

COM701 (A NOVEL IMMUNE CHECKPOINT INHIBITOR) IN PATIENTS WITH ADVANCED SOLID TUMORS.

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Objectives:

COM701 is a novel 1st in-class monoclonal antibody (checkpoint inhibitor) of poliovirus receptor related immunoglobulin domain containing (PVRIG) blocking its interaction with its ligand, PVRL2 (Fig 1). In preclinical experiments inhibition of PVRIG leads to activation of T-cells in the tumor microenvironment generating an anti-tumor immune response leading to tumor growth inhibition (Fig 2). We hypothesized that COM701 monotherapy and in combination with nivolumab will be safe and tolerable and demonstrate antitumor activity in pts with advanced solid tumors. Key primary objectives: safety and tolerability of COM701 monotherapy and in combination with nivolumab measured by the incidence of pts with adverse events and dose-limiting toxicities. The recommended dose for expansion of COM701 monotherapy and in combination with nivolumab. Key secondary objectives: the preliminary antitumor activity of COM701 monotherapy and with nivolumab in pts with endometrial, ovarian, breast and lung cancer. These tumor types were selected based on high expression of PVRL2.

Methods:

Study design: Dose escalation hybrid accelerated titration and 3+3 design. Key inclusion criteria: Age ≥18 yrs, advanced solid tumor and has exhausted all available standard therapy, prior checkpoint inhibitor permissible. Key exclusion criteria: history of immune-related events that led to immunotherapy treatment discontinuation. Expansion cohorts will enroll pts with the tumor types selected. ClinicalTrials.gov Identifier: NCT03667716.

Results:

No DLTs have been observed up to 7th COM701 monotherapy dose level and dose level 2 in Arm B (Fig 3).

Conclusions:

COM701 monotherapy and in combination with nivolumab has an acceptable safety and tolerable profile at the dose levels tested. Study enrollment is ongoing.

Fig 1.

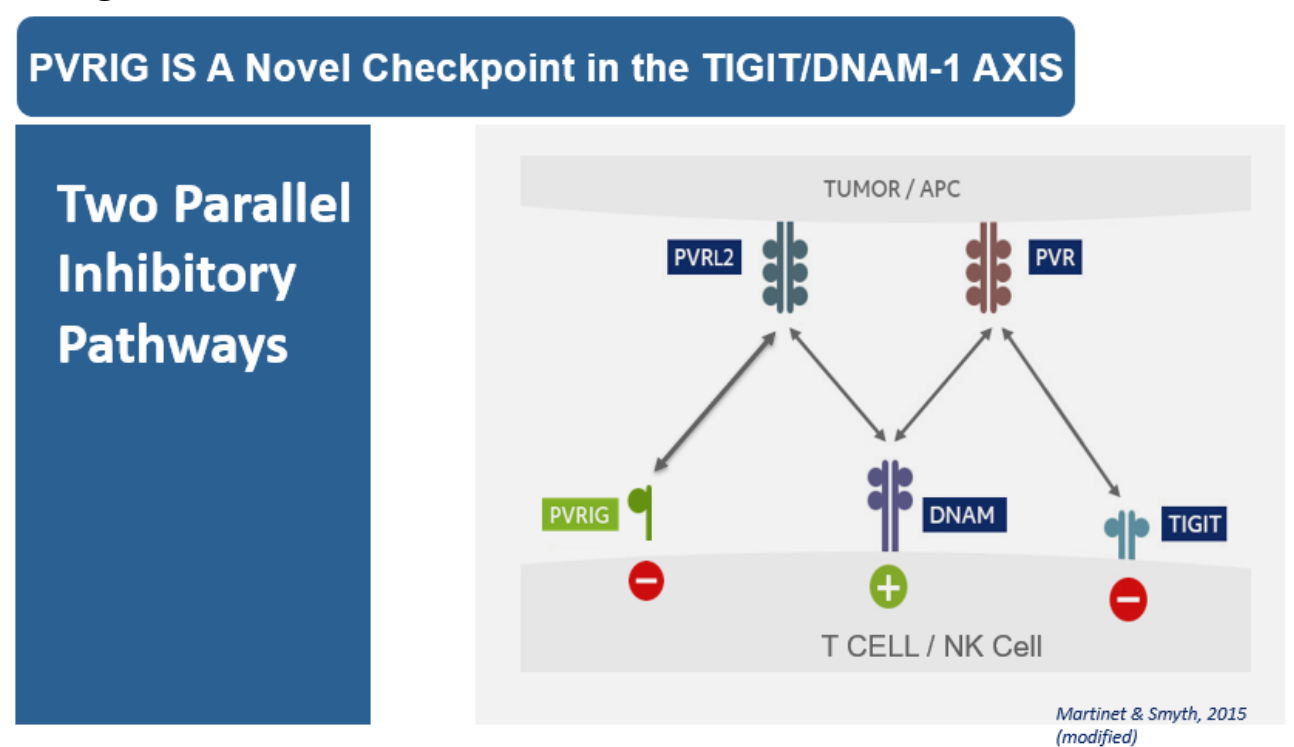


Fig 2.

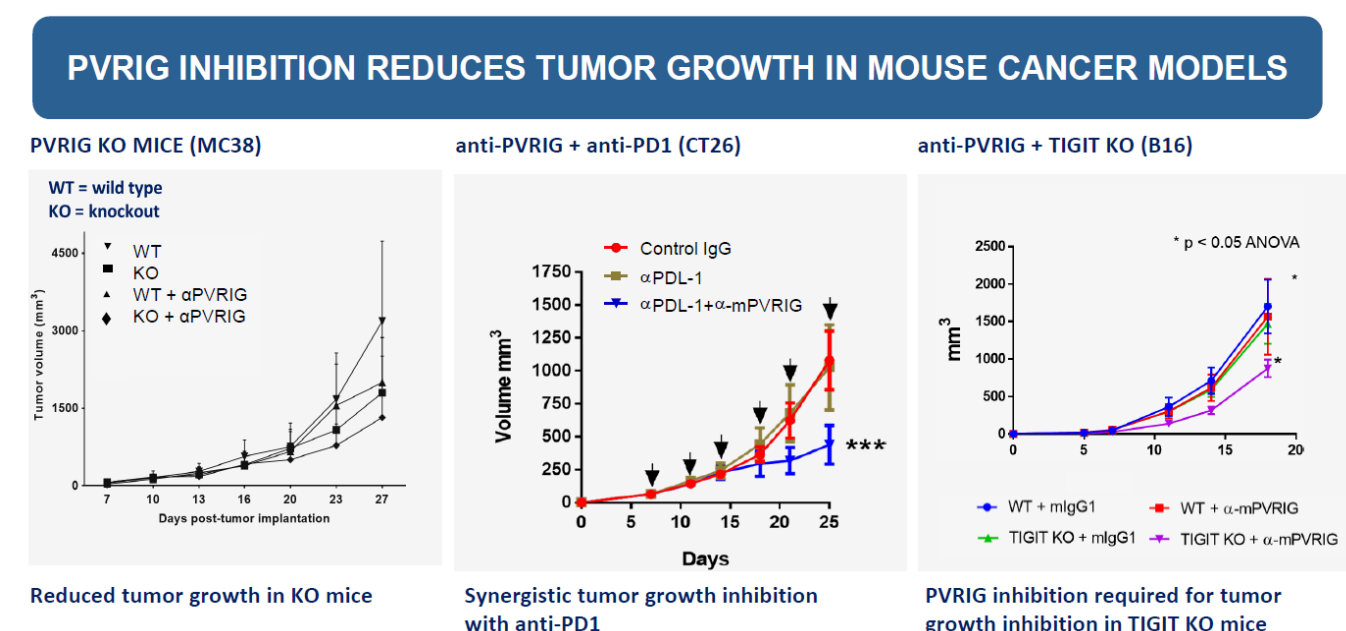


Fig 3.



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