

May 20, 2020



Intensity Therapeutics' Abstract (#3016) Selected for Oral Presentation as Part of a Poster Discussion Session at ASCO 2020

- Presentation reports safety and efficacy results of INT230-6 administered alone and in combination with pembrolizumab (Keynote A10 study); safety of combination was comparable to INT230-6 monotherapy
- Following dosing INT230-6 alone, 13 patients had stable disease for greater than 6 months and 10 subjects had regression of uninjected tumors (abscopal effects)

WESTPORT, Conn.--(BUSINESS WIRE)-- [Intensity Therapeutics, Inc.](https://www.intensitytherapeutics.com), a clinical-stage biotechnology company pioneering a novel, immune-based drug approach to treat solid tumor cancers through direct tumor injection, today announced that data highlighting the safety and efficacy results from the Company's clinical trial of lead product candidate, INT230-6 dose alone and in combination with pembrolizumab, will be presented at the American Society of Clinical Oncology (ASCO) Annual Meeting, as part of an oral discussion session. The 2020 ASCO conference is being held virtually from May 29 to May 31, 2020.

Details of the presentations are as follows:

Title: Pharmacodynamic, safety and efficacy results of a phase I/II trial of intratumoral INT230-6 alone (IT-01) or in combination with pembrolizumab (PEM) (Keynote A10) in patients with advanced solid tumors.

Abstract Number: 3016

Discussion Date/Time: Friday May 29, 2020 from 8AM to 11AM ET live, then on demand

Expert Discussing the Results: Stephanie L. Goff, M.D., Associate Research Physician, Center for Cancer Research, National Cancer Institute, Bethesda MD.

Poster Date/Time: Beginning Friday, 8AM May 29 ET

Poster Session: Developmental Immunotherapy and Tumor Immunobiology

Poster Presenter: Jacob Stephen Thomas, MD, Assistant Professor of Clinical Medicine, University of Southern California.

Methods: Patients with advanced solid tumors that progressed on standard treatment were enrolled. INT230-6 dose was set by the tumor's volume. Escalation occurred by increasing number of tumors injected, loading per tumor and total dose. INT230-6 was injected once every 2 weeks up to a total of 5 doses with an option for retreatment. In the Keynote A10 arm PEM (200mg IV Q3weeks) was combined with the INT230-6 regimen. In addition to pharmacokinetic (PK) evaluation, pharmacodynamics was assessed by measuring immune subsets via flow cytometry of peripheral blood and multiplex IHC of tumor samples.

Results: 52 patients (18 unique cancer types) were enrolled in the monotherapy arm and 7 patients (5 unique tumor types) in the PEM combination arm (59 total). Subjects had received a median of 3 prior treatments. Doses from 0.3 ml up to 160 ml of INT230-6 (80 mg

CIS and 16mg of VIN) were injected. Over 200 injections into deep tumors have occurred. PK results indicate ~95% of the drugs are retained in the injected tumors when compared to historical IV dosing. The most frequent related adverse events for the INT230-6 alone treatment were pain at injected site (50%), fatigue (35%) and nausea (33%). There were 2 drug related SAE's (both pain). No events limited dosing.

In the Keynote A10 combination arm INT230-6 injections were administered only into superficially palpable tumors. There were similar types and severity of events due to injections with no treatment related SAE's. The most common side effect was localized pain (71.4%) a rate similar to dosing of INT230-6 alone into superficial tumors. There were no immune related adverse events (irAE) reported during the two-months of combination dosing. The study steering committee approved initiating testing of the combination of PEM and INT230-6 in four phase 2 cohorts enrolling patients with MSI stable colon, pancreatic, bile duct cancers and PD-1 refractory squamous cell carcinoma.

Efficacy: INT230-6 is dosed per volume tumor and doses are set for each patient's level of disease. Enrolled subjects' tumor burden varied from 2 to 11,000 cm³. Use of INT230-6 for two months as monotherapy resulted in thirteen (13) highly refractory patients having disease stabilization for more than 6 months. Some subjects' tumors increase from baseline, then regress on subsequent scans (potential pseudo progression). Ten (10) patients showed some size reduction of one or more non-injected lesions in lymph nodes, liver, lung, perineum, and retroperitoneal areas (abscopal effects to visceral lesions). Blood and tissue biomarkers suggest increases in immune activation of CD4 and CD8 T cells. Analysis of dose response relationship is ongoing. However, a minimum threshold of dose per volume that was shown to saturate tumors in preclinical models appears to be relevant for responses in humans.

About INT230-6

[INT230-6](#), Intensity's lead proprietary product candidate, is designed for direct intratumoral injection. INT230-6 was discovered using Intensity's proprietary DfuseRxSM technology platform. The drug is comprised of two proven, potent anti-cancer agents, cisplatin and vinblastine, and a penetration enhancer molecule that helps disperse the drugs throughout tumors for diffusion into cancer cells. In preclinical studies, INT230-6 eradicated tumors by a combination of direct tumor killing, releasing tumor antigens and recruitment of immune cells to the tumor. Results generated by the National Cancer Institute (NCI) showed treatment with INT230-6 in *in vivo* models of severe cancer resulted in substantial improvement in overall survival compared to standard therapies. Further, INT230-6 provided complete responses in animals with long-term protection from multiple re-challenges of the initial cancer and resistance to other cancers. The NCI and Intensity's collaborative research, [published in July 2019 in the Journal Oncolmunology](#) showed strong synergy when INT230-6 was combined with anti-PD-1 and anti-CTLA-4 antibodies. INT230-6 is being evaluated in a Phase 1/2 clinical study ([NCT03058289](#)) in patients with various advanced solid tumors. There have been no dose limiting adverse events observed in patients to date, even when dosing into deep tumors in the lung and liver. Several patients demonstrated tumor shrinkage, symptomatic improvement, and evidence of cancer cell death and immune cell activation on tumor biopsy.

About Intensity Therapeutics

Intensity Therapeutics, Inc. is a privately held, clinical-stage biotechnology company pioneering a new immune-based approach to treat solid tumor cancers. Intensity leverages its DfuseRxSM technology platform to create new, proprietary drug formulations that, following direct injection, rapidly disperse throughout a tumor and diffuse therapeutic agents into cancer cells. Intensity's product candidates have the potential to induce an adaptive immune response that not only attacks the injected tumor, but also non-injected tumors. The Company executed a Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute's (NCI) Vaccine Branch in 2014. The Company is collaborating with Merck Sharpe & Dohme (Merck) to evaluate the combination of INT230-6, Intensity's lead product candidate, and KEYTRUDA[®] (pembrolizumab), Merck's anti-PD-1 (programmed death receptor-1) therapy, in patients with advanced solid malignancies. The Company is also collaborating with Bristol-Myers Squibb (BMS) to evaluate the clinical combination of the Company's lead product, INT230-6, with BMS's anti-CTLA-4 antibody, Yervoy (ipilimumab), in patients with advanced solid malignancies. For more information, please visit www.intensitytherapeutics.com and follow us on Twitter [@IntensityInc](https://twitter.com/IntensityInc).

Forward Looking Statements

This press release contains forward-looking statements regarding Intensity Therapeutics' plans, future operations and objectives. Such statements involve known and unknown risks, uncertainties and other factors that may cause actual performance or achievements to be materially different from those currently anticipated. These forward-looking statements include, among other things, statements about the initiation and timing of future clinical trials.

View source version on businesswire.com:

<https://www.businesswire.com/news/home/20200520005070/en/>

Investors:

Kerry Conlin

Stern Investor Relations

212-698-8685

kerry.conlin@sternir.com

Media:

Rebecca Drain

Intensity Therapeutics

203-293-4287

rdrain@intensitytherapeutics.com

Source: Intensity Therapeutics, Inc.