

# AKY-2519

# Clinical Development Strategy

May 5, 2026

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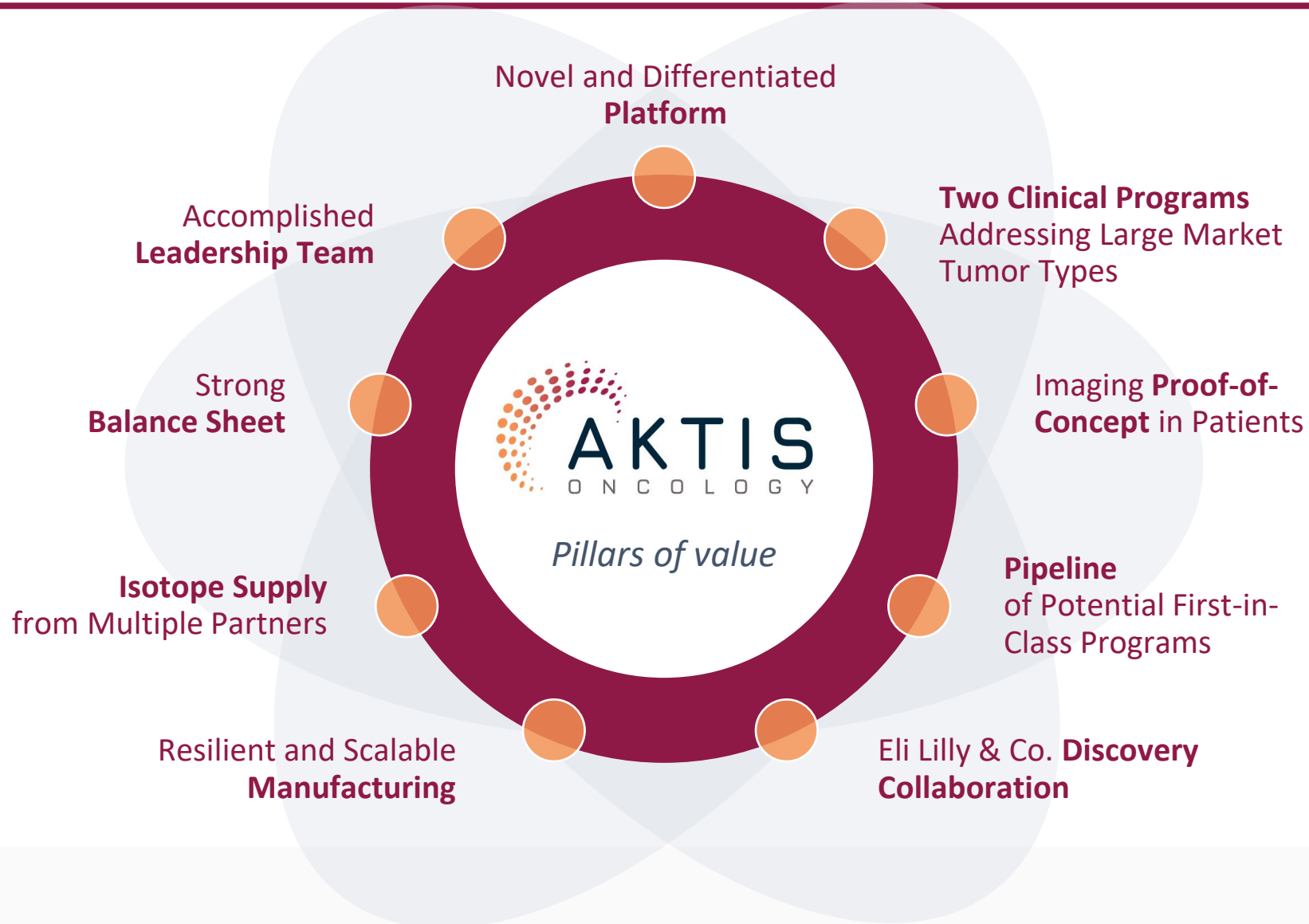
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# Agenda


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- **Aktis Corporate Overview**
- **B7-H3 Overview & Broad, Differentiated Opportunity**
- **AKY-2519 Clinical Development Strategy**
- **Next Steps & Upcoming Milestones**

# Maximizing the impact of radiopharmaceuticals



# Aktis is advancing a novel pipeline for large patient populations

PROGRAM	TARGET/INDICATION	DISCOVERY	IND-ENABLING	PHASE 1b	PHASE 2/3	UPCOMING MILESTONES
<b>AKY-1189</b>	Nectin-4 expressing solid tumors	Fast Track Designation*				Ph1b ongoing Prelim data in 1Q'27
<b>AKY-2519</b>	B7-H3 expressing mCRPC					Imaging/ dosimetry data at ASCO 2026 Ph1b initiated; Prelim data in 2027
	B7-H3 expressing lung, colorectal, and other solid tumors					Imaging/ dosimetry data at ASCO 2026 Ph1b start 2H'26
<b>Multiple Programs</b>	Undisclosed					
 <b>Lilly</b> A MEDICINE COMPANY	Undisclosed					

# **B7-H3 Overview and AKY-2519 Clinical Development Strategy**

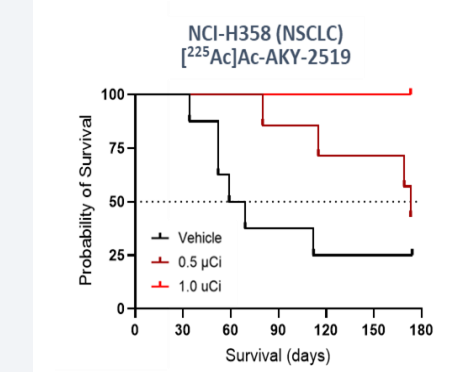
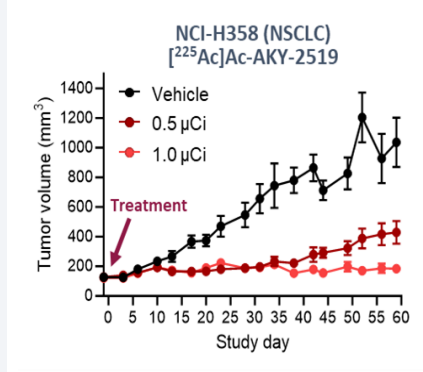
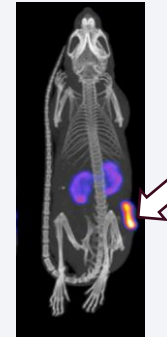
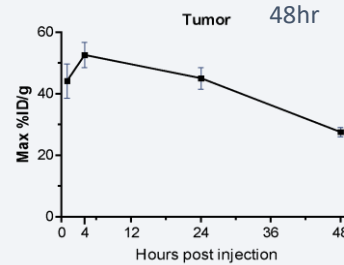
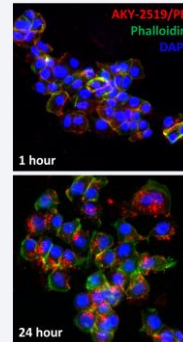
# Broad clinical development strategy for AKY-2519

- **Opportunity for broad clinical development of AKY-2519, a miniprotein radioconjugate targeting B7-H3 expressing solid tumors**
- **Two-trial clinical development strategy enables evaluation of AKY-2519 in multiple patient subsets to efficiently generate indication-relevant data for actionable, data-driven decision-making**
  - Phase 1b trial for metastatic castration-resistant prostate cancer (mCRPC) initiated: Announced yesterday
  - Phase 1b basket trial for lung, colorectal, and other solid tumor cancers initiation: Expected 2H'26
- **Strategy informed by insights from clinical advisory boards and reflects the distinct treatment patterns and clinical needs of patients with mCRPC compared to other solid tumor patients**

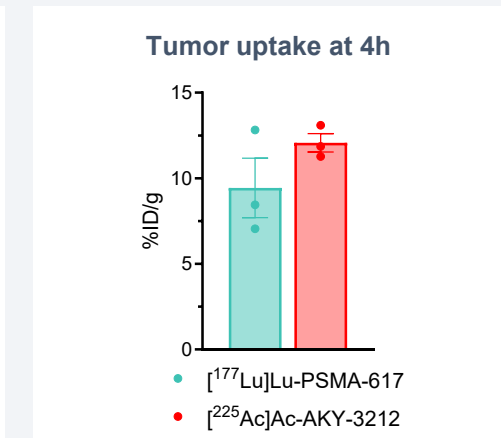
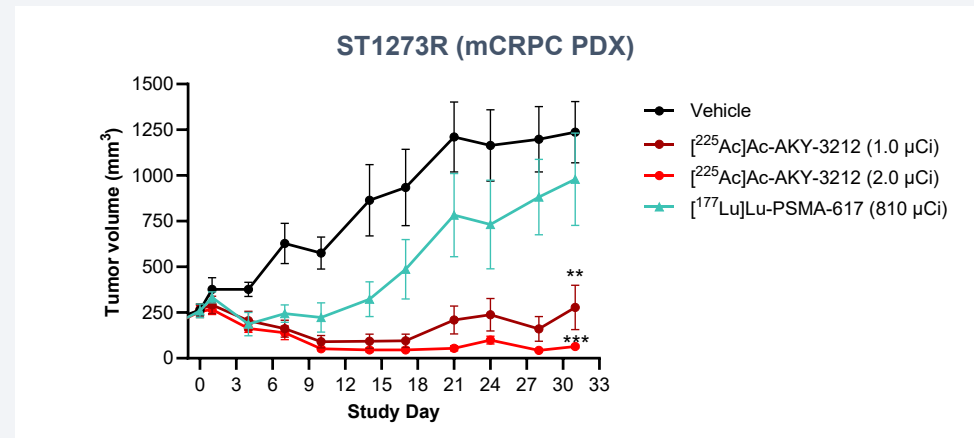


# Summarizing AKY-2519 (B7-H3) development to date

Generated from Aktis' platform, AKY-2519 (B7-H3) has demonstrated promising *in vivo* results including survival benefit



AKY-2519 tool compound, AKY-3212, has shown superior efficacy compared to PSMA-617 in an mCRPC mouse model



# Clinical imaging and dosimetry data for AKY-2519 to be presented at the 2026 ASCO Annual Meeting

Data at ASCO will highlight biodistribution and uptake of AKY-2519 in tumors and normal tissue in patients with mCRPC and other solid tumors

**AKY-2519, a novel B7-H3-targeted radioconjugate, and its biodistribution profile in patients with mCRPC\***

Date and Time: May 30, 1:30 p.m. - 4:30 p.m. CDT

**First-in-human PET/CT imaging with <sup>68</sup>Ga-AKY-2519, a B7-H3 targeted miniprotein radioconjugate, to demonstrate tumor uptake and normal tissue exposure across various advanced solid tumors\*\***

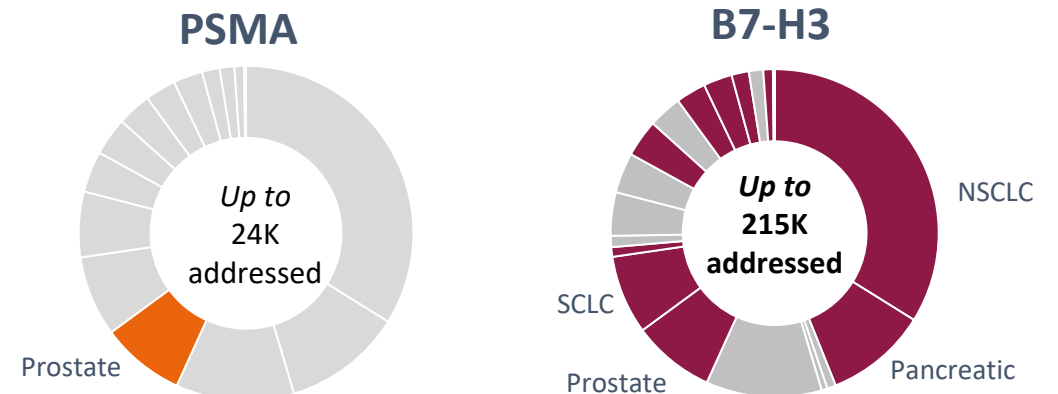
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# Significant opportunity for B7-H3 as a differentiated radiopharmaceutical target in mCRPC and other indications

- PLUVICTO® estimated global peak sales ~\$5.4 billion in prostate cancer alone<sup>1</sup>
- Persistent unmet needs remain due to:
  - PSMA downregulation or PSMA-low expression
  - Aggressive/ poorly differentiated cancer with PSMA expression loss
  - PSMA expression in the salivary glands
- **90% of mCRPC patients express B7-H3**
  - Low expression in normal tissues, including salivary glands
- **B7-H3 targeting RLT has the potential for differentiated biodistribution compared to PSMA-targeted therapies**

**B7-H3 is highly expressed in multiple solid tumors; Potential to unlock whitespace opportunities**

Indication	Metastatic incidence in US <sup>2</sup>	Initial Positioning	B7-H3 expression positive <sup>3</sup>
<b>Prostate cancer</b>	<b>~23.9k</b>	<b>2L+</b>	<b>90%</b>
NSCLC	~99.7k	2L+	80%
SCLC	~22.9k	2L+	70%



# Anticipated advantages of a dedicated mCRPC clinical trial protocol



**Radiopharmaceuticals are a key treatment modality for prostate cancer**



**Significant enthusiasm among prostate cancer investigators for early AKY-2519 data**

- **Utilizes prostate cancer-specific RLT centers**
- **Enables mCRPC-targeted dose finding and expansion as well as characterization of B7-H3 expression vs. PSMA expression**
- **Enables generation of data in both PLUVICTO-naïve and PLUVICTO-experienced patients to inform sequencing decisions**

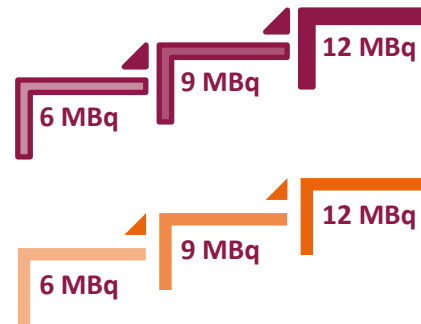


**Efficient generation of indication-relevant data**

# mCRPC-dedicated Phase 1b trial designed to rapidly generate data in PLUVICTO-naïve and -experienced patients

## AKY-2519-01 Trial design

### Dose escalation: BOIN



### Backfill (n≈30/cohort; escalation pts included)

**THERAPY**  
Backfill Dose 1 PLUVICTO-naïve  
[<sup>225</sup>Ac]Ac-AKY-2519

**THERAPY**  
Backfill Dose 2 PLUVICTO-naïve  
[<sup>225</sup>Ac]Ac-AKY-2519

**THERAPY**  
Backfill Dose 1 PLUVICTO-experienced  
[<sup>225</sup>Ac]Ac-AKY-2519

**THERAPY**  
Backfill Dose 2 PLUVICTO-experienced  
[<sup>225</sup>Ac]Ac-AKY-2519

Dose levels for backfill may be different based on cohort

All patients entering the study will have demonstrated tumor uptake following imaging with [<sup>64</sup>Cu]Cu-AKY-2519

# Positioning AKY-2519 to demonstrate its broad potential to address unmet patient needs



## Multiple tumor types

- B7-H3 highly expressed in multiple solid tumors across large patient populations
- Represent whitespace opportunities in radiopharmaceuticals



## Two focused trials

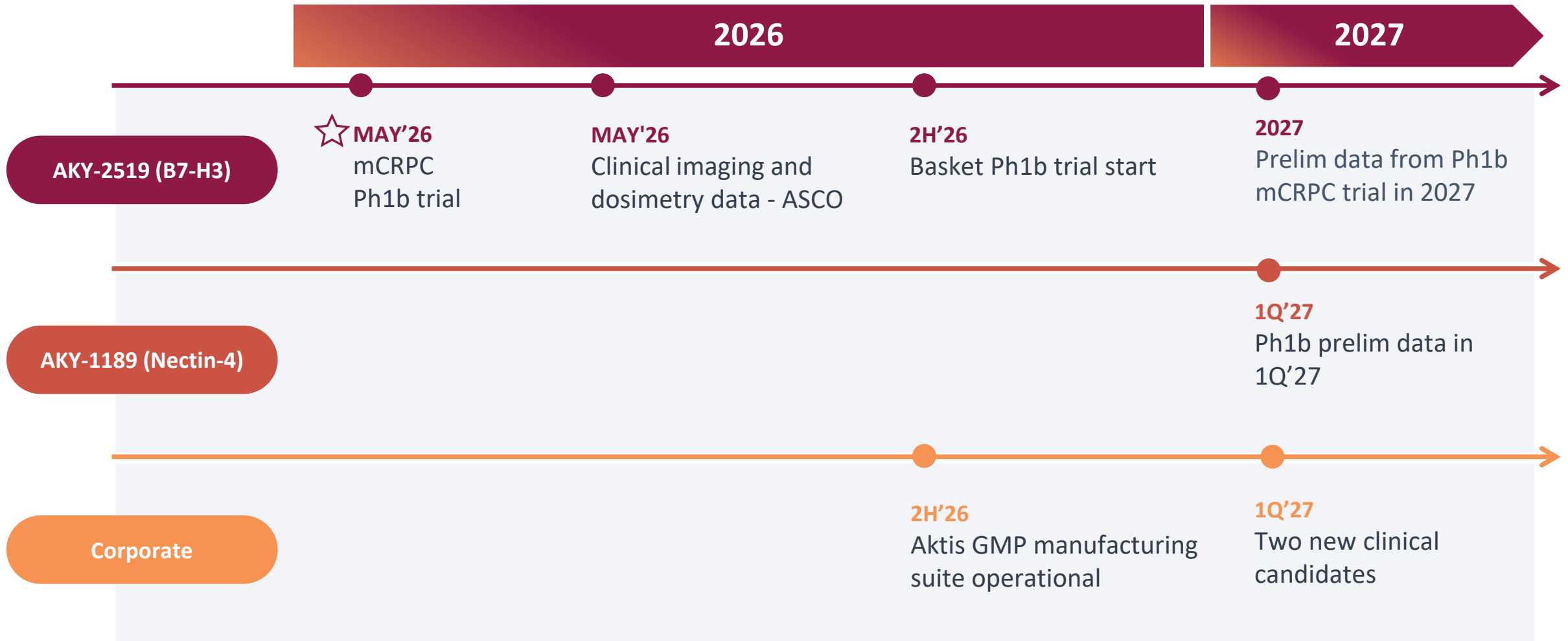
- Initiated mCRPC-dedicated Ph1b trial in PLUVICTO-naïve and -experienced patients
- Expect to start Ph1b basket trial in 2H'26



## Rapid data generation

- Preliminary data from Ph1b mCRPC trial expected in 2027

# Multiple anticipated catalysts over the next 12 months





**Thank You**