

## **Inadequate Testosterone Suppression in Prostate Cancer Patients Failing on GnRH Agonists: Preliminary Data from the Delay Study**

**Introduction and Objectives:** Inadequate testosterone (T) suppression on gonadotropin-releasing hormone (GnRH) agonist therapy has been linked with reduced time to castration-resistant prostate cancer and decreased overall survival. We report baseline T data from DELAY (Hormone Sensitive Prostate Cancer Patients Switched to Degarelix Therapy after Failing on GnRH Agonists: A Prospective, Observational, Phase IV Study).

**Materials and Methods:** Patients with biochemical PSA progression on GnRH agonist therapy defined as  $\geq 50\%$  increase in PSA between 2 measurements ( $\geq 1$  week apart) are eligible. Prior treatment with chemotherapy, radiopharmaceuticals, estrogen, ketoconazole or other secondary hormonal treatments such as antiandrogens (except  $< 3$  months for induction) is not allowed. As of January 10, 2012 baseline T had been assessed in 44 of 105 planned patients. Here we compare T suppression on GnRH agonist to 3 levels: 1.7 nmol/L (traditional castrate level), 1.1 nmol/L (previously reported in the literature) and 0.7 nmol/L (orchiectomy).

**Results:** Median age of the 44 patients was 81 (range 63-93). Overall mean baseline T and PSA were 1.0 nmol/L (range 0.1-12.4) and 17.7 ng/mL (range 1.3-141.0), respectively. The percentage of patients with baseline T levels above 1.7, 1.1 and 0.7 nmol/L was 6.8% (3/44), 11.4% (5/44) and 25.0% (11/44), respectively.

**Conclusions:** A significant number of patients on GnRH agonists and with apparent PSA progression are not adequately castrated. Monitoring T levels is recommended to ensure adequate suppression and allow for corrective action if needed. The DELAY study will examine whether switching to Degarelix improves disease progression in patients both adequately and inadequately castrated on GnRH agonists.