INTRA-PROSTATIC PRX302 FOCAL THERAPY IN TREATING CLINICALLY SIGNIFICANT LOW-INTERMEDIATE RISK PROSTATE CANCER: AN OPEN LABEL, PROOF-OF-CONCEPT STUDY

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INTRODUCTION

PRX302 (topsalysin) is a genetically modified pore-forming protein (aerolysin), activated by active PSA within the prostate. Potentially providing a focal and highly targeted approach to lysing tumor cells, therefore avoiding toxicity, potentially preserving function of healthy tissue.

OBJECTIVES

We aimed to determine toxicity and potential efficacy in the first proof-of-concept study of MRI-Ultrasound fusion-guided intra-prostatic injection of PRX302 to histologically proven, clinically significant*, localized low to intermediate risk prostate cancer with a concordant multiparametric MRI lesion.

METHODS

18 patients with clinically significant disease*. A single pre-identified lesion injected transperineally using MRI-ultrasound elastic image-fusion software (SmartTarget®), with up to 5mL 20ug/mL PRX302.

All men were followed up at 2 days, 2, 6, 12, 24 and 26 weeks postoperatively, with a mpMRI targeted transperineal biopsy of the treated area at 24 weeks.

Urinary function was assessed post-treatment with the use of IPSS and UCLA-EPIC Urinary Domain questionnaires. Sexual function was assessed post-treatment with the IIEF score questionnaire.

RESULTS: mpMRI

MpMRI acquisition was performed according to the European guidelines of Uroradiology. Using a 1.5 or 3 Tesla magnet, T2, ADC, high B value and DCE sequences were acquired.

MpMRI scans were performed pre-treatment, and at 2, 12 and 24 weeks post-treatment.

RESULTS: Response

The primary efficacy outcome was tumour control

At baseline: Median age 66.50 years [IQR 13.00] and median PSA 6.25ng/mL [IQR 2.45]. 4 men (22%) had high volume Gleason 6 lesions & 14 (78%) had Gleason 7 with median lesion size of 0.3mL [IQR 0.2-0.5]

RESULTS: Adverse Events

Adverse events were reported at each visit (2 days, 2, 6, 12, 24 and 26 weeks post-treatment)

RESULTS: Function

Secondary outcomes included sexual and urinary function.

CONCLUSIONS

Single intraprostatic administration of PRX302 (topsalysin) has biological activity to safely focally ablate prostate tumor cells with minimal genitourinary side effects.

Optimizing the dosing of PRX302 based on tumour size and the development of a more optimal PRX302 delivery system may improve response rates.

Such aspirations will be tested in a multicentre phase 2b study to further test safety and efficacy.