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# Safety and Feasibility of Intraprostatic Injection of CAN-2409 or Placebo followed by Valacyclovir in Patients on Active Surveillance for Prostate Cancer (ULYSSES Trial)

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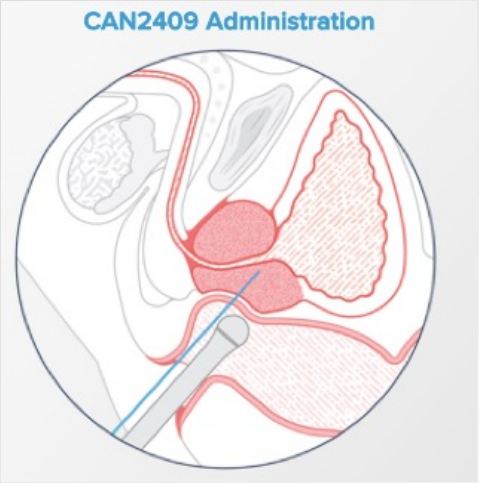
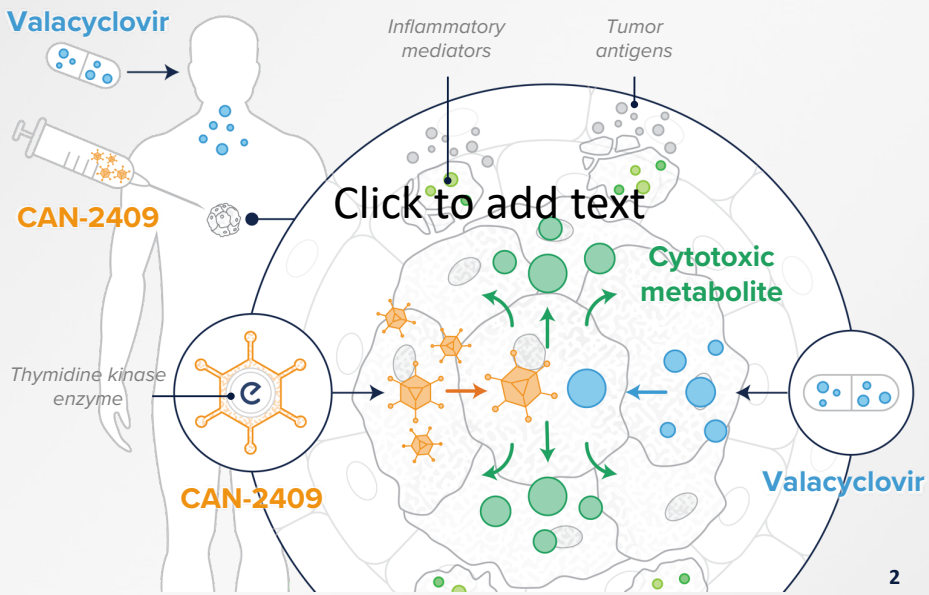
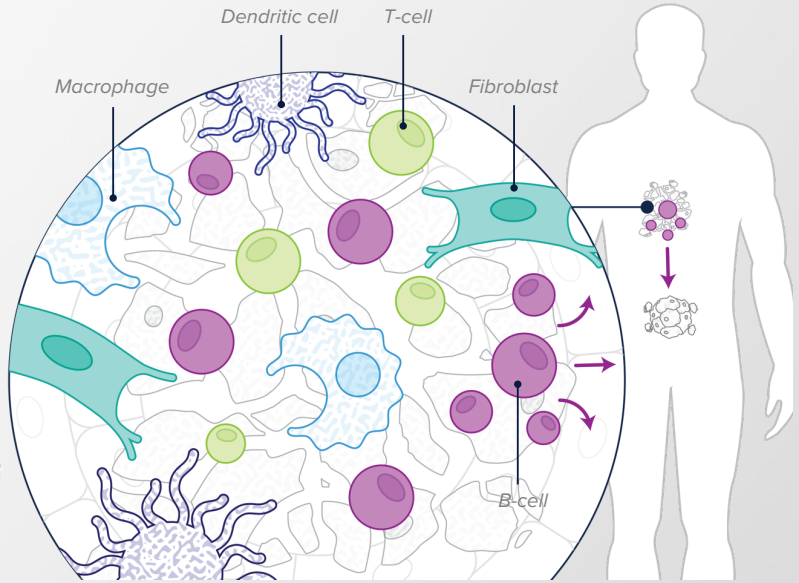
# CAN-2409: Administration and Mechanism of Action

1. CAN-2409 replication-incompetent adenoviral vector expressing HSV-tk, locally administered followed by oral anti-herpetic prodrug (valacyclovir)
2. Localized cytolytic mechanism combined with proinflammatory viral particles
3. CAN-2409 induces tumor infiltrating lymphocytes
4. Local immunization yields systemic anti-tumor response

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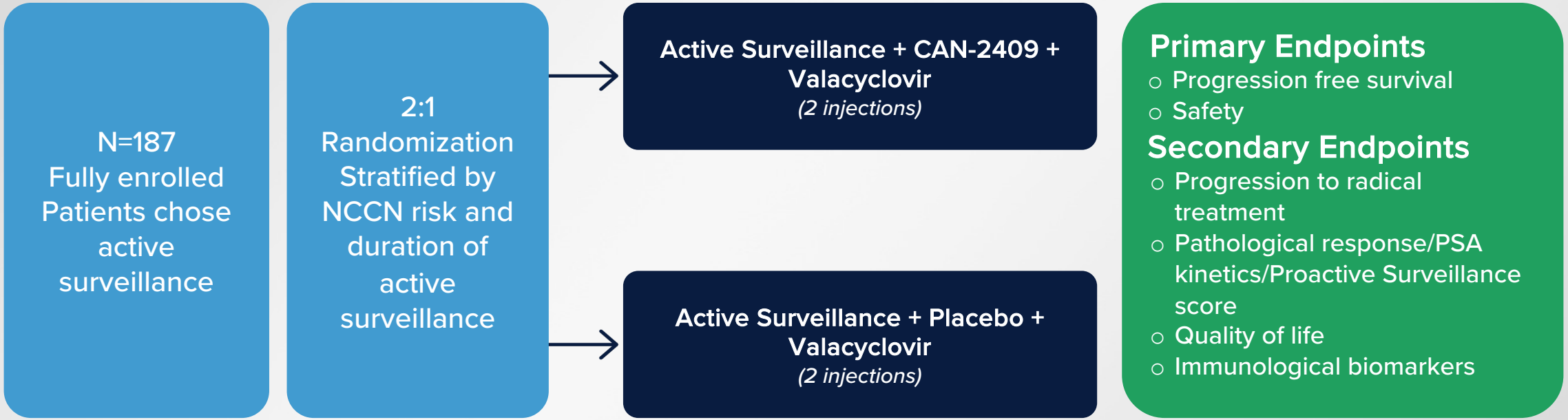
# Phase 2 placebo-controlled, double-blind clinical trial of CAN-2409 during active surveillance for prostate cancer

- NCCN low, intermediate or single NCCN high-risk factor
- Patients on or choosing active surveillance

Study still blinded with patients in follow up for PFS
Blinded safety read out reported in this presentation

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# Patient Demographics

187 patients treated, total 365 injections performed

- 175 received 2 injections + VCV
- 12 patients received 1 injection + VCV

| Characteristic | | |
|---|---|---|
| **Age, years** | | |
| Median Age | 65 | |
| Range | 40 | - 81 |
| **Race, n(%)** | | |
| White/Caucasian | 153 | ( 81.8% ) |
| Black/African American | 19 | ( 10.2% ) |
| Asian | 1 | ( 0.5% ) |
| Native Hawaiian or Pacific Islander | 0 | ( 0.0% ) |
| American Indian or Alaskan Native | 0 | ( 0.0% ) |
| Native or Indigenous | 5 | ( 2.7% ) |
| More than one race | 3 | ( 1.6% ) |
| Not reported | 6 | ( 3.2% ) |
| **Ethnicity, n(%)** | | |
| Hispanic or Latino | 40 | ( 21.4% ) |
| Not Hispanic or Latino | 115 | ( 61.5% ) |
| Not Reported | 32 | ( 17.1% ) |

| | | |
|---|---|---|
| **Tumor Stage, n(%)** | | |
| T1c | 153 | ( 81.8% ) |
| T2a | 25 | ( 13.4% ) |
| T2b | 6 | ( 3.2% ) |
| T2c | 3 | ( 1.6% ) |
| T3a | 0 | ( 0.0% ) |
| **PSA ng/ml** | | |
| Range | .96 | - 23.3 |
| <10 | 160 | ( 85.6% ) |
| 10-20 | 26 | ( 13.9% ) |
| >20 | 1 | ( 0.5% ) |
| **Gleason score,n(%)** | | |
| <7 | 155 | ( 82.9% ) |
| =7 | 31 | ( 16.6% ) |
| >7 | 1 | ( 0.5% ) |
| **NCCN risk group,n(%)** | | |
| Low | 132 | ( 70.6% ) |
| Intermediate | 53 | ( 28.3% ) |
| High | 2 | ( 1.1% ) |

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# Most Common Adverse Events (>=5%)

Out of the 365 transrectal intraprostatic injections performed, there were only 3 (0.8%) hospitalizations due to infection

| Most common PT (>=5%) | CTC grade | | | | n=187 |
|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | Total (%) |
| Flu-like symptoms | 40 (21) | 20 (11) | 1(1) | 0 | 61 (33) |
| Chills | 39 (21) | 13 (7) | 1 (1) | 0 | 53 (28) |
| Fever | 39 (21) | 9 (5) | 1(1) | 0 | 49 (26) |
| Fatigue | 27 (14) | 10 (5) | 1(1) | 0 | 38 (20) |
| Elevated AST/ALT | 28(15) | 3(2) | 1(1) | 0 | 32(17) |
| Elevated Creatinine | 23 (12) | 5 (3) | 1 (1) | 2(1) | 31(17) |
| Headache | 20(11) | 5(3) | 0 | 0 | 25(13) |
| Urinary tract infection | 1(1) | 15(8) | 2(1) | 0 | 18 (10) |
| Nausea | 12(6) | 4(2) | 0 | 0 | 16(9) |
| Low Hemoglobin | 15(8) | 0 | 0 | 0 | 15(8) |
| Diarrhea | 10(5) | 3(2) | 0 | 0 | 13(7) |
| Malaise | 10 (5) | 2(1) | 0 | 0 | 12 (6) |
| Hematuria | 12 (6) | 0 | 0 | 0 | 12 (6) |
| Urinary frequency | 9 (5) | 2 (1) | 0 | 0 | 11 (6) |
| Urinary tract pain | 6 (3) | 3 (2) | 0 | 0 | 9 (5) |
| Urinary urgency | 7 (4) | 2(1) | 0 | 0 | 9 (5) |
| Elevated Alkaline Phosphatase | 8 (4) | 1(1) | 0 | 0 | 9 (5) |
| Elevated Bilirubin | 7(4) | 3(2) | 0 | 0 | 10(5) |

## Conclusions

- Intraprostatic injections of either placebo or CAN-2409 followed by oral valacyclovir in men with prostate cancer on active surveillance are feasible and well tolerated.
- Cancer-specific efficacy endpoints will be evaluated at end of study.
- If effective, implementation of this therapeutic modality appears to be straightforward and safe.

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