A Phase 1/2, open-label, dose-escalation, and expansion study to evaluate safety, tolerability, pharmacokinetics, and therapeutic activity of GI-101 as a single agent and in combination with pembrolizumab, lenvatinib or local radiotherapy in patients with advanced or metastatic solid tumors (Keynote B59)

GI Innovation, Inc.



ONCOLOGY	Phase 1
Product Type	Bispecific fusion protein
Indication	Advanced or metastatic solid tumors
Target	CTLA-4 and IL-2Rβγ
MOA(Mechanism of Action)	GI-101 is a bispecific fusion protein containing CD80 and IL-2Rβγ. CD80 of GI-101 targets and blocks CTLA-4, and IL-2 variant selectively binds to IL-2Rβγ to expand and activation of cytotoxic T cell and NK cell.
Competitiveness	Inhibits CD80/CTLA-4 interaction Inhibits immunosuppressive function of Treg Retains CD80 expression on APCs Binding Affinity to CTLA-4 Receptors Logo Suppose Suppo
	■ Low FcγR/C1q affinity ■ No antibody or C-dependent cytotoxicity ■ Binding Affinity to IL-2 Receptor (K _D , nM)
	Substituted 2 amino acids to reduce the affinity to IL-2Rα chain Sustaineded binding to IL-2βγ receptors Substituted 2 amino acids to reduce the affinity to IL-2Rα chain IL-2Rα 49.6 (x42) 486.6 (x8) 1830 (x1.3) IL-2Rβ 2080 3951.8 1360
	 Tumor/immune cell targeting through CD80 Inhibition of regulatory T cell through CD80 Expansion and activation of cytotoxic T cell and NK cell
Development Stage	Phase 1
Route of Administration	Intravenous, Q3W