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An APC activator (IMP321 or LAG-3Ig) combined with anti-PD-1 blockade

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Society for Immunotherapy of Cancer

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Three groups of patients responding to anti-PD-1 (IFN- γ signature)

- A- Inflamed responders – respond to anti-PD-1
 - B- Inflamed non-responders (some infiltrates in the tumor margins but no response)
 - C- Non inflamed. “Cold tumor” with no response
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- Optimal checkpoint combos will target groups B and C and help them:
 - Promote cross presentation of tumor antigens
 - Induce T cell recruitment into tumor microenvironment

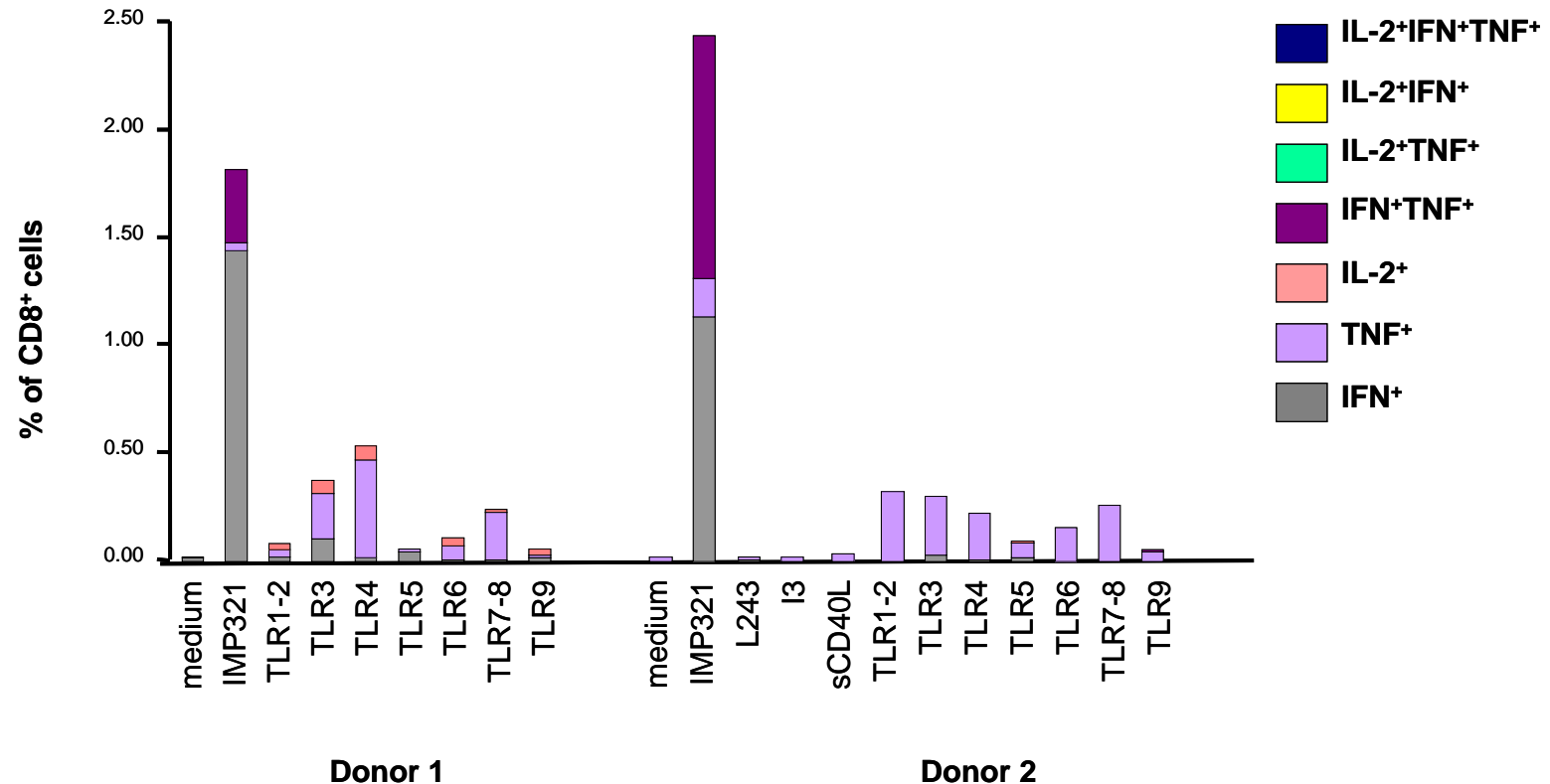
IMP321 induces a better Tc1 differentiation than sCD40L or TLR agonists

➤ Human blood lymphocytes are analyzed in a 16 hr *ex vivo* assay

➤ Intracellular staining of CD8 T cells

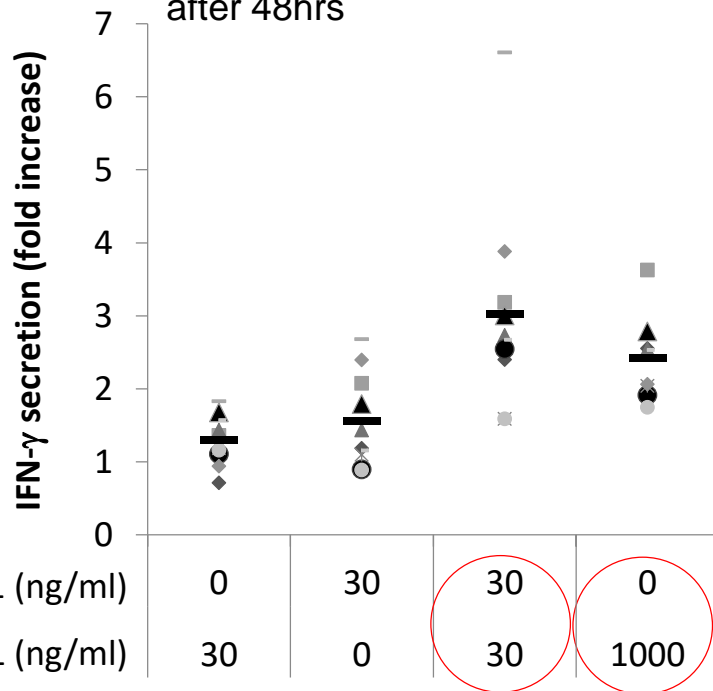
➤ Only IMP321 induces IFN⁺ CD8 T cell responses

➤ TLR agonists but not IMP321 induce IL-10 production which suppresses Tc1 differentiation

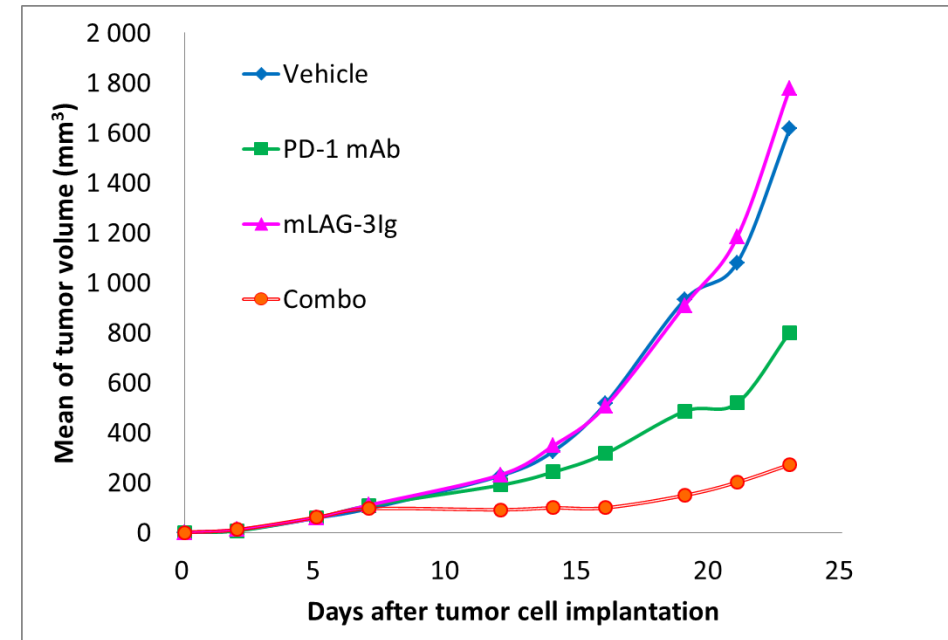


In vitro and in vivo preclinical data supporting the combination

CMV-stimulated PBMCs from 10 healthy donors after 48hrs

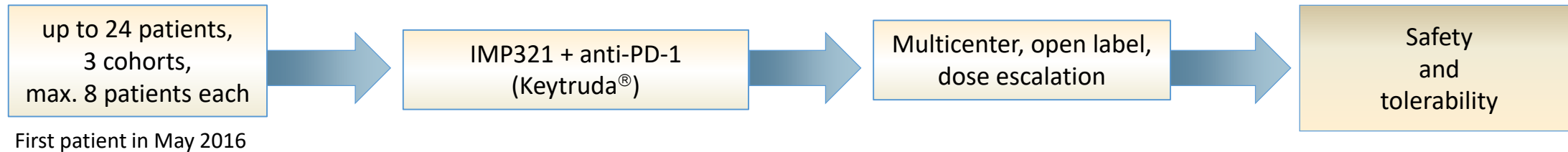


Anti-PD-1 (10 mg/kg) + mLAG-3Ig (1 mg/kg)
In a subcutaneous CT26wt colon cancer model



TACTI-mel: Two ACTIVE Immunotherapeutics in melanoma

Phase I study in immuno-immuno combination in unresectable or metastatic melanoma in Australia



Design	
Phase I, multi-centre, open-label, dose escalation	
Primary Objective	Safety, tolerability and recommended dose finding for phase II with pembrolizumab + IMP321 in unresectable or metastatic melanoma
Other Objectives	Pharmacokinetic and pharmacodynamic of IMP321, objective response rate, time to next treatment, progress-free survival
Patient Population	Patients with asymptomatic or suboptimal response after three cycles of pembrolizumab
Treatment	Up to 24 patients 3 cohorts: 1/6/30 mg IMP321; s.c. q2w + pembrolizumab; starting with the 5 th cycle of pembrolizumab

Status report

- 6 clinical sites are approved and all are activated
- Dose escalation decision of the interim data of the first cohort is expected at the end of this year

