2022 ASCO® ANNUAL MEETING

Intratumoral INT230-6 causes tumor necrosis and promotes a systemic immune response; results from a multi-center Phase 1/2 study of solid tumors with and without pembrolizumab (PEM) [Intensity Therapeutics IT-01; Merck KEYNOTE-A10]

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Developmental Therapeutics—Immunotherapy

Abstract Number: 2520; Poster: 176

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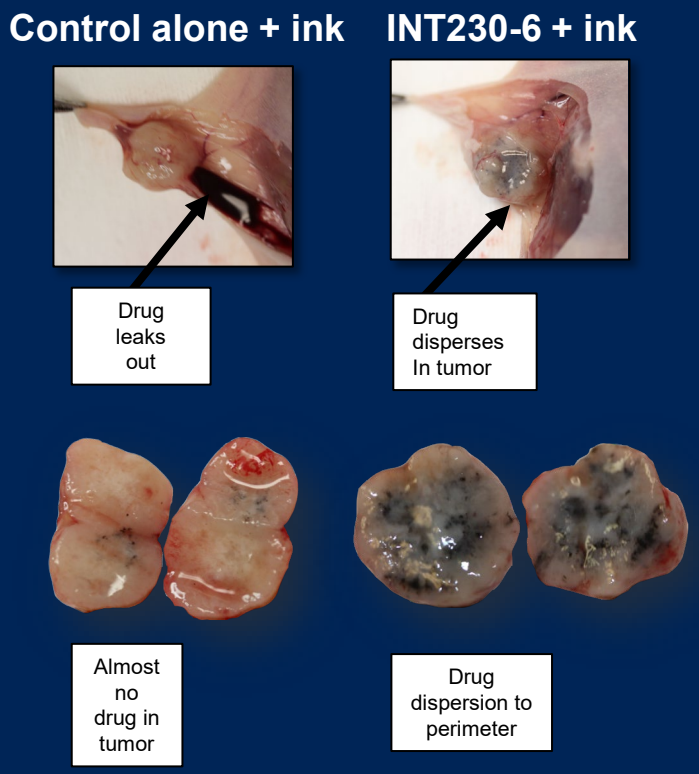
Background

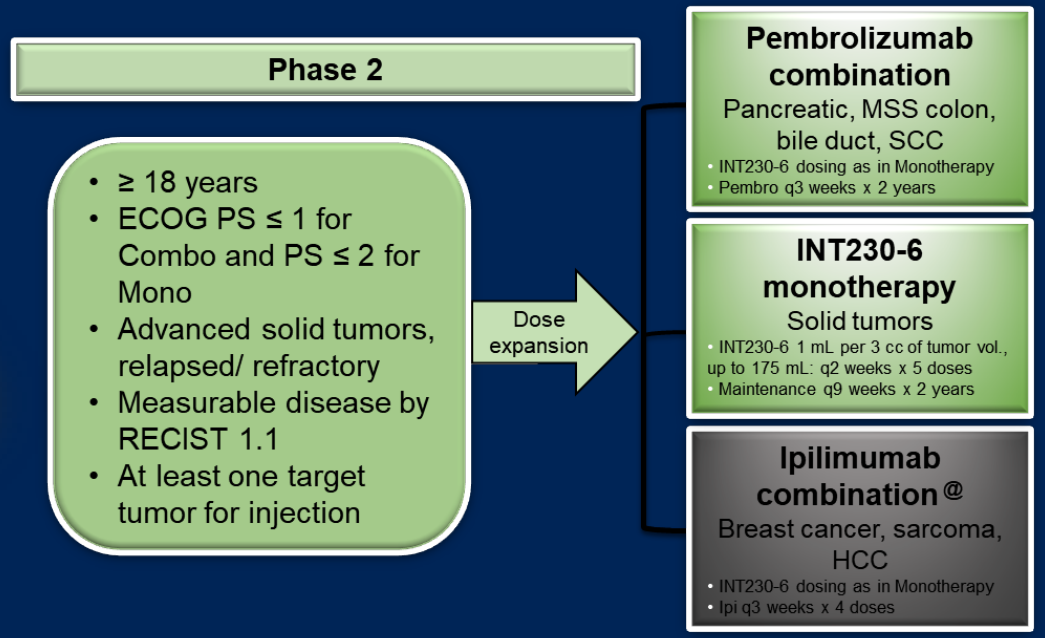
INT230-6: designed for intratumoral (IT); comprised of fixed ratio amphiphilic dispersion excipient, SHAO (10 mg/mL), Cisplatin (0.5 mg/mL,) Vinblastine (0.1 mg/mL)

Murine model of dispersion



Control: cisplatin in saline

CLINICAL STUDY DESIGN



Demographics	Mono N=61	PEM combo N=30
Age (median, range)	60.7 (35-84)	65.3 (47 – 86)
Gender	50% male	60% male
ECOG	0 (30%), 1 (62%)	0 (23%), 1 (77%)
Median # of prior Therapies (range) / % prior Pt / % prior PD-1	**4 (0-10) 48%/48%**	**3 (1-10) 77%/48%**
Overall # of tumors injected (% deep)	469 (53% deep)	164 (65% deep)
# of cancer types treated	19 (>50% sarc., BC, melanoma, ovarian)	7 (>70% Panc, CRC, Biliary, TNBC

Data as of April 1, 2022

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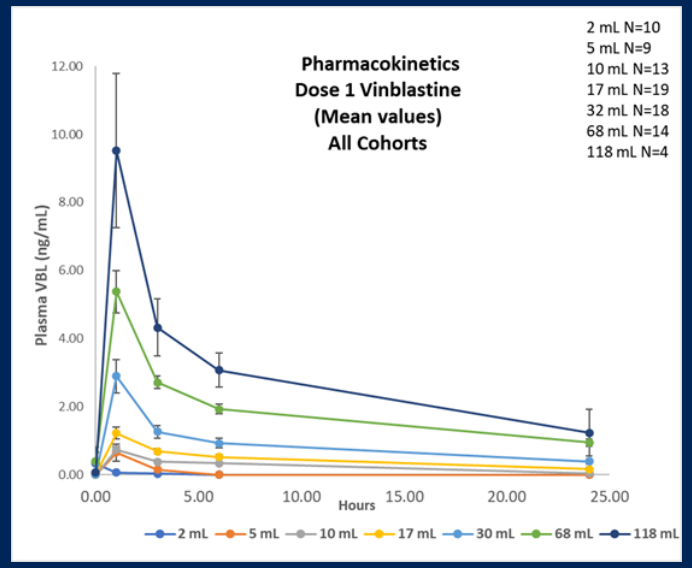
Pharmacokinetics, Safety, Efficacy



>95% of the active agents remains in the tumor relative to IV dosing

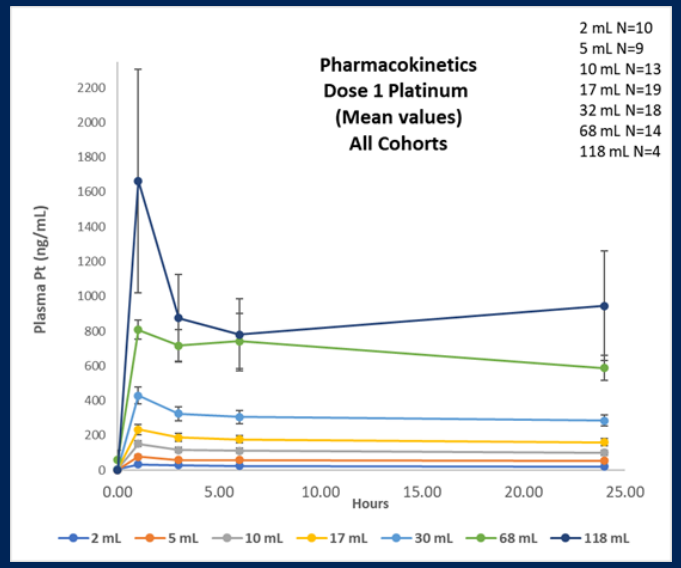
Cisplatin not measured only Pt metal (non-toxic)

Data as of April 1, 2022

	INT230-6 (N=63)	INT230-6 + PEM (N=30) [3]
No. patients having:		
at least 1 relTRAE	54 (85.7%)	23 (76.7%)
Grade 3 relTRAEs	7 (11.1%)	4 (13.3%)
Grade 4 or 5	0 (0%)	1* (3.3%)

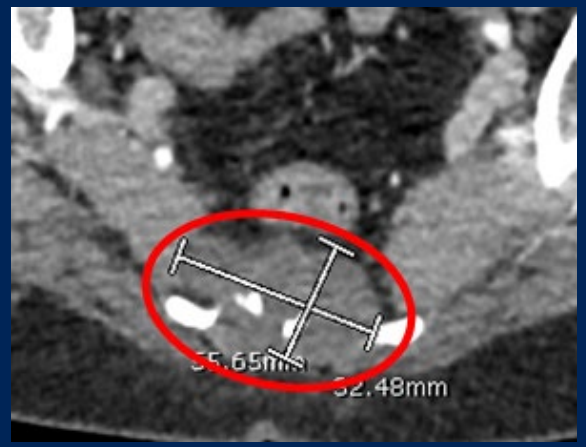
TRAEs were mainly local tumor pain, fatigue, nausea, vomiting
Combo: 4 low grad drug related immune adverse events.

* Neutrophil decrease that resolved.

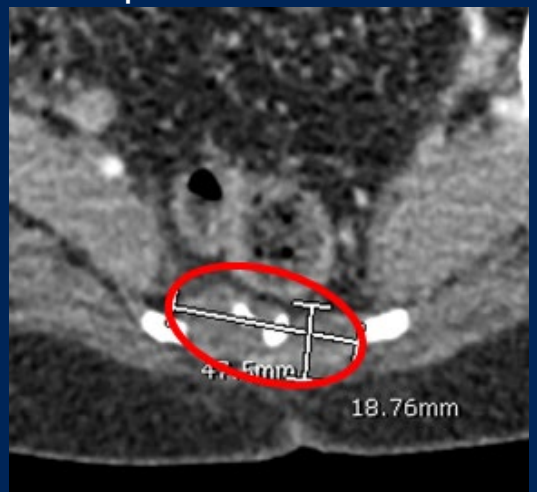


Monotherapy chordoma subject

pre dose: 55.65 x 32.48



1st scan post treatment: 47.5 x 18.78



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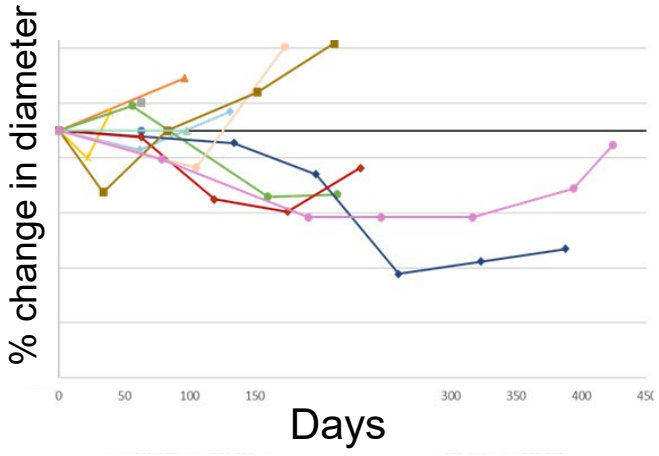
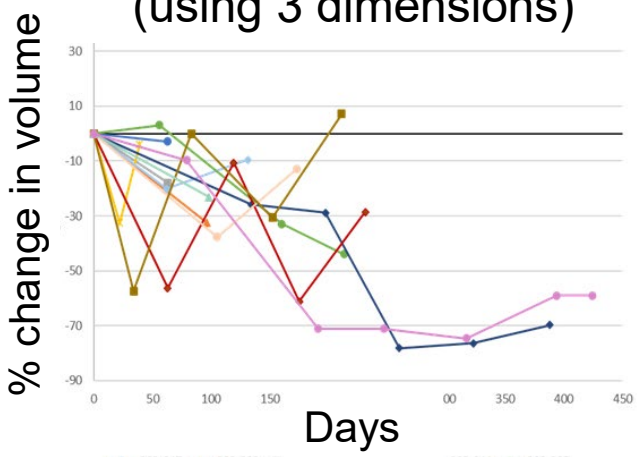
Efficacy: Phase 1/2

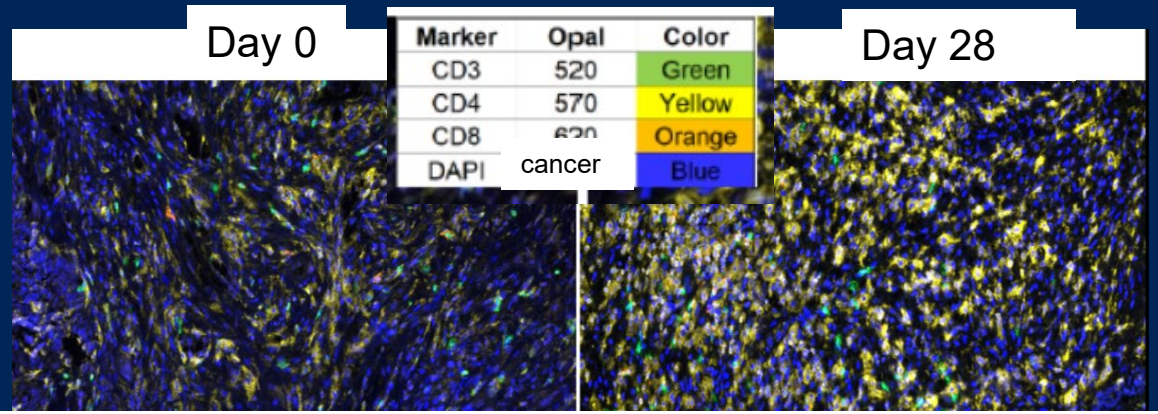
Change in Longest Diameter



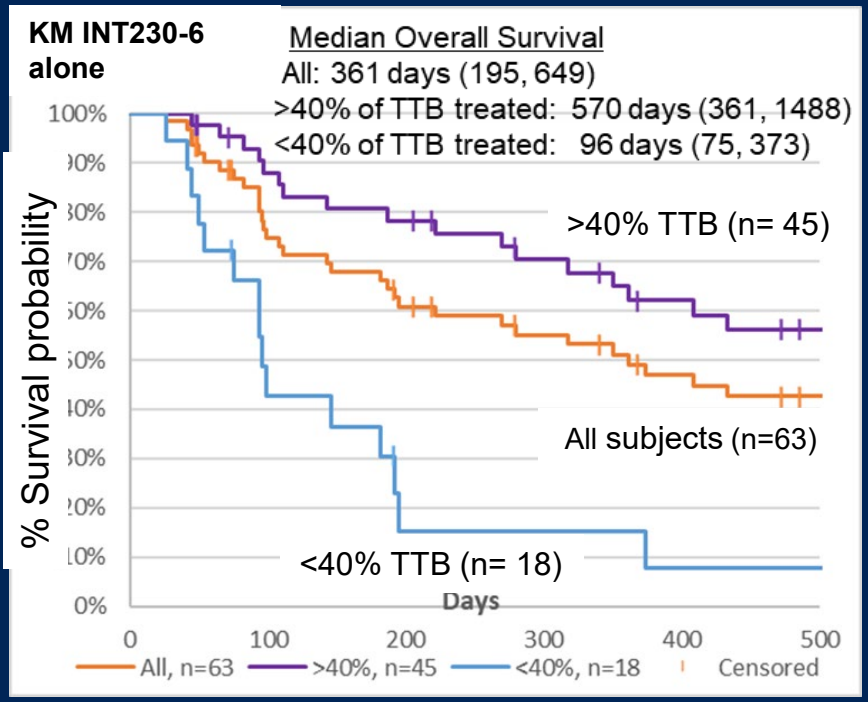
Change in Volume (using 3 dimensions)



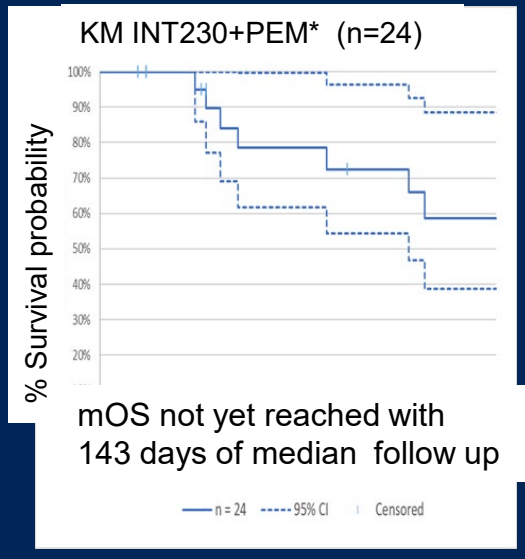
The lack of correlation between diameter and volume indicates that RECIST may be unreliable for IT INT230-6 as a metric of efficacy



Immune influx pre to post 2 doses of monotherapy (ovarian cancer)



An exploratory analysis of dose relative to a subject's incoming total tumor burden (TTB) was performed.



Monotherapy: 19 different cancers
DCR >50 days: 47% (N=49)
Data as of April 1, 2022

Combination: 7 cancer types primarily; PC, CRC, Biliary, TNBC
DCR > 50 days: 33.3% (N=15)

* Six subjects were removed from the combo efficacy analysis after when a review showed these subjects did not meet all required enrollment inclusion criteria.

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Conclusions

- INT230-6 is well tolerated as monotherapy and in combination with pembrolizumab.
- INT230-6 drugs are retained in the tumor and demonstrate direct tumor killing in injected lesions.
- IHC results in injected lesions indicate dosing INT230-6 activates a T-cell mediated immune response. *Uninjected tumor regression (previously reported SITC 2021 abstract 501) also indicates systemic immune response*
- Data suggests that INT230-6 prolongs survival compared to historical data in basket studies.
- An exploratory analysis suggests survival for monotherapy subjects receiving INT230-6 dose to ≥40% of their TTB compares favorably to the <40% group; though sample size is small
- Data is encouraging; randomized controlled studies in an earlier line population in a single cancer type would be needed to assess efficacy for the combination with PEM or INT230-6 alone

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