



## **AdvanCell Showcases Novel TheraPb Phase 2 Study Design of ADVC001 for the Treatment of Metastatic Prostate Cancer at ASCO GU Symposium 2026**

*-- The trial uses a response-driven dosing strategy and extended treatment across three prostate cancer populations, supported by the favorable clinical, pharmacokinetic and dosimetry results from Phase 1b --*

**Brisbane, Australia and Boston, USA** – February 24, 2026 – AdvanCell, a clinical-stage radiopharmaceutical company developing innovative targeted alpha therapies for cancer, today announced the novel Phase 2 design of the ongoing TheraPb clinical trial of ADVC001 in metastatic prostate cancer. ADVC001 is an investigational Lead-212-based prostate-specific membrane antigen (PSMA)-targeted alpha therapy. The study design will be showcased in a ‘Trials in Progress’ poster this week at the American Society of Clinical Oncology Genitourinary Cancers Symposium (ASCO GU 2026) in San Francisco, CA.

The TheraPb Phase 2 is an open-label, randomized expansion study incorporating dose optimization strategies in three groups of patients with metastatic hormone-sensitive (mHSPC) and castration-resistant prostate cancer (mCRPC). The study’s innovative design is supported by the [Phase 1b dose escalation results](#), which showed encouraging safety and promising anti-tumor activity of ADVC001. At the recommended Phase 2 dose, 80% of patients achieved a 50% reduction in prostate-specific antigen (PSA50), and a 100% overall response rate was observed in patients with evaluable tumors, while no dose-limiting toxicities and no toxicity-related treatment discontinuations or dose modifications were observed. ADVC001 exhibited rapid and high tumor uptake, fast renal clearance, and low normal-organ radiation exposure.

“The Phase 2 TheraPb trial employs a novel dosing strategy that incorporates more frequent up-front treatment leveraging the half-life of Lead-212, as well as taking into account patient-specific responses,” **commented Thomas Hope, MD, Vice Chair Clinical Operations and Strategy, Department of Radiology and Biomedical Imaging, University of California San Francisco.** “This approach is the first in the next generation of radioligand therapy trials that goes beyond standard dosing strategies in order to improve patient outcomes.”

“ADVC001 is a promising alpha PSMA-directed theranostic treatment that uses an innovative payload of Lead-212.” **commented Michael J. Morris, MD, Prostate Cancer Section Head, Genitourinary Oncology, Memorial Sloan Kettering Cancer Center.** “The study examines the merits of a treatment intensification strategy, adaptive dosing, and application across multiple clinical settings under the auspices of a novel study design intended to facilitate efficient development.”

“The TheraPb Phase 2 incorporates dose optimization strategies designed to improve patient outcomes in three distinct prostate cancer populations across the disease continuum, with high unmet medical need.” **said Anna Karmann, MD PhD, Chief Medical Officer at AdvanCell.** “To maximize clinical benefit and minimize toxicity, we are investigating novel dosing regimens aiming to optimize timing and duration of treatment. Encouraged by the favorable safety and tolerability results of ADVC001 in Phase 1b, the study also includes evaluation of extended treatment in participants who demonstrate ongoing benefit.”



The TheraPb Phase 2 expansion is designed to optimize ADVC001 development opportunities. Participants with mHSPC (suboptimal responders), mCRPC (pre-chemotherapy) and mCRPC (post-177Lu-PSMA) are randomized to either 160 or 200 MBq of ADVC001 and receive up to 4 doses of ADVC001 during a dose-intense induction. Additional doses may be administered as maintenance treatment for a total of up to 12 doses, allowing for a treatment pause ('treatment holiday') based on individual response.

The TheraPb Phase 2 trial ([NCT05720130](https://clinicaltrials.gov/ct2/show/study/NCT05720130)) is open at clinical sites in Australia, with planned expansion to additional sites in the United States.

### **Trials in Progress Poster at ASCO GU 2026**

- **Presentation Title:** Phase 2 Expansion Study of 212Pb-ADVC001 in Metastatic Prostate Cancer: The TheraPb Trial
- **Presenter:** Professor Aaron Hansen, Princess Alexandra Hospital, Brisbane, Australia
- **Abstract Number:** TPS280, Board N16
- **Session:** Trials in Progress Poster Session A: Prostate Cancer
- **Date and Time:** 26-February - 11:30 AM – 12:45 PM and 5:45 PM – 6:45 PM Pacific Time

The presentation will be available on AdvanCell's website at [www.advancell.com.au/presentations-publications](http://www.advancell.com.au/presentations-publications).

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### **About 212Pb-ADVC001**

212Pb-ADVC001 (ADVC001) is a proprietary and patented PSMA-targeting radioligand with optimized physicochemical properties and labelled with Lead-212 (212Pb), an alpha-emitting payload (radionuclide) with a high dose rate, 10.6-hour half-life and simple decay scheme. ADVC001 is designed to deliver radiation at a cellular level to effectively kill prostate cancer cells while minimizing toxicity.

### **About the TheraPb trial**

The TheraPb trial ([NCT05720130](https://clinicaltrials.gov/ct2/show/study/NCT05720130)) is a prospective, open-label Phase 1/2 dose escalation and expansion study evaluating ADVC001 in metastatic prostate cancer. The completed Phase 1b dose escalation assessed the safety and tolerability of escalating doses of ADVC001 administered every 6, 4, 2 or 1 week(s) ([see press release](#)). The Phase 2 expansion is assessing the efficacy and safety of ADVC001 at two dose levels. The trial utilizes a randomized dose-response design and dose optimization elements to evaluate ADVC001 in PSMA-positive mCRPC and in mHSPC.

### **About AdvanCell**

AdvanCell is a vertically integrated, clinical-stage radiopharmaceutical company dedicated to developing innovative cancer therapies that harness the power of targeted alpha-emitting radionuclides. By leveraging its proprietary Lead-212 platform, advanced and scalable manufacturing and world-class clinical development capabilities, AdvanCell aims to deliver novel treatments that improve outcomes for patients with cancer globally. For more information, visit [www.advancell.com.au](http://www.advancell.com.au) and follow us on [LinkedIn](#).

MSK disclosure: Dr. Morris has financial interests related to AdvanCell.



**Contacts**

Anna Karmann, CMO

[contact@advancell.com.au](mailto:contact@advancell.com.au)

**For media inquiries, please contact:**

MEDiSTRAVA (in the UK)

[advancell@medistrava.com](mailto:advancell@medistrava.com)

+44 (0)20 3928 6700