

# Summary of clinical trial: prostate cancer treatment

Oncolytic virus-drug: RVLYSIN

# RVLYSIN clinical overview-Phase I/II

## Combination program

- Patients: 15 Patients from Wuhan, China with metastatic castration-resistance prostate cancer
- Study design: the protocol includes the present cohort of patients who received dasatinib with or without RVLYSIN
  - Dasatinib (oral) ----80 mg (sub-optimal) or 140 mg once-daily
  - RVLYSIN: local and IV injection
- Adverse events were classified according to the NCI Toxicity Criteria, version 3.0
- Evaluation of clinical activity:
  - Endpoints:
    - changes in the bone scan finding
    - Serum bone alkaline phosphatase and urine N-telopeptide
    - PSA level
    - Response evaluable criteria in solid tumor

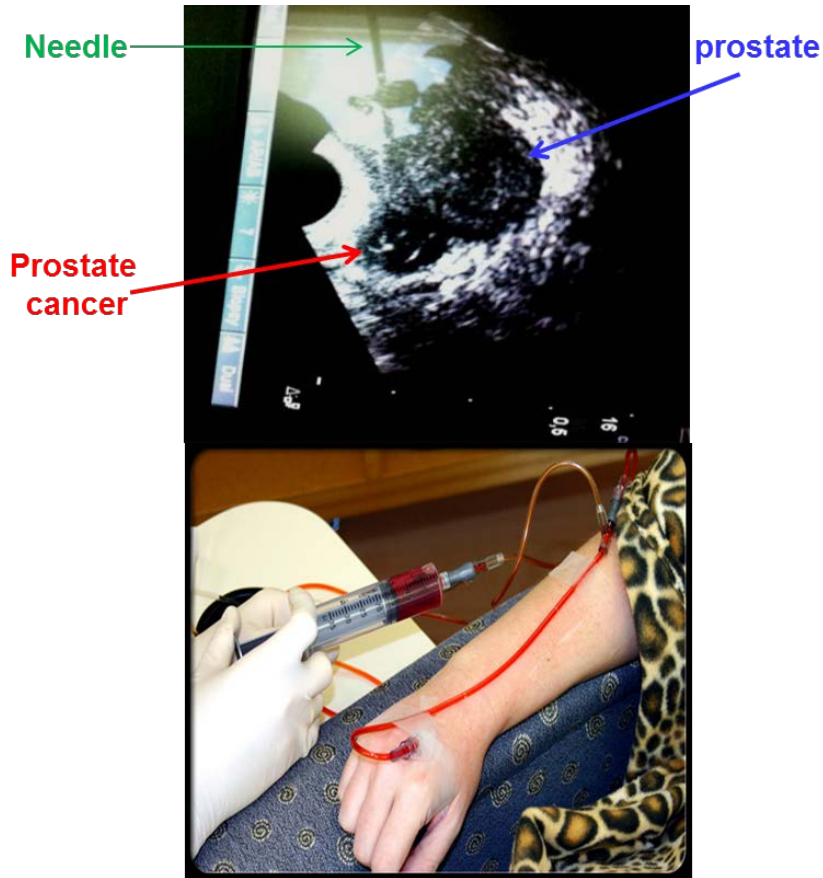
# Patient information

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Characteristic	Value
Total patients (n)	15
Age (yr)	
Median	73.2
Range	67-81
ECOG performance status (n)	
0	12
1	3
Bone metastases (n)	15
PSA (ng/mL)	
Median	52.6
Range	16-773
Urine N-telopeptide (nM/mmol creatinine)	
Median	45.10
Range	12.1-664.4
Bone alkaline phosphatase (U/L)	
Median	42
Range	16-614
Previous therapy (n)	
Surgery	0
Radiotherapy	8
Disphosphonates	15

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# Patients were treated with combination drugs



- Local injection
  - IV injection
  - Oral ----dasatinib
- } RVLYSIN

# Results

- Adverse events:
  - RVLYSIN alone: no dose-limiting toxicities, and a maximum tolerated dose was not reached in the dose escalation
  - The combination of low-dose chemo with RVLYSIN decreased adverse events in patients compared to chemo alone

## Summary for adverse events of two groups

Adverse events	Dasatinib (140 mg/d n=7)		Dasatinib (80 mg/d) + RVLYSIN (n=8)	
	Grade 1-2	Grade 3-4	Grade 1-2	Grade 3-4
Nausea	2	4	0	2
Anorexia	1	5	2	1
Diarrhea	0	0	0	0
Fatigue	3	2	1	0
Rash	1	1	0	0
Headache	1	3	0	1
Dyspnea	1	0	0	0
Superficial edema	0	0	0	0
Flushing	0	0	0	0

# Efficacy of combination therapy

- The efficacy of anti-tumor of combination therapy is better than single chemo therapy
- Bone alkaline phosphatase was reduced in 4 patients
- Urine N-telopeptide was decreased in 3 patients
- Serum PSA was dropped in 3 patients at day 8 and 1 patient at day 12
- MRI and bone scan will be done 24w after treatment