Dazostinag (TAK-676) alone and in combination with pembrolizumab in patients with advanced or metastatic solid tumors: Preliminary safety, pharmacokinetics/pharmacodynamics, and anti-tumor activity in a phase 1 dose-escalation study supporting a recommended dose for expansion

**Background**

- Dazostinag is a novel, small molecule, immunostimulatory (IS) “kiss of the Ribosome” (IS100) agonist, agonized for systemic delivery. It activates the innate immune system and modulates innate immunity. (Figure 1)

- Pharmacologically, dazostinag promoted inside-out and adaptive immune responses via activation of systemic, natural killer (NK), and CD8+ T cells. In vitro and, more recently, in vivo studies with pharmaceutical-grade dazostinag support a potential role for dazostinag as an immunomodulatory agent in a variety of cancer settings.

**Methods**

- Study design: In a single-arm, dose-escalation study, 98 patients were enrolled on 13 dose levels of dazostinag alone and in combination with pembrolizumab. Patients were treated in a 3+3 dose-escalation scheme.

- Pharmacokinetics: Dazostinag IV infusion over 30 minutes.

- Anti-tumor responses

**Results**

- Dose-escalation (Part 1 [n=98∗])

**Conclusions**

- Preliminary safety, pharmacokinetics/pharmacodynamics, and anti-tumor activity support the designation of the recommended dose for expansion of dazostinag 5 mg in combination with pembrolizumab.

**Disclosures**

For full conflict of interest details, please contact Dr. Anthony J. Olaszinski: Anthony.Olaszinski@tddc.org or Dr. Xin Gao: xgao@khub.org

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