AOU Città della Salute e della Scienza di Torino – PO Molinette

Titolo:	PASenger. A Phase 3 Randomized, Open-label Study of Pasritamig (JNJ-78278343), a T-cell-redirecting Agent Targeting Human Kallikrein 2, With Docetaxel Versus Docetaxel for Metastatic Castration-resistant Prostate Cancer
Patologia:	Metastatic Castration-resistant Prostate Cancer
Tipo di Studio:	Interventional, randomized, open-label
Fase:	Phase II
Principali criteri di inclusione:	-Histologically confirmed adenocarcinoma of the prostate. -Have disease that is metastatic at the time of the screening as determined by the investigator. -Have progressive disease defined as at least one of the following: PSA level ≥2 ng/mL that has increased on at least 2 successive occasions at least 1 week apart. - Progressive disease or new lesion(s) in the lymph nodes, bones, or viscera as defined by RECIST v1.1 and/or in bone scan per PCWG3 while on medical or surgical castration -Participants must receive ongoing ADT -Have progressed on at least 1 novel ARPI but received no more than 2 different ARPI -Have an ECOG performance status of 0 to 1
Principali criteri di esclusione:	-Known history of either brain or leptomeningeal prostate cancer metastases. -Patients with known BRCA 1/2 mutations (germline or somatic) who have not received treatment with a PARP inhibitor, unless not available or contraindicated. -Suspected or known allergies, hypersensitivity, or intolerance to pasritamig excipients (refer to the pasritamig IB and Addenda) or docetaxel excipients (Taxotere PI). -Not recovered from recent surgery. -Solid organ or bone marrow transplantation. - Active autoimmune disease within the 12 months prior to signing consent that requires systemic immunosuppressive medications (eg, chronic corticosteroid, methotrexate, or tacrolimus). Prior or concurrent second malignancy Received cytotoxic chemotherapy for prostate cancer in any setting

	Received prior treatment for prostate cancer with: CD3 redirector therapies or Radiopharmaceutical agents or Immunotherapy agents for prostate cancer (eg, sipuleucel-T, PD-1 inhibitors, T-cell redirectors, costimulatory agents, etc) or PARP inhibitors (other than for BRCA1/2 mutation) or Any other investigational agent for the treatment of mCRPC.
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