Clinical Study Proposal

pasritamig (JNJ-78278343) in prostate cancer Study Proposal

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Proposal Overview

Drug:
pasritamig (JNJ-78278343) **Indication:**
prostate cancer
Strategic Goals:
accelerate uptake
Geography:
US, EU
Concept Count:
3 study concepts

Generated Study Concepts

Concept 1: PAS-PSMA-RESCUE: Pasritamig versus Physician’s Choice After PSMA-RLT Failure in mCRPC

Study Phase:
Phase III

PICO Framework

Population:
n=92 patients with metastatic castration-resistant prostate cancer (mCRPC) (mCRPC patients progressing <6 months after completion of 177Lu-PSMA-617 (Pluvicto®) or equivalent PSMA-radioligand therapy). 400 men with mCRPC within 6 months post-PSMA-RLT progression, prior ARPI & taxane allowed.

Intervention:
Pasritamig 80 µg/kg IV weekly (outpatient) with step-up first dose.

Comparator:
Physician’s choice SOC (cabazitaxel, docetaxel, PARP-i, platinum).

Outcomes:
Primary: rPFS (BICR). Secondary: OS, PSA50, time-to-symptomatic skeletal events, QoL (FACT-P), safety.

Feasibility Analysis

Concept 2: PAS-INTENSE: Pasritamig + Enzalutamide as First-Line Intensification in mCSPC

Study Phase:
Phase II

PICO Framework

Population:
n=92 patients with metastatic castration-sensitive prostate cancer (mCSPC) (De novo high-volume mCSPC (CHAARTED criteria) with high KLK2 serum levels). 250 men with de novo high-volume mCSPC, KLK2 "e1.5 ng/mL, no prior systemic therapy.

Intervention:
Pasritamig weekly + Enzalutamide 160 mg daily + ADT.

Comparator:
Enzalutamide 160 mg daily + ADT.

Outcomes:
Primary: Proportion with undetectable PSA (<0.2 ng/mL) at 12 m. Secondary: rPFS, OS @36 m, depth of KLK2 decline, safety, QoL.

Feasibility Analysis

Concept 3: NEO-KLK2: Neoadjuvant Pasritamig to Eradicate Minimal Residual Disease in High-Risk Localized Prostate Cancer

Study Phase:
Phase Ib/II

PICO Framework

Population:
n=92 patients with high-risk localized prostate cancer undergoing radical prostatectomy (Gleason "e8, PSA "e20 ng/mL, cT3a/b, KLK2-high tumors scheduled for surgery). 120 men with high-risk localized PCa, KLK2 IHC "e2+, fit for radical prostatectomy.

Intervention:
Pasritamig 80 µg/kg Day-1 & Day-8 pre-surgery + optional 4 postoperative doses.

Comparator:
Control arm observation then surgery (1:1 randomization).

Outcomes:
Primary: pCR/"dypT2N0 rate. Secondary: residual tumor volume, immune infiltration score, 2-yr biochemical recurrence-free survival, safety.

Feasibility Analysis

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