June 3, 2022

Intensity Therapeutics' INT230-6 Demonstrates Increased Survival as Either Monotherapy or in Combination with Pembrolizumab in Patients with Relapsed, Refractory, Metastatic Solid Tumor Cancers

Data Show INT230-6 is Well Tolerated and Elicits Both Direct Tumor Killing and Immune Activating Effects in a Variety of Solid Tumors

Patients Receiving a Dose of INT230-6 Alone (n=63) had a Median Overall Survival (mOS) of 361 Days

Combined with Pembrolizumab in a Population Consisting of Patients with Primarily Pancreatic, Bile Duct, Colorectal, and Triple Negative Breast Cancer (n=24), the mOS has not Been Reached with 143 Days of Median Follow Up

Full Set of Results to be Presented at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting in Both Poster and Podium Discussion Sessions

WESTPORT, Conn., June 3, 2022 /PRNewswire/ -- **Intensity Therapeutics, Inc.** ("Intensity"), a clinical-stage biotechnology company focused on the discovery and development of proprietary, novel immune-based intratumoral cancer therapies designed to kill tumors and increase immune system recognition of cancers, announced that data from its ongoing phase 1/2 clinical trial demonstrating the efficacy and tolerability of INT230-6, either as monotherapy or in combination with pembrolizumab in patients with relapsed, refractory and metastatic solid tumors, will be presented on June 5, at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting being held in Chicago and virtually from June 3-7, 2022.

Abstract Title: *Effect of intratumoral INT230-6 on tumor necrosis and promotion of a systemic immune response: Results from a multicenter phase 1/2 study of solid tumors with and without pembrolizumab (PEM) [Intensity IT-01; Merck KEYNOTE-A10].*
Presenter/First Author: Jacob Stephen Thomas, MD
Session Type/Title: Poster Discussion Session/Developmental Therapeutics—Immunotherapy
Poster Discussion Session Date and Time: Sunday, June 5, 2022, 12:30 PM – 2:00 PM EDT
Location: In-Person & Live Stream | Hall D2
Abstract Number: 2520

Poster: 176 (9:00 am to 12:00 am EDT)

Copies of the presentation materials will also be available on the Intensity Therapeutics website on the publications and posters page, following completion of the live presentation.

"Despite significant innovation in immunotherapeutic and checkpoint inhibitor therapy approaches for cancer treatment, patients with metastatic and refractory disease continue to have poor survival and response rates remain low in most tumor types," stated Jacob S. Thomas, M.D., Assistant Professor of Clinical Medicine, Keck School of Medicine of the University of Southern California (USC) and an oncologist at USC Norris Comprehensive Cancer Center, part of Keck Medicine of USC. "The active drug agents of INT230-6 remain in the tumor following injection and cause some cancer cell death and tumor shrinkage, as suggested by this study. This effect appears to have some positive impact on the tumor immune microenvironment with increasing levels of CD4+ and CD8+ T-cells. While the analysis is exploratory, survival seems to be extended with increased dosing, relative to incoming tumor burden. That said, using the tumor diffusive product, INT230-6, appears to be a new approach in metastatic disease alone and in combination with pembrolizumab."

"We are excited to have had our abstract, 2520, selected for both a poster and a podium discussion at ASCO this year," stated Lewis H. Bender, President and Chief Executive Officer of Intensity Therapeutics. "The biomarker and clinical data generated in this study provide strong proof-of-concept evidence for our approach and underscore the potential of this new, potential treatment. As recent data readout events in the field of oncology have shown, there remains a high unmet need for novel therapeutic approaches. With that in mind, we are planning for later stage studies in order to advance INT230-6 toward potential, future commercialization."

The presentations report the mOS and disease control rate (DCR: CR + PD + SD per the Response Evaluation Criteria in Solid Tumors (RECIST)). However, RECIST metrics (sum of longest diameters) to gauge efficacy are only validated for use with systemically delivered therapies. Data suggests that RECIST is inadequate with intratumorally (IT) administered INT230-6. In this study, RECIST response is complicated by the amount of INT230-6 repeatedly injected and retained in the tumors prior to the first radiographic scan. Biomarker findings suggest immune infiltration into the tumor microenvironment that is occurring could also increase tumor size. Additionally, results in a neoadjuvant setting (see ASCO 2022 Abstract Number: 605, Poster: 376) show a single injection of INT230-6 can cause near complete necrosis of the tumor without change in diameter. Finally, data reported shows that tumor volume, when calculated using all three dimensions, can be decreasing, while the longest diameter of the corresponding tumor is increasing or stable. The lack of correlation between longest diameter and actual volume illustrates that RECIST may be unreliable for use as an efficacy endpoint for IT INT230-6.

The presentations report results from 93 patients on the preliminary efficacy and safety of either INT230-6 alone (n=63) or in combination with Merck's anti-PD-1 therapy, pembrolizumab (n=30) from Intensity's ongoing open-label phase 1/2 clinical trial. Patients enrolled had over 20 different types of relapsed, refractory metastatic solid tumors and progressed following a median of four prior therapies (monotherapy) and three prior therapies (combination). INT230-6 was administered intratumorally every two weeks for five doses either alone or with 200 mg pembrolizumab dosed every three weeks. Using RECIST criteria, the DCR rate >50 days for monotherapy was 47%; however, the INT230-6 in

combination with pembrolizumab DCR was 33.3%.

Survival in phase 1/2 studies can be predicted using the Royal Marsden Hospital Index (RMHI), a validated score that uses 3 incoming enrollment criteria (number of metastatic sites, albumin concentrations, and lactose dehydrogenase levels) to assess a patient's likelihood of survival (*Cancer* 2012;118:1422–8). The mOS of historical basket studies, INT230-6 alone all subjects, INT230-6 relative to the subject's reported incoming total tumor burden (TTB), are shown in the table below. The INT230-6 all patients and those receiving a cumulative dose ≥40% of TTB compare favorable to historical phase 1/2 data (Chau et al. BMC Cancer 10/2011) where the mOS typically is 3 to 6 months for patients with one or more risk factors in mixed cancer populations.

Phase 1/2 studies	Historical (Chau)	INT230-6 all	INT230-6 <40% TTB	INT230-6 >40% TTB
Median OS	90 to 180 days	361 days	96 days	570 days
Confidence Interval	-	(195, 649)	(75, 373)	(361, 1488)
Sample size		63	18	45

The mOS of the INT230-6 with pembrolizumab combination arm has not been reached with a median follow up of 143 days (n=24). These data are still maturing. Six patients were not included in the combination efficacy analysis after results obtained following enrollment showed that the six patients had not met all required inclusion criteria.

The pharmacokinetic profiles for the individual drug components of INT230-6 (cisplatin and vinblastine sulfate) were measured and indicate that more than 95% of the active agents remain in the tumor. INT230-6, either as monotherapy or in combination with pembrolizumab, was well tolerated. The most common treatment related adverse events (TRAEs) were localized tumor-related pain, nausea, fatigue, and vomiting. TRAEs were mild to moderate with 11% grade 3 in the monotherapy group and 13% in the combination with pembrolizumab. There was one Grade 4 (neutrophil decline that resolved) and no grade 5 TRAEs.

About INT230-6

INT230-6, Intensity's lead proprietary investigational product candidate, is designed for direct intratumoral injection. INT230-6 was discovered using Intensity's proprietary DfuseRx℠ technology platform. The drug is composed of two proven, potent anti-cancer agents, cisplatin and vinblastine, and a penetration enhancer molecule that helps disperse potent cytotoxic drugs throughout tumors for diffusion into cancer cells. These agents remain in the tumor resulting in a favorable safety profile. In addition to local disease control, direct killing of the tumor by INT230-6 releases a bolus of neoantigens specific to the patient's malignancy, leading to engagement of the immune system and systemic anti-tumor effects. Importantly, these effects are mediated without the immunosuppression of concomitant systemic chemotherapy.

About Intensity Therapeutics' Clinical Studies

INT230-6 is currently being evaluated in several phase 2 cohorts (NCT03058289) in patients with various advanced solid tumors as part of Study IT-01. In 2019, the Company signed a clinical collaboration agreement 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 pancreatic, colon, squamous cell and bile duct malignancies. In 2020, the Company executed a clinical collaboration agreement with Bristol-Myers Squibb to evaluate the combination INT230-6 with Bristol-Myers Squibb's anti-CTLA-4 antibody, Yervoy® (ipilimumab), in patients with advanced liver, breast and sarcoma cancers. Intensity is managing the individual combination arms separately with each respective partner via a joint development committee. In 2021 the Company executed agreements with the Ottawa Hospital Research Institute (OHRI) and the Ontario Institute of Cancer Research (OICR) to study INT230-6 in a randomized controlled neoadjuvant phase 2 study in women with early stage breast cancer (the INVINCIBLE study) (NCT04781725).

About Intensity Therapeutics
Intensity Therapeutics, Inc. is a clinical-stage biotechnology company pioneering a new immune-based approach to treat solid tumor cancers. Intensity leverages its DfuseRx℠ 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. In addition to its clinical collaborations, the Company executed a Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute's (NCI) Vaccine Branch in 2014. For more information, please visit www.intensitytherapeutics.com and follow the Company on Twitter @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.

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