758 Intra-prostatic injection of PRX302 to focally ablate clinically significant prostate cancer: An open label, phase 2a study

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INTRODUCTION

PRX302 is a genetically modified pore-forming protein (aerolysin) activated by active PSA within the prostate.

**Potential mechanism of action:**
- Binding to the prostate surface
- Cleavage of the cell membrane
- Permeabilization of cell membrane
- Oligomerisation & Transmembrane Pore
- Cell death

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 MRI lesion.

*Gleason 7 (3+4, 4+3) with a maximum cancer core length (MCCL) 10mm or less, or Gleason pattern 3+3 the MCCL had to exceed 3mm

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, with a mpMRI targeted transperineal biopsy of the treated area at 24 weeks.

Urinary function assessed post-treatment with IPSS and UCLA-EPIC Urinary Domain.
Sexual function assessed post-treatment with IIEF.

RESULTS: Response

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%) Gleason 7 with median (IQR) lesion size of 0.3ml (IQR 0.2-0.5)

**Chart demonstrating the AEs attributable to PRX302 & or injection procedure. These AEs were all assessed as mild in severity. 6% represents one patient.**

**Score** | **Mean at Baseline (SD)** | **Mean at 24 Wks (SD)** | **Mean Change from Baseline (SD)**
---|---|---|---
IPSS | 8.9 (6.28) | 7.3 (6.63) | -1.6 (2.4)
ULCA EPIC urinary Domain | 87.6 (13.07) | 88.1 (12.7) | 0.5 (9.63)
IIEF | 50.5 (20.98) | 50.6 (18.86) | 0.1 (17.47)

Urinary and sexual function preserved post-treatment.

Single intraprostatic administration of PRX302 (topalysin) 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 PRX302 delivery system may improve response rates and will be tested in a multicentre phase 2b study to test safety and efficacy.