NEW CLINICAL TRIAL OPEN FOR INCLUSION

PROTOCOL TITLE

A Phase 3 Randomized, Double-blind, Placebo-controlled Study of Pasritamig (JNJ-78278343), a T-cell-redirecting Agent Targeting Human Kallikrein 2, + Best Supportive Care Versus Best Supportive Care for Metastatic Castration-resistant Prostate Cancer

ALIAS	CTO NUMBER	SPONSOR
KLK2-comPAS	CTO24079JNJ	Janssen

KEY INCLUSION AND EXCLUSION CRITERIA

- Histologically confirmed adenocarcinoma of the prostate.
- mCRPC: Disease that is metastatic either to bone, any lymph node, or both. No visceral disease allowed.
- PSA ≥2 ng/mL at screening
- Prior treatment specifications include receipt of the following:
  - At least 1 ARPI
  - At least 2 previous taxane-based regimens (if only 1, unsuitable for second taxane)
  - At least 1 dose of PSMA-targeted lutetium radioligand therapy (unless not clinically indicated or patient unsuitable)
  - PARPi (if the participant has a known germline or somatic BRCA mutation)

DESIGN

KEY ELIGIBILITY CRITERIA

- Progressive disease after ARPI, 2 prior taxane regimens, PARPi (for BRCA 1/2 +), and PSMA-targeted lutetium radioligand therapy (if eligible/available)
- No visceral disease

RANDOMIZATION [2:1; N~663]

ARM 1 [N~442] — Pasritamig + BSC (IV)

ARM 2 [N~221] — PLACEBO + BSC (IV)

Primary Endpoint

OS

Key Secondary Endpoints

- rPFS
- Time to skeletal related event
- Time to symptomatic progression
- PFS (clinical and unconfirmed rPFS)

- **Permitted BSC = radiation, ADT, low dose steroids (<10 mg prednisone or equivalent), bone agents, pain medications, needed palliative procedures at investigator discretion**
- Other systemic anti-cancer therapy not allowed as BSC

PRINCIPAL INVESTIGATOR

Dr Tom Van den Mooter
tom.vandenmooter@zas.be

STUDY COORDINATOR(S)

Kathleen Traets
kathleen.traets@zas.be

Tine Loeman
tine.loeman@zas.be