INT230-6 is a novel intratumoral agent consisting of cisplatin (CIS), vinblastine (VBL), and an adjuvant (SHAO) cell penetration enhancer (SAFORT). The SHAO is designed to improve cancer treatment by more efficiently killing tumors, presenting antigen (by more efficiently killing tumors, presenting antigen), and enhancing the immune system’s ability to recognize cancer cells. The SHAO has demonstrated the ability to substantially reduce the tumor. In contrast, the control did not disperse or enter the tumor. INT230-6 is designed to improve cancer treatment by more efficiently killing tumors, presenting antigen to activate immune system, and reducing the side effects associated with systemic therapy (T022 [BMS # CA184-592] is an open-label phase 1/2 trial in sarcoma patients that includes 2 subjects who were retreated multiple times.

## Background

INT230-6 is alone and in combination with Ipilimumab in subjects with advanced sarcomas. No evidence of clinical benefit was observed in the monotherapy cohort, however a trend towards clinical benefit and improved survival was seen in the combination cohort. This analysis was performed at the March 2021 interim data cut-off. RECIST methodology may not be a good measure of clinical benefit with INT230-6. Overall survival may be a more appropriate endpoint to assess clinical benefit in subjects that receive INT230-6.

### Phase 1

**Primary Outcome Measures for Phase 2:**

- INT230-6 alone or in combination with Ipilimumab is safe and tolerable at the highest doses assessed.
- Clinical responses were observed in all dose levels of INT230-6 in combination with Ipilimumab.

**Additional Outcome Measures for Phase 2:**

- Response rates in INT230-6 alone or in combination with Ipilimumab were higher than those previously observed (100% in INT230-6 alone and 80% in the combination).

## Dosimetry & Exposure

**Demographics & Exposure:**

- INT230-6 or control (aqueous cisplatin solution) was injected with index risk for the series of a monocentric tumor.
- Demographics were similar in subjects enrolled in monotherapy and combination arms.
- INT230-6 (0.75 mg/VBL) injections were given at 48-72 hour intervals, 14-34 weeks post-dose.
- Males were enrolled as of April 1 2021.

## Efficacy

**REGAIN methodology may not be a good measure of clinical benefit with INT230-6 when driven by tumor burden or RECIST methodology may not be a good measure of clinical benefit with INT230-6.**

### Safety

- The exploratory analysis of dose-response to tumor burden showed that 100% of subjects receiving INT230-6 had a CR at 30-60 days. While subjects that received 0-50% of their total tumor burden reached a CR at 30-60 days. The exploratory analysis of dose-response to tumor burden showed no further improvement in overall survival.

## Conclusions

- INT230-6 is well tolerated as monotherapy and in combination with Ipilimumab in a heterogeneous group of sarcoma patients.
- Clinical responses were observed in all dose levels of INT230-6 in combination with Ipilimumab.
- RECIST methodology may not be a good measure of clinical benefit with INT230-6. Overall survival may be a more appropriate endpoint to assess clinical benefit in subjects that receive INT230-6.

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**Figure 1:** Boxplot showing the ratio of Ki67+ cells in uninjected tumors compared to injected tumors in subjects treated with INT230-6 or control. (Each line is an uninjected tumor in a subject).

**Figure 2:** Comparison of overall survival (OS) and progression-free survival (PFS) in INT230-6 group. (Each line is a subject treated with INT230-6).

**Figure 3:** Time from first dose (Days)

**Figure 4:** Time from first dose (Days)

**Figure 5:** Time from first dose (Days)

**Figure 6:** Time from first dose (Days)

**Figure 7:** Time from first dose (Days)

**Figure 8:** Time from first dose (Days)

**Figure 9:** Time from first dose (Days)