**BACKGROUND**

INT230-6 is a novel intratumoral agent consisting of polyclonal (Colo), emulsifying (VHL) and a cell penetration enhancer (SMAD) that enables increased diffusion into cancer cells.

INT230-6 has demonstrated the ability to kill large tumors and induce an adaptive T-cell mediated immune response that attacks not only the injected tumor, but also non-injected tumors and unseen micrometastases. In animal models, preclinical data indicates INT230-6 increases influx of antigen presenting cells (APCs) to the tumor microenvironment and improves APCs ability to recognize expressed antigens.

The role of cytotoxic agents in augmenting the response of checkpoint inhibitors was established based on the KEYNOTE-189 trial in NSCLC. It is our aim to improve cancer treatment. New side effects associated with systemic therapies and improve patient outcomes using intratumoral INT230-6. In addition, the intratumoral injection approach has the potential to deliver the cancer and reduce greater quality and amounts of tumor specific antigens to prime the immune system.

In animal models, systemic chemotherapy limits the immune response induced by a PD-1 antibody while local delivery of potent agents potentiates activity.

We report updated safety, efficacy and biomarker data from an ongoing Phase 1b/2 clinical study at 7 major academic centers in the US and Canada, IT-01 KEYNOTE A01.

**PRECLINICAL DATA**

- **INT230-6 or control (aqueous solution of spiked) was injected with India ink in the center of a murine pancreatic tumor (BxPc3 ~1.2 cm).** Tumors were immediately imaged and excised for sectioning. Results indicated enhanced INT230-6 dispersion throughout the tumor. While the control tumors did not disperse or enter the cancer cells and mostly leaked out of the tumor.  

**DEMOGRAPHICS & EXPOSURE**

60 subjects (12 men, 7 combo with PD1) have been treated as of September 2020. PK data reflects analysis as of May 31, 2020. 

- **Most adverse events were low grade and transient.** There were no events that were dose limiting. Safety profile of Pembrolizumab combo is similar to monotherapy. 

**SAFETY**

- **Most adverse events were low grade and transient.** There were no events that were dose limiting. Safety profile of Pembrolizumab combo is similar to monotherapy.

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**RESULTS AND CONCLUSIONS**

- **INT230-6 is well tolerated as monotherapy or in combination with pembrolizumab.**
- **PK data indicate that ~95% of INT230-6 active agents are retained in the tumor.**
- Increases in activated CD8+ T-cell in the tumors.
- INT230-6 demonstrated tumor killing (increase on CT and biopsy); and, 
- Associations with 50% or greater tumor burden (recommended treatment strategy) leads to overall benefit (PD + SD) in multiple tumor types.
- Overall survival is significantly higher in subjects dosed ≥50% tumor burden vs. <50% tumor burden.