ASCO 2017 GLOBAL DISEASE TOOLKIT:

LATITUDE Study Fact Sheet[1]

Overview

- The LATITUDE study is a Phase 3, multinational, multicentre, randomised, double-blind, active-controlled study
- Designed to determine if newly diagnosed high-risk metastatic hormone-naïve prostate cancer (mHNPC, also sometimes referred to as castration-naïve prostate cancer) patients will benefit from the addition of ZYTIGA® (abiraterone acetate) and prednisone (5 mg daily) to androgen deprivation therapy (ADT)
- The international study began in 2013 and enrolled 1199 patients at 235 sites in 34 countries in Europe, Asia-Pacific, Latin America, and Canada

Study Design

The study has two arms:

1. ***Treatment arm:*** patients receiving abiraterone acetate 1,000 mg once daily, prednisone 5 mg daily, and ADT
2. ***Control arm:*** patients receiving placebos (for abiraterone acetate and prednisone) and ADT

Study Population

The study includes adult men over the age of 18 who:

- Are newly diagnosed with metastatic prostate cancer and may have received ADT for three months or less with luteinizing hormone-releasing hormone (LHRH) agonists or antagonists or orchiectomy (surgical castration), with or without concurrent antiandrogens prior to cycle one, day one
- Are diagnosed within three months prior to randomisation with confirmed adenocarcinoma (malignant tumour formed from glandular structures in epithelial tissue) of prostate without neuroendocrine differentiation or small cell histology (types of cell examination)
- Have at least two of the following high-risk prognostic factors:
  1. Gleason score ≥8 (a grading system used to evaluate the prognosis of someone with prostate cancer)
  2. Presence of three or more lesions on a bone scan
  3. Presence of measurable visceral metastasis (spread to other organs) on CT or MRI, excluding lymph node disease
- Have a ECOG PS grade of 0, 1, or 2 (a grading system used to describe a patient's level of functioning)
- Have adequate hematologic, hepatic and renal function

Study Endpoints

Co-primary endpoints:

- Radiographic Progression-Free Survival (rPFS)
- Overall Survival (OS)

Secondary endpoints:

- Time to next skeletal-related event
- Time to initiation of chemotherapy
- Time to next subsequent therapy for prostate cancer
- Time to pain progression
- Time to prostate-specific antigen (PSA) progression

References:

1. Clinical trials.gov. A Study of Abiraterone Acetate Plus Low-Dose Prednisone Plus Androgen Deprivation Therapy (ADT) Versus ADT Alone in Newly Diagnosed Participants With High-Risk, Metastatic Hormone-Naive Prostate Cancer (mHNPC). Available at: https://clinicaltrials.gov/ct2/show/NCT01715285. Accessed May 2017.

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