# LATITUDE Study Fact Sheet

## 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
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