Prospective Monitoring of Prostate Specific Membrane Antigen (PSMA) in Biochemically Recurrent Prostate Cancer (BCR): Preliminary Data from 1 Year Follow-up

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Background:

For prostate cancer patients (pts) with a rising PSA after definitive surgery and/or radiation (BCR), PSMA imaging is used to identify site(s) of recurrent disease. Although there is often a false equivalency between PSMA-defined metastasis and metastasis seen on CT/bone scan, there is no data defining what happens to PSMA+ BCR over time without therapy. Such data is required to better define which PSMA+ BCR pts would benefit from therapeutic intervention.

Methods:

NCT05588128 enrolls BCR pts after definitive +/- salvage therapies. Pts must have a PSA>0.5 ng/ml, testosterone>100 ng/dL, and negative CT/bone scans. Lymph nodes (LNs) up to 1.5 cm and prior therapies are permitted. Enrolled pts have a PSMA at baseline and if positive repeated, every 6 months (mos). If negative initial PSMA, it is done annually. CT/bone scan are also repeated annually. Radiation therapy or systemic therapies for $\leq$6 mos are permitted on-study. Pts are followed up to 5 years.

Results:

Over 140 pts have enrolled and 81 pts have had 1 year of follow-up. Baseline median age=71 years, PSA=2.3 ng/ml, PSA Doubling Time (DT)=11.0 mos (28 pts/35% have a DT $\leq$ 6 mos.) PSMA findings at baseline include no disease (10 pts), prostate only (15), LNs (50), bone (8), serosal (3), pulmonary (1). Among pts with LNs, 19 had 1 LN, 14 had 2-4 LNs, and 17 had 5+LNs. Over the first year, 7 pts chose standard of care therapy, 12 pts chose protocol treatment without androgen suppression. Among the remaining 62 pts, 53 pts had baseline PSMA+ findings, only 2 pts (3.8%) had metastatic findings on CT/bone scan at 1 year; 1 pt had baseline PSMA+ bone findings later seen on bone scan and the 2nd pt had PSMA- pulmonary nodules that grew >1.0 cm and became PSMA+.

Conclusion:

These preliminary data from this ongoing study at the NCI (Bethesda, MD, USA) suggests that PSMA+ BCR is an indolent disease process with low risk for clinically meaningful changes (e.g. metastatic progression on CT/bone scan) over the short term, even among pts with PSA DT $\leq$ 6 months or with many PSMA+ LNs. Additional data is being collected including how PSMA imaging metrics (e.g PSMA tumor volume) and PSA kinetics should inform clinical practice and future clinical trials.

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