CAN-2409 plus prodrug with standard of care immune checkpoint inhibitor for patients with stage III/IV NSCLC

Poster 138b
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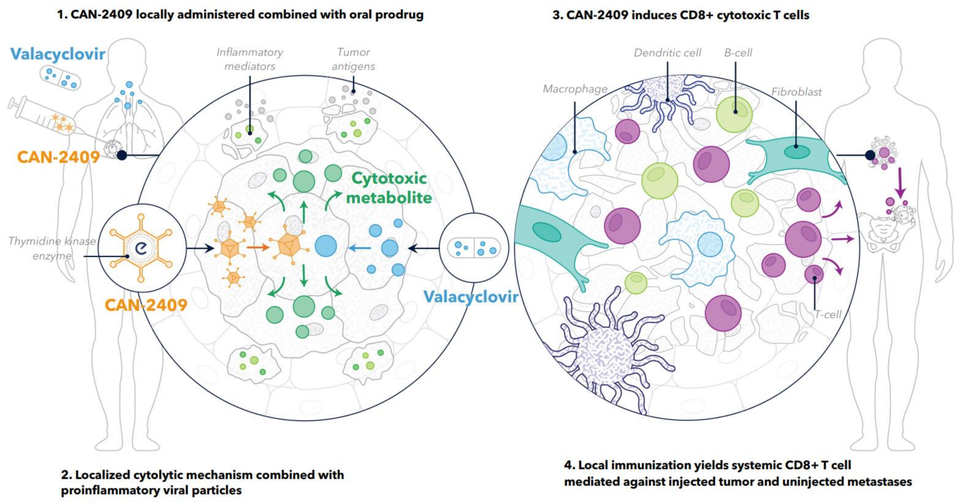
Introduction

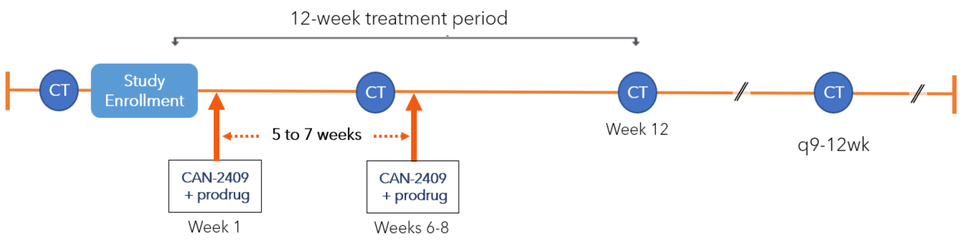
- Despite improved outcomes for patients with advanced non-small cell lung cancer (NSCLC) treated with immune checkpoint inhibitors (ICI), most patients ultimately progress and 5-year survival remains low (~20-25%).
- CAN-2409 (aglatimagene besadenovec) + prodrug (oral valacyclovir) is a novel investigational viral immunotherapy designed as an off-the-shelf therapy producing an individualized cancer response (MoA figure below).
- Each treatment course involves intratumoral injection of CAN-2409 followed by 2 weeks of oral prodrug valacyclovir.
- To date, CAN-2409 + prodrug has produced encouraging results and a favorable safety/tolerability profile from multiple Ph1 and Ph2 clinical trials in several solid tumor types (>2000 doses in >950 patients).
- This Ph2 clinical trial evaluates the safety, clinical efficacy, and immunologic effects of adding CAN-2409 + prodrug to ongoing 1L anti-PD-(L)1 therapy in patients with stage III/IV NSCLC who have either stable or radiographically progressing disease.

Mechanism of Action

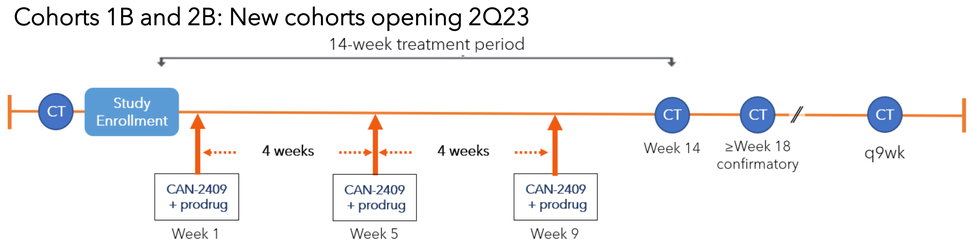


Study Treatment Schema

Cohorts 1A and 2A



Cohorts 1B and 2B: New cohorts opening 2Q23



Key inclusion criteria

- Stage III/IV NSCLC on 1L treatment with anti-PD-(L)1 ± chemo and the following:
  - Cohort 1: stable disease at ≥18 weeks after starting ICI treatment
  - Cohort 2: progressive disease ≥18 weeks after starting ICI treatment
- RECIST-evaluable disease with an injectable lesion
- Ability to continue ICI for the treatment period
- No changes of ICI or interruption >4 weeks within 6 months prior to enrollment
- Previous focal therapy allowed if ≤3 sites of disease within 12 months prior to enrollment
- Age ≥18 years

Key exclusion criteria

- Known *EGFR* mutation, *ALK* fusion, or *ROS1* fusion
- History of:
  - ICI immune-related adverse events
  - TKI/ALK/ROS1 inhibitors
  - VEGF inhibitors within past 2 months or 5 half-lives prior to enrollment
- Interstitial lung diseases requiring active therapy
- Ongoing therapy with DMARDs, immuno-modulators, or immunosuppressive drugs including systemic corticosteroids

Study Locations

Actively recruiting at 14 sites
Phase II, multi-center, multi-cohort, open-label clinical trial

Study Objectives and Endpoints

Objective

- Evaluate the safety and clinical efficacy of 2-3 courses of CAN-2409 plus prodrug in combination with standard of care ICI ± chemotherapy

Endpoints

Primary

- Overall response rate and/or disease control rate per RECIST 1.1 criteria
- Safety based on laboratory and adverse event monitoring

Secondary

- Duration of response
- Overall survival
- Progression-free survival (PFS)
- Biomarker studies
- Quality of life (measured by the NSCLC-SAQ v1.0 survey)
- Tumor response and PFS per iRECIST criteria

Exploratory

- Tumor response and PFS per itRECIST criteria
- Evaluation of abscopal effect
- Changes in non-target lesions
- Tumor growth trajectory
- Molecular markers of tumor growth
- Viral shedding

Additional Resources

Scan for access to the ClinicalTrials.gov listing.