



Clinical Trial for Androgen-Independent Prostate Cancer

Novacea ASCENT-2

A Phase III, Randomized, Open-Label Study Evaluating DN-101 in Combination with Docetaxel in Androgen-Independent Prostate Cancer (AIPC)

Inclusion Criteria

- Patient must be ≥ 18 years old; Signed Informed Consent
- Histologically or cytologically proven adenocarcinoma of the prostate
- Metastatic prostate adenocarcinoma documented by CT, MRI, or bone scan
- Prior therapy by androgen ablation either by orchiectomy and/or LHRH agonists or antagonists. If using LHRH agonists or antagonists, therapy must be continued
- Subjects receiving the following treatments are eligible
 - Anti androgens
 - Monotherapy with estramurine
 - Prior therapy with corticosteroids and/or ketoconazole
 - Other hormonal agents for therapy of prostate cancer
 - Bisphosphonate treatment
- Prior radiation therapy is allowed (exclude whole pelvic irradiation, to less than 25% of the bone marrow only) is allowed if at least 4 weeks have elapsed since completion of therapy
- Prior surgery is allowed if at least 4 weeks have elapsed since completion of the surgery
- Maintaining castrate status (for those not having surgical orchiectomy); for those subjects receiving anti-androgen as part of 1st line hormonal therapy must have shown progression of disease of the anti-androgen prior to enrollment
- Documented progression while on androgen ablation therapy
- Life expectancy ≥ 3 months
- Willing to discontinue prohibited concomitant medications or diet supplements
- ECOG performance status 0, 1, or 2

Inclusion criteria (cont.); Laboratory Requirements:

- Hematology:
 - $ANC \geq 1.5 \times 10^9/L$
 - Hemoglobin ≥ 10 g/dL
 - Platelets $\geq 100 \times 10^9/L$
 - Hepatic Function:
 - Total bilirubin $< ULN$
 - ALT and AST ≤ 1.5 times the ULN
 - Renal Function:
 - Serum creatinine concentration ≤ 1.5 times the ULN
 - Serum calcium $\leq ULN$
 - Testosterone < 50 ng/mL
-

Exclusion Criteria

- Prior cytotoxic chemotherapy (including docetaxel), except monotherapy with estramurine; Prior isotope therapy.
- Prior malignancy other than prostate cancer except the following: adequately treated basal cell or squamous cell skin cancer, or any other cancer from which the subject has been disease free for > 5 years
- Known brain or leptomeningeal involvement. Patients with stable treated epidural lesions are eligible for participation
- History of cancer related hypercalcemia, known hypercalcemia, or Vitamin D toxicity
- Active uncontrolled infection
- Active symptomatic peptic ulcer disease, unstable diabetes mellitus or other contraindications for the use of corticosteroids
- Other serious illness or medical condition that in the opinion of the investigator would be expected to interfere with the subject's ability to comply with study procedures
- Symptomatic peripheral neuropathy $> Grade 2$ according to the NCI-CTCAE version 3.0
- Hypersensitivity to drugs formulated with polysorbate-80 (a component of the docetaxel formulation); Hypersensitivity to calcitriol
- Prior investigational therapy within the 28 days prior to randomization

- Prior use of calcitriol (generic calcitriol, Rocaltrol®, Calcijex®, and DN-101) or paricalcetriol (Zemplar®) within 28 days prior to randomization