

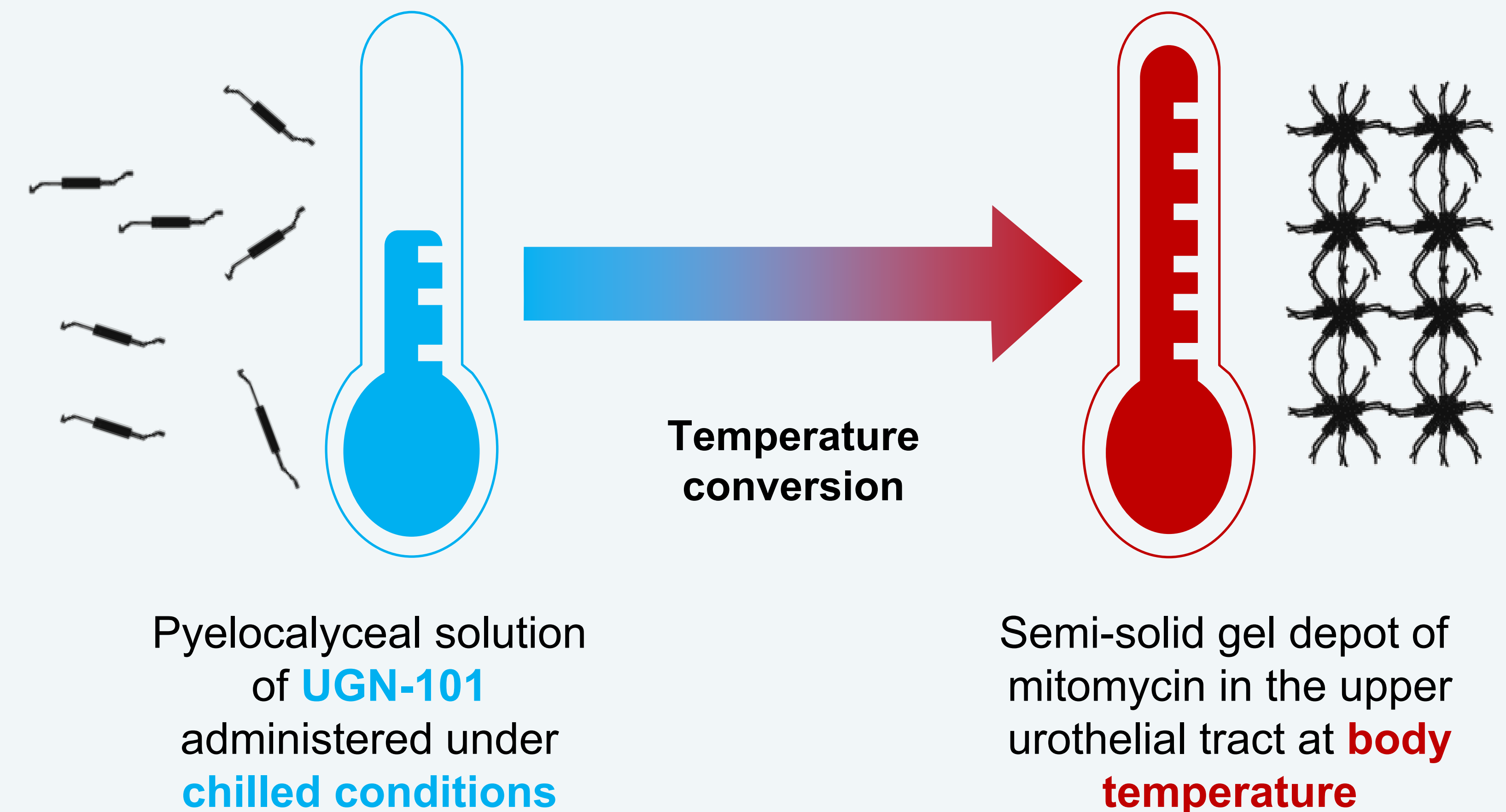
Adam S. Feldman^{1,2}, Yair Lotan³, Soloman Woldu³, Mehrad Adibi⁴, Marc A. Bjurlin⁵, Eliza DeFroda⁶, Rian J. Dickstein⁷, Khurshid R. Ghani⁸, David Hoenig⁹, Joseph M. Jacob¹⁰, Hristos Z. Kaimakliotis¹¹, Jennifer Linehan¹², Joshua J. Meeks¹³, Katie Murray^{14*}, Nirmish Singla¹⁵, Karthik Tanneru¹⁶, Hetal Pandya¹⁷, Nikky Ugwuoke¹⁷, Brent Burger¹⁷, Michael J. Louie¹⁷; on behalf of the uTRACT Registry Study Group

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BACKGROUND

- Upper tract urothelial carcinoma (UTUC) affects 2 in 100,000 people in the US annually, with peak incidence in patients aged 70–90 years¹⁻³
- Low-grade (LG) UTUC represents 40% of the total disease burden³
- Endoscopically guided ablation is often used to treat LG-UTUC; however, recurrence is common, and the long-term surveillance risks potential complications in this elderly patient population
- UGN-101** is FDA approved for the treatment of adult patients with LG-UTUC
- UGN-101** is a reverse thermal hydrogel containing mitomycin administered as a liquid in a chilled state, which converts to a gel depot at body temperature, resulting in a dwell time of 4–6 hours (**Figure 1**)
- In the phase 3 OLYMPUS trial, 71 LG-UTUC patients were treated with **UGN-101**.⁴ 41 out of 71 had a complete response (CR) at 3 months and were included in a long-term Kaplan-Meier analysis, with a median follow-up of 28.1 months (95% CI 13.1, 57.5), and median duration of response (DoR) of 47.8 months (95% CI 13.0, not estimable).⁵ Twenty patients had additional long-term follow-up (median 53.3 months [95% CI, 27.9, 65.3]), with the median duration of response not estimable due to the low event rate⁵
- The uTRACT registry (NCT05874921) is evaluating real-world data from patients administered **UGN-101**, with data collected retrospectively and prospectively

FIGURE 1. UGN-101 FORMS A SEMI-SOLID GEL DEPOT FOLLOWING INSTILLATION



Enrollment target: N=400
Including retrospective and prospective data collection

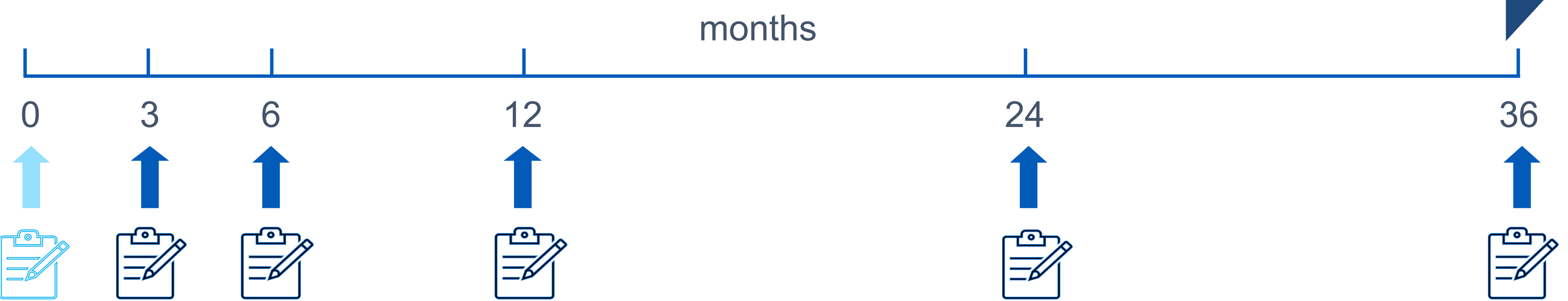
Key inclusion criteria

Patients aged >18 years old with UTUC who receive ≥1 dose of **UGN-101**

Retrospective data capture

3 years of follow-up from first dose

3 years of follow-up



First dose of **UGN-101**

DATA COLLECTION

- Participant history and disease status will be collected at baseline (**prior to UGN-101 dosing**), and dosing information, surveillance endoscopy, and imaging results will be captured over a period of 3 years
- Assessment of response will be based on investigator's assessment of no evidence of disease
- Data analysis will be performed on the overall cohort (~400 participants) and the LG-UTUC cohort (expected ~340 participants)
- Outcomes collected will include no evidence of disease at 3 months, DoR, recurrence-free survival, time to recurrence/progression, and adverse events

References

- Siegel RL, et al. CA Cancer J Clin. 2022;72:7-33. 2. Roupriet M, et al. Eur Urol. 2023;84:49-64. 3. Raman J, Shore ND. Rev Urol. 2020;22:1-8. 4. Kleinmann N, et al. Lancet Oncol. 2020;21:776-85. 5. Pierorazio PM, et al. J Urol. 2025;213:313-22.

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As of May 2025

- 22 sites are participating from across the US
- 274 patients have been recruited to date

For more information

- Email: registry@urogen.com