**Background**

QL301 blocks PD-1 and restores TCR signaling in a MAF reporter assay.

**Target Validation**

QL301 has a 40-fold higher affinity for PD-L1 over 4-1BB, designed for enhanced tumor accumulation. QL301 binds to HEK293 cells expressing PD-L1 or 4-1BB.

**Disclosures**

S Gu, WJ Price, J Tang, HV Tran, A Chan, AM McClain, A Kuzmats, and S Chen are current or former employees of QLSF Biopharmaceuticals, Inc. receiving salary compensation and stock options.

Y Sun, X Kang, Y Wu, Y Zhang, G Jia are current employees of QSU Pharmaceutical Co., Ltd., receiving salary compensation.

**In Vivo Activity**

Human PBMCs were stimulated with anti-CD3 (OKT3) and incubated with QL301, anti-PD-L1 or anti-4-1BB monoclonal antibodies or their combination. In the presence of PD-L1/4-1BB A431 cells, QL301 induced IL-2 and IFNγ release while anti-PD-L1 or 4-1BB antibodies alone or in combination did not.

The presence of PD-L1+/4-1BB A431 cells results in enhanced IL-2 induction. Enhanced IL-2 expression was also observed in an SEB stimulation assay in the presence of QL301, but not with anti-PD-L1 or 4-1BB monomeric or their combination.

**References**


**NHP Toxicology**

QL301 was well tolerated in a repeated dose toxicology study in rhesus monkeys, without inducing chronic elevation of AST and ALT.

**Phase I Clinical Study**

- **Ongoing.** The first patient was dosed in November of 2021. NCT05150405.
- **Objectives:** safety, tolerability, and early efficacy
- **Format:** 3+3, Q2W IV infusion, DLT period = 28 days.
- **Indications:** locally advanced, recurrent or metastatic solid tumors, or hematological tumors refractory to standard of care

**Summary**

- QL301 is a bispecific antibody that blocks PD-L1 and activates 4-1BB.
- The silenced IgG1 backbone eliminates FcγR binding and therefore prevents non-specific 4-1BB activation, ADC, and CDC.
- Activation of 4-1BB signaling via receptor cross-linking is restricted to the presence of PD-L1+/4-1BB cells.
- QL301 has robust anti-tumor efficacy in vivo.
- QL301 was well tolerated in rhesus monkeys.
- A phase 1 clinical trial is ongoing.