

# TPS912: CONSOLIDATE: Interim Results from a Phase I/II study of radiotherapy combined with enfortumab vedotin (EV) for locally advanced bladder cancer with paired translational ctDNA and utDNA

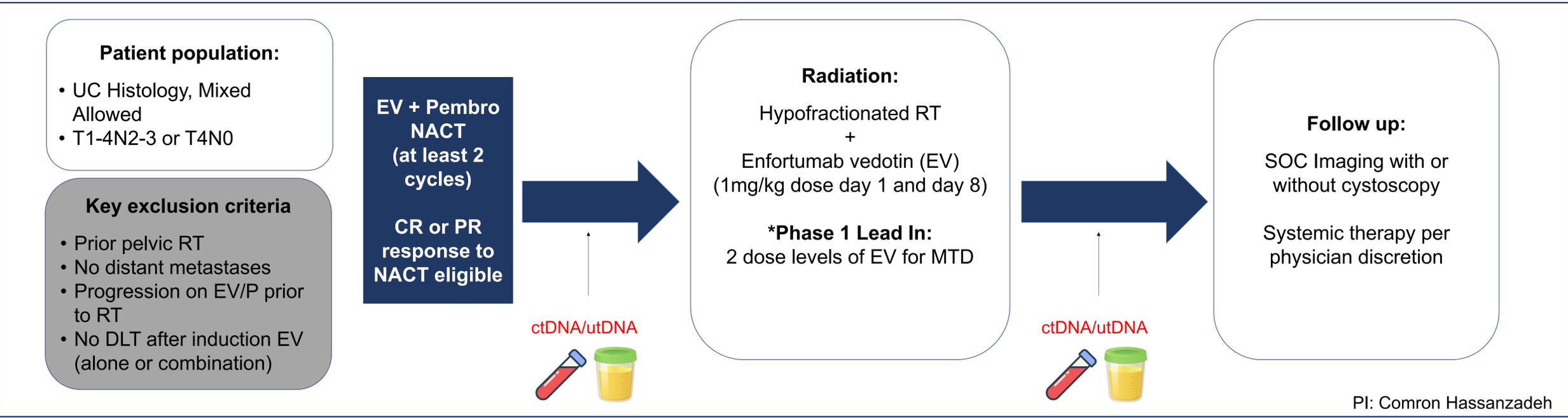
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## BACKGROUND

- Muscle-invasive bladder cancer (MIBC) carries high risks of local recurrence and distant progression.
- Radical cystectomy is standard of care but has high morbidity and quality-of-life implications.<sup>1</sup>
- Trimodality therapy (TMT)—combining TURBT, chemotherapy, and RT—is a bladder-sparing alternative with comparable survival in select patients.<sup>2</sup>
- TMT use is limited due to patient selection challenges and toxicities of radiosensitizing chemotherapy, particularly in older or comorbid patients.<sup>3</sup>
- Enfortumab vedotin (EV), an antibody-drug conjugate targeting Nectin-4, has shown robust efficacy in advanced urothelial carcinoma, even after prior chemotherapy and immunotherapy.<sup>4</sup>
- Combining EV with RT may enhance local control while expanding eligibility for bladder preservation.<sup>1</sup>

## METHODS/STUDY DESIGN



## STUDY OBJECTIVES

- Primary Objective:**
- Estimate progression-free survival (PFS) with EV and concurrent RT in patients with locally advanced MIBC
- Secondary Objectives:**
- Evaluate overall survival (OS) and metastasis-free survival (MFS) at 12 months
  - Assess treatment-related toxicity
  - Measure rates of genitourinary (GU) events (e.g., strictures, hematuria)
- Exploratory Objectives:**
- Identify blood- and urine-based biomarkers predictive of treatment response
  - Evaluate patient-reported outcomes (PROs) including health-related quality of life

## TRIAL STATUS

- **Current Status:** Actively recruiting
- **Target Enrollment:** 41 patients
- **Study Start:** October 2024
- **Primary Completion:** September 2025
- **Estimated Study Completion:** September 2027
- **ClinicalTrials.gov Identifier:** NCT06434350

## ACKNOWLEDGEMENTS

We sincerely thank the patients and families participating in the CONSOLIDATE trial. We also recognize the invaluable contributions of the clinical research teams, radiation oncology staff, collaborating institutions, and Myriad Genetics for their support of this study.

## EXPECTED OUTCOMES

We are currently in phase I component with interim analysis pending.

**We hypothesize that concurrent EV and RT will:**

- Improve local disease control and PFS
- Serve as a viable bladder-preserving alternative
- Identify biomarkers predictive of treatment response

## CONTACT INFORMATION

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