Table 1. *Clinical trials assessing the efficacy and/or safety of Immune Checkpoint Inhibitors in the treatment of chronic viral infections.*

Clinical trial number (NCTID)	Study	Infection or disease	Target Inhibitory protein	Agent	Study design/ Number of participants/patient population	Clinical Outcomes	Safety Outcomes
NCT03239899	PD-1 Inhibition to Determine CNS Reservoir of HIV-Infection	HIV	PD-1	Pembrolizumab	12 patients with HIV-1 infection receive a one-time dose of 200mg pembrolizumab with a baseline study period of 3 weeks, a one-day treatment phase, and a 6-month post treatment phase.	No results posted	No results posted
NCT03787095	Safety and Immunotherapeutic Activity of an Anti-PD-1 Antibody (Cemiplimab) in HIV-1-infected Participants on Suppressive cART	HIV	PD-1	Cemiplimab	Experimental: Cohort 1: Cemiplimab 4 Participants received 0.3 mg/kg of cemiplimab, administered at Day 0 and Week 6 for a total of two infusions. Comparator: Cohort 1: Placebo 1 Participant received placebo, administered at Day 0 and Week 6 for a total of two infusions.		One participant revealed hyperthyroidism on routine safety labs at 4 weeks after 1st infusion. Per protocol for possible irAEs, 2nd infusion was held; one week later repeat labs confirmed thyroiditis judged probably related to study drug. One participant, had asymptomatic Grade 3 AST and ALT elevations 2 weeks after 1st infusion, resolved 35 later without intervention. Transaminase enzyme elevation pattern (AST=ALT) and slow resolution were deemed inconsistent with acute alcohol toxicity and therefore were judged possibly related to study drug. Two participants received both infusions without report of adverse events or laboratory abnormalities.

Table 1. *Clinical trials assessing the efficacy and/or safety of Immune Checkpoint Inhibitors in the treatment of chronic viral infections (continued).*

Clinical trial number (NCTID)	Study	Infection or disease	Target Inhibitory protein	Agent	Study design/ Number of participants/patient population	Clinical Outcomes	Safety Outcomes
NCT03354936	Assess the safety of the use of immune checkpoint inhibitors in HIV infected patients	HIV	IMC	Nivolumab Pembrolizumab	50 HIV Infected Patients with Cancer Treated by immune checkpoint inhibitors will be recruited. Blood samples will be collected to constitute cell bank, plasma bank, serum bank, DNA bank in order to meet the objectives of this substudy and possibly for complementary research	No results posted	No results posted
NCT03367754	A Single Dose of Pembrolizumab in HIV-Infected People	HIV	PD-1	Pembrolizumab	Participants will either receive a single dose of 200mg (iv infusion) of pembrolizumab or a single dose (iv infusion) of placebo	No results posted	no results posted
NCT03407105	An open-label, multiple ascending dose study of the anti-CTLA-4 antibody ipilimumab in viremic HIV patients	HIV	CTLA-4	Ipilimumab	24 participants received 2 or 4 doses of ipilimumab (0.1, 1, 3, or 5 mg/kg) every 28 days.	Two participants (8.3%), one each in the 0.1- and 1-mg/kg dose groups, had a decrease from baseline HIV-1 RNA of 0.85 and 1.36 log10 copies/mL. Fourteen participants (58.3%) had an increase from baseline HIV-1 RNA (mean, 0.87 log10 copies/mL; range, 0.59–1.29). Of these 14 participants, all but 1 were in the higher ipilimumab dose groups (3 or 5 mg/kg). No pattern was noted regarding change from baseline in CD4 or CD8 T cells	No serious adverse events (AEs) or dose-limiting toxicities were reported; one participant discontinued ipilimumab for an AE of grade 2 facial palsy. Twenty participants (83.3%) had ≥1 AE; all but 1 were grade 1 or 2. Eight participants (33.3%) had potentially immune-related AEs (7 had grade 1 diarrhea not requiring corticosteroids; 1 who had diarrhea also had transient antinuclear antibody positivity; 1 had grade 2 facial palsy requiring corticosteroids).

Table 1. *Clinical trials assessing the efficacy and/or safety of Immune Checkpoint Inhibitors in the treatment of chronic viral infections (continued).*

Clinical trial number (NCTID)	Study	Infection or disease	Target Inhibitory protein	Agent	Study design/ Number of participants/patient population	Clinical Outcomes	Safety Outcomes
NCT03899428	Immune Checkpoint Therapy vs Target Therapy in Reducing Serum HBsAg Levels in Patients with HBsAg+ Advanced Stage HCC	HBV	PD-L1	Durvalumab Sorafenib Lenvatinib Regorafenib Cabozantinib (Tyrosine kinase inhibitors)	The participants will receive durvalumab 1500 mg Q4W (iv infusion) or tyrosine kinase inhibitors, including sorafenib, lenvatinib, regorafenib, or cabozantinib, daily	No results posted	No results posted
NCT00703469	A Study of MDX-1106 to Treat Patients with Hepatitis C Infection (MDX1106-02)	HCV	PD-1	BMS-936558 (MDX-1106) – a fully human anti-PD-1 monoclonal immunoglobulin-G4 that blocks ligand binding	Interferon-alfa treatment-experienced patients (n=42) were randomized 5:1 to receive a single infusion of BMS-936558 (0.03, 0.1, 0.3, 1.0, 3.0 mg/kg [n=5 each] or 10 mg/kg [n=10]) or of placebo (n=7). An additional 12 HCV treatment-naïve patients were randomized to receive 10 mg/kg BMS-936558 (n=10) or placebo (n=2).	Five patients who received BMS-936558 (0.1 [n=1] or 10 mg/kg) and one placebo patient achieved the primary study endpoint of a reduction in HCV RNA ≥0.5 log10 IU/mL on at least 2 consecutive visits; 3 (10 mg/kg) achieved a >4 log10 reduction. Two patients (10 mg/kg) achieved HCV RNA below the lower limit of quantitation (25 IU/mL), one of whom (a prior null-responder) remained RNA-undetectable 1 year post-study.	One patient (10 mg/kg) experienced an asymptomatic grade 4 ALT elevation coincident with the onset of a 4-log viral load reduction. Six patients exhibited immune-related adverse events of mild-to-moderate intensity, including two cases of hyperthyroidism consistent with autoimmune thyroiditis.