# Intermittent Short Course Enzalutamide in Biochemically Recurrent Prostate Cancer

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Background
Androgen deprivation therapy (ADT) and surveillance are standard options for patients (pts) with biochemically recurrent (non-metastatic, castration sensitive) prostate cancer (BCRpc) after localized therapy. Enzalutamide (enz) extends survival in advanced prostate cancer and is being tested in earlier stages of disease.

Methods
Eligible pts had a PSA between 2.0-20.0 ng/ml, no metastatic disease, normal testosterone (T), and a PSA doubling time of less than 12 months. Treatment for all pts included enz 160 mg daily for 84 days (D) with/without PROSTVAC (recombinant poxvirus PSA vaccine), but no ADT. After an amendment, pts were eligible for a 2nd course of enz after PSA returned to baseline and confirmation of non-metastatic disease. This analysis evaluated all pts for the impact of enz on PSA and T regardless of randomization as findings were similar in each group.

Results
Median age for all pts (n=36) was 64 years (range: 54-85) with a median baseline PSA of 5.02 (range: 2.02–19.43). The median PSA decline during the first course of enz was >99% (range: 84 - >99). After enz was discontinued, the median time to first PSA rise was 28 D (range:13–182) and median recovery to baseline PSA was 224 D (range:84–924+). 22 of the 36 evaluable pts received a 2$^{nd}$ course of enz. Similarly, these patients had a median PSA decline of 99% (range 87->99). After the 2$^{nd}$ course of enz, the median time to first PSA rise was 29 D (range:0–83) with a median time to 2nd PSA recovery of 189 D (range:78–400). Enz was well tolerated with no grade 4 or 5 adverse events (AEs). Grade 3 AEs included increased ALT (5%) and decreased ANC (3%). The most common grade 2 AEs included fatigue (18%), dizziness (8%), decreased WBC (8%), and a decreased ALC (8%). T increased above normal limits in 20/36 pts (median Tmax = 834 ng/dl).

Conclusion:
Intermittent, short course (84 d) enz without ADT leads to deep and prolonged PSA suppression below baseline in pts with BCRpc, a median of more than 7.5 months beyond treatment period. Pts who received a 2$^{nd}$ 84 D course of enz had similar depth and duration of PSA suppression below baseline (more than 6.5 months after enz treatment). Intermittent enz was well tolerated and warrants further study in BCRpc.

Conflicts of Interest: None

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