LATITUDE Study Fact Sheet[1]

Overview

- The LATITUDE study is a Phase 3, multinational, multicentre, randomised, double-blind, placebo-controlled study
- Designed to determine if newly diagnosed high-risk metastatic hormone-naïve prostate cancer (mHNPC) patients will benefit from the addition of ZYTIGA® (abiraterone acetate) and low-dose prednisone to androgen deprivation therapy (ADT)
- The international study began in 2013. It enrolled 1199 patients at 235 sites in 34 countries

Study design

The study has two arms:

1. *Treatment arm:* patients receiving abiraterone acetate plus prednisone and ADT
2. *Control arm:* patients receiving placebo 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 with metastatic prostate cancer within three months prior to randomisation with confirmed adenocarcinoma (malignant tumour formed from glandular structures in epithelial tissue) of the 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 of eight or above (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 an 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

About the data[2]

Study findings presented at the 2017 American Society of Clinical Oncology (ASCO) Annual Meeting revealed that treatment with abiraterone acetate plus prednisone, in combination with ADT:

- Reduced risk of death by 38% compared to ADT and placebo (Hazard Ratio [HR]=0.62; 95% CI [0.51 to 0.76], p<0.0001)
- Reduced the risk of progression of metastasis by radiographic test or death by 53% compared to placebo in patients with mHNPC (HR=0.47; 95% CI [0.39 to 0.55], P <0.0001)
- In addition, all secondary endpoints were met

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.
2. Fizazi, K. LATITUDE: A phase III, double-blind, randomized trial of androgen deprivation therapy with abiraterone acetate plus prednisone or placebos in newly diagnosed high-risk metastatic hormone-naive prostate cancer. Abstract LBA3. Presented at the 2017 American Society of Clinical Oncology (ASCO) Annual Meeting, 4th June 2017. Available at: http://abstracts.asco.org/199/AbstView_199_181729.html Accessed May 2017.

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