

# A Phase I Study of JSB462 (Luxdegalutamide) in Japanese Patients With Metastatic Prostate Cancer

NCT07174063

Status	RECRUITING
Phase	Phase 1
Sponsor	Novartis Pharmaceuticals
Enrollment	15 participants

## Plain Language Summary

This phase I study is testing a drug called JSB462 (luxdegalutamide) — a new type of androgen receptor degrader — in Japanese men with metastatic prostate cancer who have progressed on standard hormone therapy. The study is checking safety and finding the right dose.

**\*\*You may be eligible if...\*\***

- You are a man with confirmed prostate cancer that has spread to bones or other organs (not just lymph nodes)
- Your prostate cancer has failed or is not eligible for standard hormone treatments
- Your testosterone levels are at castrate levels (very low, as achieved by hormone therapy or surgical removal of testes)
- You are in good physical condition (ECOG 0–1)

**\*\*You may NOT be eligible if...\*\***

- Your prostate cancer has spread to the brain
- You have another active cancer
- You have had a prior cancer that might recur or interfere

Talk to your doctor to see if this trial is right for you.

## Key Eligibility Criteria

### Inclusion (5)

- Adult male patients with histologically or cytologically confirmed and documented adenocarcinoma of the prostate.
- At least 1 bone or visceral metastatic lesion (according to local radiology assessment by the investigator) present on baseline CT, MRI, or bone scan imaging obtained d28 days prior to enrollment. Lymph nodes as only site of metastases are not allowed.
- Patients with prostate cancer must have failed or refused available standard therapies, be intolerant or ineligible to receive such therapy, or for whom no standard therapy exists.
- Patients must have a castrate level of serum/plasma testosterone ( $<50$  ng/dL or  $<1.7$  nmol/L). Ongoing ADT (as defined by prior orchiectomy and/or ongoing GnRH analog/antagonist) is allowed prior to enrollment.
- Patients with an Eastern Cooperative Oncology Group (ECOG) Performance Status (PS) d 1.

### Exclusion (2)

- Patients with CNS metastases.
- Patients with any other active malignancy other than prostate cancer. Exceptions to this criterion include the following: malignancies that were treated curatively at least 3 years before starting study treatment which have not recurred; basal cell carcinoma of the skin or squamous cell carcinoma of the skin that has undergone potentially curative local therapy or other tumors that will not affect life expectancy.

## Locations (4 total)

Novartis Investigative Site, Nagoya, Aichi-ken, Japan  
[Novartis Investigative Site, Bunkyo-ku, Tokyo, Japan](#)  
[Novartis Investigative Site, Koto-ku, Tokyo, Japan](#)

DISCLAIMER: This study is for informational purposes only and does not constitute medical advice. Always consult your healthcare provider before enrolling in any clinical trial. Information may not be up to date — verify details at [ClinicalTrials.gov](https://clinicaltrials.gov). Generated by [ClinicalTrialsFinder.org](https://clinicaltrialsfinder.org).

... and 1 more locations

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