69-78.

ESMO GOOD SCIENCE BETTER MEDICINE BEST PRACTICE

ANNALS OF ONCOLOGY DRIVING INNOVATION IN ONCOLOGY

ORIGINAL ARTICLE

Adjuvant nivolumab versus placebo for high-risk muscle-invasive urothelial carcinoma: 5-year efficacy and ctDNA results from CheckMate 274☆

M. D. Galsky[1*], J. E. Gschwend[2], M. I. Milowsky[3], M. Schenker[4], B. P. Valderrama[5], Y. Tomita[6], A. Bamias[7], T. Lebret[8], S. F. Shariat[9], S. H. Park[10], M. Agerbaek[11], G. Jha[12], F. Stenner[13], D. Ye[14], F. Giudici[15], J. Connors[16], S. Gupta[17], A. Chhibber[17], J. Zhang[18], D. F. Bajorin[19] & J. A. Witjes[20]

SUMMARY

ctDNA is a prognostic and predictive tool in the adjuvant setting

It can help select patients for adjuvant therapy in immune therapy naive patients

The levels as well as positive vs negative status are relevant

EVP in perioperative disease is the standard making these data less relevant

Courtesy of Thomas Powles, MBBS, MRCP, MD

Select Key Datasets
NIAGARA ctDNA Analysis

- Meeks JJ et al. The first report of disease-free survival analyses from the NIAGARA trial of perioperative durvalumab plus neoadjuvant chemotherapy in muscle-invasive bladder cancer. AUA 2025;Abstract PD37-09.
- Powles T et al. Circulating tumor DNA (ctDNA) in patients with muscle-invasive bladder cancer (MIBC) who received perioperative durvalumab (D) in NIAGARA. ASCO 2025;Abstract 4503.
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Abstract # PD37-09

AUA 2025 Las Vegas APR 26-29

The first report of disease-free survival analyses from the NIAGARA trial of perioperative durvalumab plus neoadjuvant chemotherapy in muscle-invasive bladder cancer

Joshua J. Meeks,[1] Michiel S. van der Heijden,[2] Thomas Powles,[3] Matthew D. Galsky,[4] Hikmat Al-Ahmadie,[5] Hiroyuki Nishiyama,[6] Alexandra Drakaki,[7] Toan Quang Vu,[8] Lorenzo Antonuzzo,[9] Pawel Wiechno,[10] Vagif Atduev,[11] Ariel G. Kann,[12] Tae-Hwan Kim,[13] Cristina Suárez,[14] Albert Font Pous,[15] Chao-Hsiang Chang,[16] Wenjing Xin,[17] Svetlana Ho,[18] Małgorzata Gula,[19] James W. F. Catto[20]

[1]Departments of Urology, Biochemistry, and Molecular Genetics, Northwestern University, Feinberg School of Medicine, Chicago, IL; [2]Department of Medical Oncology, The Netherlands Cancer Institute, Amsterdam, The Netherlands; [3]Barts Cancer Institute ECMC/BRC, Queen Mary University of London, Barts Health NHS Trust, London, UK; [4]Icahn School of Medicine at Mount Sinai, New York, NY; [5]Department of Pathology and Laboratory Medicine, Memorial Sloan Kettering Cancer Center, New York, NY; [6]Department of Urology, University of Tsukuba, Tsukuba, Japan; [7]Division of Hematology/Oncology, David Geffen School of Medicine, Los Angeles, CA; [8]Department of Internal Medicine 3, Vietnam National Cancer Hospital, Hanoi, Vietnam; [9]Sodc Oncologia Medica - Azienda Ospedaliera - Universitaria Careggi, Florence, Italy; [10]Maria Skłodowska-Curie National Research Institute of Oncology, Warsaw, Poland; [11]Volga District Medical Center, Federal Medical-Biological Agency, Nizhny Novgorod, Russia; [12]Clinical Oncology, Hospital Alemão Oswaldo Cruz, São Paulo, Brazil; [13]Department of Urology, Kyungpook National University School of Medicine, Daegu, South Korea; [14]Medical Oncology, Vall d'Hebron Institute of Oncology, Hospital Universitari Vall d'Hebron, Vall d'Hebron Barcelona Hospital Campus, Barcelona, Spain; [15]Medical Oncology Department, Institut Català d'Oncologia, Badalona Applied Research Group in Oncology (BARGO), Hospital Universitari Germans Trias i Pujol, Badalona, Barcelona, Spain; [16]Department of Urology and School of Medicine, China Medical University and Hospital, Taichung, Taiwan; [17]AstraZeneca, Gothenburg, Sweden; [18]AstraZeneca, Gaithersburg, MD; [19]AstraZeneca, Warsaw, Poland; [20]University of Sheffield, Sheffield, UK

Abstract 4503

2025 ASCO ANNUAL MEETING

Circulating tumor DNA (ctDNA) in patients with muscle-invasive bladder cancer (MIBC) who received perioperative durvalumab (D) in NIAGARA

Thomas Powles,[1] Michiel S. van der Heijden,[2] Ying Wang,[3] James W. F. Catto,[4] Joshua J. Meeks,[5] Hikmat Al-Ahmadie,[6] Hiroyuki Nishiyama,[7] Agrin Moeini,[8] Toan Quang Vu,[9] Lorenzo Antonuzzo,[10] Tae-Hwan Kim,[11] Vagif Atduev,[12] Hiroaki Kikukawa,[13] Bernhard Eigl,[14] Yousef Zakharia,[15] Kazuo Nishimura,[16] Svetlana Ho,[17] Wenjing Xin,[18] Yashaswi Shrestha,[17] Matthew D. Galsky[19]

[1]Queen Mary University of London, Barts Health NHS Trust, London, UK; [2]The Netherlands Cancer Institute, Amsterdam, The Netherlands; [3]AstraZeneca, Waltham, MA; [5]Northwestern University, Feinberg School of Medicine, Chicago, IL; [6]Memorial Sloan Kettering Cancer Center, New York, NY; [7]University of Tsukuba, Tsukuba, Japan; Barcelona, Spain; [9]Vietnam National Cancer Hospital, Hanoi, Vietnam; [10]Azienda Ospedaliera, Universitaria Careggi, Florence, Italy; [11]Kyungpook National University S Medical-Biological Agency, Nizhny Novgorod, Russia; [13]National Hospital Organization Kumamoto Medical Center, Kumamoto, Japan; [14]BC Cancer, Vancouver, BC, Ca Center, Iowa City, IA, and Mayo Clinic Comprehensive Cancer Center, Mayo Clinic, Phoenix, AZ; [16]Osaka International Cancer Institute, Osaka, Japan; [17]AstraZeneca, Gothenburg, Sweden; [19]Icahn School of Medicine at Mount Sinai, New York, NY

2025 ASCO ANNUAL MEETING #ASCO25

ASCO Genitourinary Cancers Symposium

Abstract #636

Urinary tumor DNA and circulating tumor DNA in patients with muscle-invasive bladder cancer who received perioperative durvalumab in NIAGARA

Michiel S. van der Heijden,[1] Matthew D. Galsky,[2] Ricky Joshi,[3] James W. F. Catto,[4] Joshua J. Meeks,[5] Hiroyuki Nishiyama,[6] Hikmat Al-Ahmadie,[7] Lorenzo Antonuzzo,[8] Toan Quang Vu,[9] Yousef Zakharia,[10] Vagif Atduev,[11] Bernhard Eigl,[12] Cristina Suárez,[13] Svetlana Ho,[14] Huiling Xiong,[15] Agrin Moeini,[3] Yashaswi Shrestha,[14] Thomas Powles[16]

[1]Department of Medical Oncology, Netherlands Cancer Institute, Amsterdam, The Netherlands; [2]Icahn School of Medicine at Mount Sinai, New York, NY; [3]AstraZeneca, Barcelona, Spain; [4]University of Sheffield, Sheffield, UK; [5]Departments of Urology, Biochemistry, and Molecular Genetics, Northwestern University, Feinberg School of Medicine, Chicago, IL; [6]Department of Urology, University of Tsukuba, Tsukuba, Japan; [7]Department of Pathology and Laboratory Medicine, Memorial Sloan Kettering Cancer Center, New York, NY; [8]Sodc Oncologia Medica-Azienda Ospedaliera-Universitaria Careggi, Florence, Italy; [9]Department of Internal Medicine 3, Vietnam National Cancer Hospital, Hanoi, Vietnam; [10]University of Iowa Hospitals and Clinics, Holden Comprehensive Cancer Center, Iowa City, IA; [11]Volga District Medical Center, Federal Medical-Biological Agency, Nizhny Novgorod, Russia; [12]British Columbia Cancer Agency, Vancouver, BC, Canada; [13]Medical Oncology, Vall d´Hebron Institute of Oncology, Hospital Universitari Vall d´Hebron, Vall d´Hebron Barcelona Hospital Campus, Barcelona, Spain; [14]AstraZeneca, Gaithersburg, MD; [15]AstraZeneca, Waltham, MA; [16]Barts Cancer Institute ECMC/BRC, Queen Mary University of London, Barts Health NHS Trust, London, UK

ASCO Genitourinary Cancers Symposium #GU26 PRESENTED BY: Dr Michiel S. van der Heijden ASCO AMERICAN SOCIETY OF CLINICAL ONCOLOGY KNOWLEDGE CONQUERS CANCER

RTP Year in Review 2026

SUMMARY

ctDNA in the neoadjuvant therapy is strongly prognostic

Failure to clear ctDNA with therapy is incresasingly bad news

ctDNA is not able to tell us when to stop immune therapy early

utDNA may improve accuracy of the cancer status in the bladder

Courtesy of Thomas Powles, MBBS, MRCP, MD

Select Key Datasets
Perioperative Enfortumab Vedotin with Pembrolizumab

- Vulsteke C et al. Perioperative enfortumab vedotin and pembrolizumab in bladder cancer. *N Engl J Med* 2026 April 2;394(13):1257-69.
- Galsky M et al. Neoadjuvant and adjuvant enfortumab vedotin (EV) plus pembrolizumab (pembro) for participants with muscle-invasive bladder cancer (MIBC) who are eligible for cisplatin: Randomized, open-label, phase 3 KEYNOTE-B15 study. Genitourinary Cancers Symposium 2026;Abstract LBA630.

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Perioperative Enfortumab Vedotin and Pembrolizumab in Bladder Cancer

C. Vulsteke,[1,2] N. Adra,[3] P. Danchaivijitr,[4] M. Sabadash,[5] A. Rodriguez-Vida,[6] Z. Zhang,[7] V. Atdu
S. Rausch,[10] S.-H. Kang,[11] Y. Loriot,[12] J. Bedke,[13] M.D. Galsky,[14] P.H. O'Donnell,[15] G. von A
N. Alimohamed,[17] G. Sulimka,[18] S. Gupta,[19] V. Paramonov,[20] K. Nakane,[21] M. Mihm,[22] C. Meng,
C. Ramamurthy,[24] B. Homet Moreno,[24] and A. Ullén,[25,26] for the KEYNOTE-905/EV-303 Inv

Abstract LBA630

ASCO Genitourinary Cancers Symposium

Neoadjuvant and Adjuvant Enfortumab Vedotin Plus Pembrolizumab for Participants With Muscle-Invasive Bladder Cancer Who Are Eligible for Cisplatin: Randomized, Open-Label, Phase 3 KEYNOTE-B15 Study

Matthew D. Galsky[1], Begoña Pérez-Valderrama[2], Marco Maruzzo[3], Albert Font[4], Tudor Ciuleanu[5], Jonathan Chatzkel[6], Takuya Koie[7], Christopher Hoimes[8], Javier Puente[9], Yousef Zakharia[10], Eli Rosenbaum[11], Katharina Boehm[12], Yohann Loriot[13], Jens Bedke[14], Thomas B. Powles[15]; Heidi S. Wirtz[16], Michael Mihm[17], Qinlei Huang[18], Aljosja Rogiers[18], Blanca Homet Moreno[18], Alfonso Gómez de Liaño[19]

[1]Icahn School of Medicine at Mount Sinai, Tisch Cancer Institute, New York, NY, USA; [2]Hospital Universitario Virgen del Rocío, Seville, Spain; [3]Istituto Oncologico Veneto IRCCS-Oncologia Medica 1, Padova, Italy; [4]Catalan Institute of Oncology (ICO) Badalona, Barcelona, Spain; [5]Institutul Oncologic Prof. Dr. Ion Chiricuta Cluj-Napoca, Cluj-Napoca, Romania; [6]University of Florida, Gainesville, FL, USA; [current affiliation] Moffitt Cancer Center, Tampa, FL, USA; [7]Gifu University Hospital, Gifu, Japan; [8]Duke University Medical Center, Durham, NC, USA; [9]Hospital Clinico Universitario San Carlos de Madrid, Madrid, Spain; [10]Mayo Clinic, Phoenix, AZ, USA; [11]Rabin Medical Center-Oncology, Petah Tikva, Israel; [12]University Hospital Carl Gustav Carus, TU Dresden, Dresden, Germany; [13]Institut Gustave Roussy, Université Paris-Saclay, Villejuif, France; [14]Eva Mayr-Stihl Cancer Center, Klinikum Stuttgart, Stuttgart, Germany; [15]Barts Health NHS Trust and the Royal Free NHS Foundation Trust, Barts Cancer Institute, and Queen Mary University of London, London, United Kingdom; [16]Pfizer, Bothell, WA, USA; [17]Astellas Pharma Inc, Northbrook, IL, USA; [18]Merck & Co., Inc., Rahway, NJ, USA; [19]Complejo Hospitalario Universitario Insular-Materno Infantil de Gran Canaria, Las Palmas, Spain

SUMMARY

ADC/immune checkpoint combinations are standard 1st line therapy for UC (M1 and MIBC)

Early immune therapy saves lives in MIBC

Duration of therapy and biomarker development are the next important steps

EVP in perioperative disease is the standard too. Platinum chemotherapy is the next treatment option.

“Enfortumab vedotin and pembrolizumab first, and ask questions later.” is probably where this ends

Courtesy of Thomas Powles, MBBS, MRCP, MD

Select Key Datasets
Bladder-Sparing Approaches

- Mellema JJ et al. Ipilimumab and nivolumab followed by chemoradiotherapy as bladder-sparing treatment in muscle-invasive bladder cancer: A phase 2 trial. *Nat Med* 2026;[Online ahead of print].
- Ghatalia P et al. Circulating tumor DNA (ctDNA) to guide response-adapted bladder preservation in muscle invasive bladder cancer (MIBC): Integrated analysis of the RETAIN trials. Genitourinary Cancers Symposium 2026;Abstract LBA632.

Mellema JJ et al. *Nat Med* 2026;[Online ahead of print].

nature medicine

Article

https://doi.org/10.1038/s41591-026-04271-3

Ipilimumab and nivolumab followed by chemoradiotherapy as bladder-sparing treatment in muscle-invasive bladder cancer: a phase 2 trial

ASCO Genitourinary Cancers Symposium

Abstract LBA632

Circulating tumor DNA (ctDNA) to guide response-adapted bladder preservation in muscle invasive bladder cancer (MIBC): Integrated analysis of the RETAIN trials

Pooja Ghatalia[1], Eric Ross[1], Li Zhang[1], Matthew R. Zibelman[1], Fern Anari[1], Philip Abbosh[1], Cameron Herberts[2], William J Tester[3], Patrick Mille[3], Tracy Rose[4], Suzanne Cole[5], James R. Mark[1], Rosalia Viterbo[1], Erika Jerome[1], Eric M. Horwitz[1], Mark Hallman[1], Andres Correa[1], Marc C. Smaldone[1], Robert Uzzo[1], David Chen[1], Alexander Kutikov[1], Elizabeth R. Plimack[1], Daniel M. Geynisman[1]

[1]*Fox Chase Cancer Center*
[2]Natera, Inc, Austin, TX, USA
[3]*Thomas Jefferson University Hospital*
[4]*University of North Carolina- Chapel Hill*
[5]*UT Southwestern Medical Center*

SUMMARY

Bladder sparing approaches are increasingly important in MIBC

Systemic therapy alone may be enough for some with MIBC

A lot more data is needed

ctDNA is not great at identification of NMIBC post systemic therapy

Courtesy of Thomas Powles, MBBS, MRCP, MD

Year in Review:
Non-Muscle-Invasive and Muscle-Invasive Bladder Cancer

INTRODUCTION: Life After Radical Cystectomy

MODULE 1: Muscle-Invasive Bladder Cancer — Prof Powles

MODULE 2: Non-Muscle-Invasive Bladder Cancer — Dr Kamat

- BCG with immunotherapy
- TAR-200
- Erdafitinib in NMIBC
- Nogapendekin-alfa inbakicept
- ctDNA monitoring for NMIBC

RTP Year in Review 2026

Select Key Datasets
BCG with Immunotherapy

- Shore ND et al. Sasanlimab plus BCG in BCG-naive, high-risk non-muscle invasive bladder cancer: The randomized phase 3 CREST trial. *Nat Med* 2025;31(8):2806-14.
- De Santis M et al. Durvalumab in combination with BCG for BCG-naive, high-risk, non-muscle-invasive bladder cancer (POTOMAC): Final analysis of a randomised, open-label, phase 3 trial. *Lancet* 2025;406(10516):2221-34.
- Rouprêt M et al. ALBAN (GETUG-AFU 37): A phase III, randomized, open-label international trial of intravenous atezolizumab and intravesical bacillus Calmette-Guerin (BCG) versus BCG alone in BCG-naive high-risk, non-muscle-invasive bladder cancer (NMIBC). *Ann Oncol* 2026;37(1):44-52.

Shore ND et al. *Nat Med* 2025;31(8):2806-14.

nature medicine

Article

https://doi.org/10.1038/s41591-025-03738-z

Sasanlimab plus BCG in BCG-naive, high-risk non-muscle invasive bladder cancer: the randomized phase 3 CREST trial

Articles

Durvalumab in combination with BCG for BCG-naive, high-risk, non-muscle-invasive bladder cancer (POTOMAC): final analysis of a randomised, open-label, phase 3 trial

*Maria De Santis, Joan Palou Redorta, Hiroyuki Nishiyama, Michał Krawczyński, Artur Seyitkuliev, Andrey Novikov, Félix Guerrero-Ramos, Ruslan Zukov, Minoru Kato, Takashi Kawahara, Lieven Goeman, Javier Puente, Eva Hellmis, Thomas Powles, Piotr Radziszewski, Kilian M Gust, Paul Vasey, Pierre Bigot, Yves Fradet, Jarmo Hunting, Jon Armstrong, Suliman Boulos, Stephan Hois, Neal D Shore, on behalf of the POTOMAC Investigators**

Lancet 2025;406(10516):2221-34.

Ann Oncol 2026;37(1):44-52.

ESMO GOOD SCIENCE BETTER MEDICINE BEST PRACTICE

ANNALS OF ONCOLOGY DRIVING INNOVATION IN ONCOLOGY

ORIGINAL ARTICLE

ALBAN (GETUG-AFU 37): a phase III, randomized, open-label international trial of intravenous atezolizumab and intravesical Bacillus Calmette—Guérin (BCG) versus BCG alone in BCG-naive high-risk, non-muscle-invasive bladder cancer (NMIBC)☆

M. Roupret[1*], A. Bertaut[2], G. Pignot[3], Y. Neuzillet[4], N. Houede[5], R. Mathieu[6], L. Corbel[7], D. Besson[8], T. Seisen[1], L. Jaffrelot[9], C. Lebacle[10], S. Champiat[11], S. Lebdai[12], M.-O. Timsit[13], C. Thibault[14], L. Goeman[15], Á. Juárez Soto[16], C. La[17], C. Léger[17] & Y. Loriot[18*]

MY PERSPECTIVE

CREST & POTOMAC


Comments and Controversies

Bacillus Calmette-Guérin (BCG) and Beyond: Is Systemic Immunotherapy for BCG-Naïve Non–Muscle-Invasive Bladder Cancer Progress or Overreach?

Ashish M. Kamat, MD, MBBS[1]; Patrick J. Hensley, MD[2]; Brigida A. Maiorano, MD, PhD, MSc[3]; Roger Li, MD[4]; Sarah P. Psutka, MD, MS[5]; Kent W. Mouw, MD, PhD[6]; Amir Horowitz, PhD[7,8]; Shilpa Gupta, MD[9]; and Andrea Necchi, MD[10]

DOI https://doi.org/10.1200/JCO-25-02670

The Expanding Reach of Immunotherapy

ACCOMPANYING CONTENT

Appendix

- Both CREST & POTOMAC are robustly positive Phase 3 trials — HR 0.68 for EFS in the largest BCG-naive HR-NMIBC trial to date (N=1,055)
- The 7.3% - 5.4% absolute EFS improvement at 36 months matters when framed correctly
- The maintenance lesson is now confirmed in two independent Phase 3 trials: BCG maintenance is mandatory for checkpoint inhibition to work — Arm B (induction only, HR 1.16) provides zero benefit and must not be adopted
- The 5-fold increase in grade 3-4 toxicity (29.1% and 21%) with no OS benefit yet demands an honest risk-benefit discussion — we cannot recommend routine adoption until survival data mature
- OS data remain immature — the defining unanswered question across all checkpoint+BCG trials; we are prescribing 2 years of systemic immunotherapy based on DFS alone, and survival benefit must ultimately be demonstrated

Select Key Datasets
TAR-200

- Daneshmand S et al. TAR-200 for bacillus Calmette-Guerin-unresponsive high-risk non-muscle-invasive bladder cancer: Results from the phase IIb SunRISe-1 study. *J Clin Oncol* 2025;43(33):3578-88.
- Jacob JM et al. TAR-200 monotherapy in patients with bacillus Calmette-Guérin-unresponsive high-risk non–muscle-invasive bladder cancer carcinoma in situ: 1-year durability and patient-reported outcomes from SUNRISE-1. AUA 2025.
- Guerrero-Ramos F et al. TAR-200 monotherapy in patients with bacillus Calmette-Guérin–unresponsive papillary disease–only high-risk non–muscle-invasive bladder cancer: First results from cohort 4 of SUNRISE-1. AUA 2025.

J Clin Oncol 2025;43(33):3578-88.

Original Reports | Genitourinary Cancer

TAR-200 for Bacillus Calmette-Guérin–Unresponsive High-Risk Non–Muscle-Invasive Bladder Cancer: Results From the Phase IIb SunRISe-1 Study

Siamak Daneshmand, MD[1]; Michiel S. Van der Heijden, MD, PhD[2]; Joseph M. Jacob, MD[3]; Felix Guerrero-Ramos, MD, PhD[4]; Martin Bögemann, MD[5,6]; Giuseppe Simone, MD, PhD[7]; Christopher M. Pieczonka, MD[8]; Nelson Canales Casco, MD[9]; Daniel Zainfeld, MD[10]; Philipp Spiegelhalder, MD[11]; Evanguelos Xylinas, MD[12]; David Cahn, MD[13]; Yair Lotan, MD[14]; Katie S. Murray, DO[15]; Takashi Kawahara, MD[16]; Katharine Stromberg, PhD[17]; Jason Martin, PhD[18]; Abhijit Shukla, PhD[19]; Christopher J. Cutie, MD[19]; Kristi Bertzos, PhD[20], Shalaka Hampras, PhD, MPH, MBBS[17]; Hussein Sweiti, MD[21]; and Andrea Necchi, MD[22,23]

TAR-200 Monotherapy in Patients With Bacillus Calmette-Guérin–Unresponsive High-Risk Non–Muscle-Invasive Bladder Cancer Carcinoma in Situ: 1-Year Durability and Patient-Reported Outcomes From SunRISe-1

Joseph M Jacob[1], Félix Guerrero-Ramos[2], Andrea Necchi[3], Martin Bögemann[4], Michiel S Van der Heijden[5], Daniel Zainfeld[6], Philipp Spiegelhalder[7], Giuseppe Simone[8], Evanguelos Xylinas[9], David Cahn[10], Yair Lotan[11], Katie S Murray[12], Takashi Kawahara[13], Katharine Stromberg[14], Jason Martin[15], Abhijit Shukla[16], Kristi Bertzos[17], Shalaka Hampras[14], Hussein Sweiti[18], Siamak Daneshmand[19]

[1]Department of Urology, Upstate Medical University, Syracuse, NY, USA; [2]Department of Urology, Hospital Universitario 12 de Octubre, Madrid, Spain; [3]IRCCS San Raffaele Hospital, Vi Salute San Raffaele University, Milan, Italy; [4]Department of Urology, Münster University Hospital, Münster, Germany; [5]Department of Medical Oncology, Netherlands Cancer Institute Amsterdam, Netherlands; [6]Urology San Antonio, San Antonio, TX, USA; [7]Urologie Neandertal, Gemeinschaftspraxis für Urologie, Mettmann, Germany; [8]Department of Urology, 'Regin Elena' National Cancer Institute, Rome, Italy; [9]Department of Urology, Bichat-Claude Bernard Hospital, Assistance Publique-Hôpitaux de Paris, Université de Paris Cité, Paris, France; [10]Colorado Urology, Lakewood, CO, USA; [11]Department of Urology, UT Southwestern Medical Center, Dallas, TX, USA; [12]Department of Urology, NYU Langone Health, New York, NY, U [13]Department of Urology and Renal Transplantation, Yokohama City University Medical Center, Yokohama, Japan; [14]Johnson & Johnson, Raritan, NJ, USA; [15]Johnson & Johnson, High Wycombe, UK; [16]Johnson & Johnson, Lexington, MA, USA; [17]Johnson & Johnson, Horsham, PA, USA; [18]Johnson & Johnson, Spring House, PA, USA; [19]Department of Urology, University Southern California Norris Comprehensive Cancer Center, Los Angeles, CA, USA

Presented by JM Jacob at the 120th AUA Annual Meeting; April 26-29, 2025; Las Vegas, NV, USA

TAR-200 Monotherapy in Patients With Bacillus Calmette-Guérin–Unresponsive Papillary Disease–Only High-Risk Non–Muscle-Invasive Bladder Cancer: First Results From Cohort 4 of SunRISe-1

Félix Guerrero-Ramos[1], Joseph M Jacob[2], Michiel S Van der Heijden[3], Martin Bögemann[4], Siamak Daneshmand[5], Andrea Necchi[6], Daniel Zainfeld[7], Philipp Spiegelhalder[8], Evanguelos Xylinas[9], David Cahn[10], Yair Lotan[11], Katie S Murray[12], Takashi Kawahara[13], Katharine Stromberg[14], Jason Martin[15], Abhijit Shukla[16], Christopher J Cutie[16], Shalaka Hampras[14], Hussein Sweiti[17], Giuseppe Simone[18]

[1]Department of Urology, Hospital Universitario 12 de Octubre, Madrid, Spain; [2]Department of Urology, Upstate Medical University, Syracuse, NY, USA; [3]Department of Medical Oncology, Netherlands Cancer Institute, Amsterdam, Netherlands; [4]Department of Urology, Münster University Hospital, Münster, Germany; [5]Department of Urology, University of Southern California Norris Comprehensive Cancer Center, Los Angeles, CA, USA; [6]IRCCS San Raffaele Hospital, Vita-Salute San Raffaele University, Milan, Italy; [7]Urology San Antonio, San Antonio, TX, USA; [8]Urologie Neandertal, Gemeinschaftspraxis für Urologie, Mettmann, Germany; [9]Department of Urology, Bichat-Claude Bernard Hospital, Assistance Publique-Hôpitaux de Paris, Université de Paris Cité, Paris, France; [10]Colorado Urology, Lakewood, CO, USA; [11]Department of Urology, UT Southwestern Medical Center, Dallas, TX, USA; [12]Department of Urology, NYU Langone Health, New York, NY, USA; [13]Department of Urology and Renal Transplantation, Yokohama City University Medical Center, Yokohama, Japan; [14]Johnson & Johnson, Raritan, NJ, USA; [15]Johnson & Johnson, High Wycombe, UK; [16]Johnson & Johnson, Lexington, MA, USA; [17]Johnson & Johnson, Spring House, PA, USA; [18]Department of Urology, 'Regina Elena' National Cancer Institute, Rome, Italy

Presented by F Guerrero-Ramos at the 120th AUA Annual Meeting; April 26-29, 2025; Las Vegas, NV, USA

MY PERSPECTIVE

TAR-200 (SunRISe-1 C2) — Highest CR Rate to Date in BCG-Unresponsive CIS

- An 82.4% complete response rate in BCG-unresponsive CIS - exceeds every currently approved and investigational option in this setting, achieved without reinduction
  - 25.8-month median DOR and 86.6% cystectomy-free rate at 12 months
- Robust activity in papillary only disease
  - Across the spectrum – Ta and T1
- NO REINDUCTION ALLOWED in SunRISe studies
- Safety is exceptional: grade ≥3 toxicity ~13%, predominantly LUTS-driven and self-limited; no systemic immunotoxicity
- Phase 3 SunRISe-5 will be definitive; pending those results, TAR-200 is already the most promising bladder-preserving option in BCG-unresponsive CIS HR-NMIBC

Select Key Datasets
Erdafitinib in NMIBC

- Daneshmand S et al. Erdafitinib in patients with high- and intermediate-risk non-muscle-invasive bladder cancer: Final analysis of THOR-2 Study. *Eur Urol* 2026;89(2):165-73.

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European Association of Urology

Original Article – Editor's choice

Erdafitinib in Patients with High- and Intermediate-risk Non–muscle-invasive Bladder Cancer: Final Analysis of THOR-2 Study

Siamak Daneshmand[a,*], *Renata Zaucha*[b], *James W.F. Catto*[c], *Ben Tran*[d], *Viraj Master*[e], *Yair Lotan*[f], *Geraldine Pignot*[g], *Andrea Tubaro*[h], *Nobuaki Shimizu*[i], *Nikhil Vasdev*[j,k], *Eugene K. Lee*[l], *Giuseppe Procopio*[m], *Fernando Galanternik*[n], *Lauren Crow*[o], *Kris Deprince*[p], *Vahid Naini*[q], *Spyros Triantos*[r], *Mahadi Baig*[o], *Wei Zhu*[r], *Jodi K. Maranchie*[s]

THOR-2 — Erdafitinib in FGFR-Altered NMIBC

- Proof-of-concept that oral FGFR inhibition can deliver clinically meaningful activity in NMIBC, a first for a systemic agent in this space
- The RFS hazard ratio of 0.28 in Cohort 1 is biologically compelling
- Premature closure due to poor accrual limits interpretation but does not negate the signal
- FGFR molecular testing must become part of routine NMIBC workup
  - 34% detection rate
  - This trial validates precision oncology as a viable and necessary strategy
- A completed randomized trial is required; the premature closure leaves an evidence gap the field must resolve to enable regulatory approval and practice change

Select Key Datasets
Nogapendekin-alfa Inbakicept

- Chang SS et al. Prolonged progression-free survival, disease-free survival, and cystectomy avoidance with IL-15 receptor lymphocyte-stimulating agent NAI plus bacillus Calmette-Guerin in bacillus Calmette-Guerin-unresponsive papillary-only nonmuscle-invasive bladder cancer. *J Urol* 2026;215(1):44-56.

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J Clin Oncol 2025;43(33):3578-88.

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Bladder Cancer

JU Insight

Prolonged Progression-Free Survival, Disease-Free Survival, and Cystectomy Avoidance With IL-15 Receptor Lymphocyte–Stimulating Agent NAI Plus Bacillus Calmette-Guérin in Bacillus Calmette-Guérin–Unresponsive Papillary-Only Nonmuscle-Invasive Bladder Cancer

Sam S. Chang, Karim Chamie, Eugene Kramolowsky, et al.

MY PERSPECTIVE

Nogapendekin + BCG in BCG-Unresponsive Papillary NMIBC — Filling a Critical Gap

- No approved treatments exist for BCG-unresponsive papillary-only HR-NMIBC
- NAI+BCG : 58.2% 12-month DFS rate that is competitive with other investigational approaches
  - The declining DFS curve (58% → 38%, 12 to 36 months) is concerning and expected
- The 92.2% cystectomy-free rate at 12 months and 96% disease-specific survival at 36 months are the numbers that matter most clinically
- Safety is favorable : 61% grade 1-2 TRAEs, only 3% grade 3, no grade 4/5 events; this is a well-tolerated combination that integrates readily into clinical practice
- Single-arm design limits definitive conclusions
  - A randomized trial with an active comparator (intravesical chemotherapy) is needed to establish the incremental value of NAI+BCG over alternatives in this setting

Select Key Datasets
ctDNA Monitoring for NMIBC

- Wang B et al. Real-world experience with a commercial circulating tumor DNA assay in non-muscle-invasive bladder cancer. *Eur Urol Oncol* 2025 August; 8(4):883-7.

EUROPEAN UROLOGY ONCOLOGY 8 (2025) 883–887

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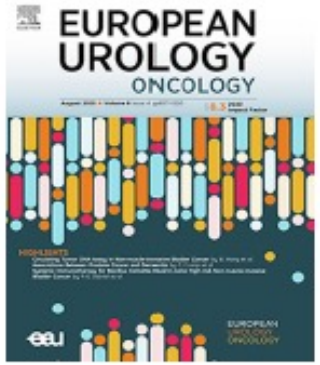

European Association of Urology

Brief Report

Real-World Experience with a Commercial Circulating Tumor DNA Assay in Non–muscle-invasive Bladder Cancer

Betty Wang [a], *Laura E. Davis* [b], *Christopher J. Weight* [a], *Robert Abouassaly* [a], *Laura Bukavina* [a,*]

ctDNA Monitoring in NMIBC - Validation Urgently Needed

- Proof-of-concept :
- Case 19 (occult cT4N1 disease): ctDNA prompted staging that changed treatment from intravesical to systemic
- Case 22 (early T2b detection): demonstrates that ctDNA can identify progression weeks before the next scheduled cystoscopy
- The false-positive case is equally instructive: without clinical correlation and validated cutoffs, ctDNA results can drive unnecessary procedures and profound patient anxiety
- I am enthusiastic about ctDNA in NMIBC but the field is not ready for routine clinical adoption
- We must not over-react to positive signals
    - The community must design prospective trials with pre-specified clinical decision algorithms and patient outcomes as benchmarks - detectability alone is not sufficient to justify routine use

Year in Review: Clinical Investigator Perspectives on the Most Relevant New Datasets and Advances in Oncology

Localized HR-Positive Breast Cancer

A CME/MOC-Accredited Live Webinar

Wednesday, May 6, 2026
5:00 PM – 6:00 PM ET

Faculty

Harold J Burstein, MD, PhD
Joyce O'Shaughnessy, MD

Moderator

Neil Love, MD

RTP Year in Review 2026

Thank you for joining us!

Please take a moment to complete the survey currently up on Zoom. Your feedback is very important to us. The survey will remain open for 5 minutes after the meeting ends.

Information on how to obtain CME, ABIM MOC and ABS credit is provided in the Zoom chat room. Attendees will also receive an email in 1 to 3 business days with these instructions.

RTP Year in Review 2026

APPENDIX

Select Key Datasets
BCG with Mitomycin

- Hayne D et al. Mitomycin plus BCG as adjuvant intravesical therapy for high-risk, non–muscle-invasive bladder cancer: A randomized phase 3 trial (ANZUP 1301). ASCO 2025;Abstract LBA4504.

2025 ASCO ANNUAL MEETING

ANZUP Cancer Trials Group Limited

Mitomycin plus BCG as adjuvant intravesical therapy for high-risk, non-muscle-invasive bladder cancer: a randomised phase 3 trial (ANZUP 1301)

Dickon Hayne [1,3], Alison Y. Zhang [2], Hayley Thomas [2], Stephen P. McCombie [3], Cynthia Hawks [3], Paul Anderson [4], Patricia A. Bastick [5], Emma K. Beardsley [6], William Green [7], Mark Frydenberg [8,9], Jeremy Grummet [9], Joseph Ischia [10], Laurence Krieger [11], Andrew Mitterdorfer [12], Manish Patel [13], Shomik Sengupta [14], Ratnesh Kumar Srivastav [15], Andrew D. Redfern [1,3], Ian D. Davis [14,16], Martin R. Stockler [2] & on behalf of the **Australian and New Zealand Urogenital and Prostate (ANZUP) Cancer Trials Group**

[1] University of Western Australia, Medical School, Perth, Australia; [2] NHMRC Clinical Trials Centre, University of Sydney, Sydney, Australia; [3] Fiona Stanley Hospital, Murdoch, Australia; [4] Royal Melbourne Hospital, Department of Urology, Melbourne, Australia; [5] Southside Cancer Care, Kogarah, Australia; [6] Frankston Hospital, Dept. of Medical Oncology, Frankston, Australia; [7] Nottingham University Hospitals, Dept. of Urology, Nottingham, United Kingdom; [8] Monash Medical Centre, Department of Surgery, Clayton, Australia; [9] Monash University, Melbourne, Australia; [10] University of Melbourne, Austin Health, Heidelberg, Australia; [11] Genesis Care, North Shore, Sydney, Australia; [12] Concord Repatriation General Hospital, Department of Urology, Sydney, Australia; [13] University of Sydney, Sydney, Australia; [14] Monash University, Eastern Health Clinical School, Box Hill, Australia; [15] The Tweed Hospital, Tweed Heads, Australia; [16] Eastern Health, Melbourne, Australia

NHMRC Clinical Trials Centre

MY PERSPECTIVE

BCG + Mitomycin — Negative Primary Endpoint With a Signal Worth Pursuing in Selected Patients

- A negative primary endpoint - BCG+MM does not improve DFS over BCG alone in unselected HR-NMIBC (HR 0.87, p=0.34);
- The subgroup interaction is compelling: in higher-risk patients (all T1 or any CIS), HR is 0.69 with a significant interaction p-value (0.043) - a meaningful signal in the population at greatest risk of progression
- Equally critical: BCG+MM may be inferior in lower-risk HG Ta patients (HR 1.28)
- BCG+MM across all HR-NMIBC is not just unsupported; it could cause harm in the lower-risk group
- My perspective: do not adopt BCG+MM universally; consider it selectively in T1 or CIS disease and where there is BCG shortage