Safety results of a phase III trial evaluating androgen deprivation therapy (ADT) + Docetaxel versus ADT alone in hormone-naive metastatic prostate cancer

**GETUG-AFU 15/0403 Trial**


(1) Institut Paul Cottonelle, Marseille, France; (2) Institut Gustave Roussy, Villeur, France; (3) Centre Francois Bocage, Caen, France; (4) Hopital Européen Georges Pompidou, Paris, France; (5) Centre Hospitalier Alencon, Le Havre, France; (6) Hopital Saint Joseph, Paris, France; (7) Hopital Jean Minjoz, Besancon, France; (8) Olympied Saint Maurice, Colombes, France (Falcon CC, Paris, France; (9) Etablissement de Roissy, Tours, France)

A French national multicentric study sponsored by the National Federation of Comprehensive Cancer Centers (FNCLCC) with the collaboration of the French Association of Urologists (AFU).

### ABSTRACT # 30377

No standardized paralysis + ADT. ADT + Docetaxel vs ADT alone. An enriched population with a higher proportion of glandular metastatic disease. ADT + Docetaxel is superior to ADT alone.

### STUDY DESIGN AND TREATMENT

**Randomization**

- With the addition of ADT, 21 patients were randomly assigned to either ADT alone (100) or ADT with additional docetaxel (192).

**Features**

- All randomization criteria were met.
- Usability, investigator use, and subsequent data were obtained.

### STUDY POPULATION

- Patients with metastatic hormone-refractory prostate cancer were randomly assigned to either ADT alone (192) or ADT plus docetaxel (192).

### TREATMENT ASSESSMENTS

**Patient characteristics**

- ADT + Docetaxel: 100 patients
- ADT alone: 192 patients

**Hematologic toxicity grade 3-4**

- **Toxicity**
  - All grades 3-4
  - Fatigue: 73% of patients
  - Alopecia: 54% of patients
  - Nausea: 29% of patients
  - Sensory neuropathy: 29% of patients
  - Constipation: 22% of patients
  - Hot flushes: 36% of patients
  - Erectile dysfunction / decreased libido: 11% of patients
  - Weight modification (gain or loss): 20% of patients
  - Gynecomastia: 4% of patients

**Extra-hematologic toxicity**

- **Toxicity**
  - Fatigue: 73% of patients
  - Alopecia: 54% of patients
  - Nausea: 29% of patients
  - Sensory neuropathy: 29% of patients
  - Constipation: 22% of patients
  - Hot flushes: 36% of patients
  - Erectile dysfunction / decreased libido: 11% of patients
  - Weight modification (gain or loss): 20% of patients
  - Gynecomastia: 4% of patients

**Treatment-related death (%)**

- **ADT + Docetaxel**: 1.6%
- **ADT alone**: 0%

### CONCLUSION

- The target of the GETUG-AFU 15/0403 phase III trial evaluating Docetaxel in hormone-naive metastatic prostate cancer was confirmed. From October 2004 to December 2009, 385 patients were included.

- The addition of ADT to Docetaxel was associated with a significant increase of toxicity.

- Apart from a higher incidence of hematotoxicity, overall toxicity was comparable to toxicity noted observed in previous studies in metastatic castration-resistant prostate cancer patients.

- Systematic use of G-CSF is recommended in this setting.

### ACKNOWLEDGEMENTS

- The patients and their families had contributed to this study.
- All investigators participated in the trial.
- The Ligue National Contre le Cancer.
- The French Health Ministry (PHRC).
- The TMC partners.
- All financial partners.

### PARTICIPATING CENTERS


- In Belgium: Cliniques Universitaires St. Luc, Brussels