

PROSTATE-SPECIFIC ANTIGEN (PSA) PROGRESSION: DEGARELIX VERSUS LEUPROLIDE IN PROSTATE CANCER (PCA)

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Objectives: The gonadotropin-releasing hormone (GnRH) blocker degarelix was previously reported to be as effective as the GnRH agonist leuprolide in suppressing testosterone to castrate levels in PCa patients in a pivotal 1-year phase III trial (CS21). We report long-term PSA PFS data from an ongoing 5-year extension study (CS21A).

Methods: Patients completing CS21 either continued on the same monthly degarelix maintenance dose of 160 mg (n=125) or 80 mg (n=125) or were re-randomised from leuprolide 7.5 mg to degarelix 240/80 mg (n=69) or 240/160 mg (n=65). Data are presented for the approved degarelix 240/80 mg dose. PSA progression-free survival (PFS) was defined as time to first of PSA failure (two consecutive increases in PSA of $\geq 50\%$ and ≥ 5 ng/mL above nadir) or death.

Results: Patients receiving degarelix 240/80 mg had a significantly lower risk of PSA failure or death compared with leuprolide during the first year ($p=0.05$; log-rank). Beyond 1 year, patients initially receiving leuprolide experienced a lower rate of PSA failure or death after switching to degarelix. After a median follow-up of 27.5 months, PSA PFS hazard rates decreased significantly from 0.20 events/year in the first year to 0.08 events/year following the switch to degarelix ($p=0.003$, chi-square test); corresponding rates for patients continuing on degarelix were 0.11 and 0.14 events/year.

Conclusions: These data support the durability of the significant PSA PFS benefit for degarelix treatment over monthly leuprolide seen during the first treatment year and the use of degarelix as first-line androgen deprivation therapy.