November 11, 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

Patients Receiving INT230-6 Alone (n=64) had a Median Overall Survival (mOS) of 373 Days

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

Combined with Pembrolizumab in a Population Consisting of Heavily Pretreated Patients with Primarily Pancreatic, Bile Duct, Colorectal, and Triple Negative Breast Cancer (n=24), Whose Cancer Progressed, the mOS was 205 Days

Full Set of Results to be Presented at the 2022 Society for Immunotherapy of Cancer (SITC) Annual Meeting

WESTPORT, Conn., Nov. 11, 2022 /PRNewswire/ -- **Intensity Therapeutics, Inc.** ("Intensity"), a clinical-stage biotechnology company focused on the discovery and development of proprietary, novel immune-based intratumoral 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 today at the 2022 Society for Immunotherapy of Cancer (SITC) Annual Meeting being held in Boston and virtually November 8-12, 2022.

Abstract Number: 710
Title: *Safety and Survival Results From a Phase 1/2 Trial of Intratumoral Agent INT230-6 (cisplatin vinblastine) Induces Immunological Cancer Cell Death Alone or With Pembrolizumab in Patients with Refractory, Metastatic Cancers*
First Author: Jacob Stephen Thomas, M.D.
Session Date and Time: Friday, November 11, 2022, 9:00 am - 9:00 pm EST
Location: Boston Convention Center Hall C; In-Person & On Demand

Copies of the presentation materials will be available on the Intensity Therapeutics website on the publications and posters page.

"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 many tumor types," stated Jacob S. Thomas, M.D., Assistant Professor of Clinical Medicine, Keck School of Medicine of USC at the University of Southern California (USC) and an oncologist at USC's 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 and refractory disease alone and in combination with pembrolizumab."

"We continue to see exciting safety and efficacy data with INT230-6 in patients with metastatic and refractory disease," stated Lewis H. Bender, President and Chief Executive Officer of Intensity Therapeutics. "The ability of our drug to both cause necrosis and induce the influx of immune cells into tumors provides strong proof-of-concept evidence for our immunological cell death mechanism and underscores the potential of this novel, new treatment. There remains a high unmet need for improved therapeutic approaches for many solid tumors. With that in mind, we are planning later stage studies to advance INT230-6 toward potential, future commercialization."

The presentation reports the mOS and disease control rate (DCR: CR + PD + SD per the Response Evaluation Criteria in Solid Tumors (RECIST)). As previously reported, RECIST metrics (sum of longest diameters) to gauge efficacy are only validated for use with systemically delivered therapies. Significant data generated and previously reported suggests that RECIST is inadequate as a measure of efficacy for the highly-absorbed intratumorally (IT) administered INT230-6.

The presentation reports results from 94 patients on the preliminary efficacy and safety of either INT230-6 alone (n=64) 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 50.9%; INT230-6 in combination with pembrolizumab showed a DCR of 47.6%.

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	373 days	96 days	570 days
Confidence Interval	-	(221, 649)	(75, 373)	(361, 1621)
Sample size		64	17	47

The mOS of the INT230-6 in combination with pembrolizumab arm was 205 days (n=24). Six patients were not included in the combination efficacy analysis after results obtained following enrollment showed those subjects 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 20% in combination with pembrolizumab. There was one Grade 4 (neutrophil decline that resolved) in the combination arm that resolved quickly 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 (SHAO) 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 (NCT 03058289) 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) (NCT 04781725).

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 partnerships with Merck and Bristol-Myers Squibb, 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

Certain statements in this press release may constitute "forward-looking statements" within the meaning of the United States Private Securities Litigation Reform Act of 1995, as amended to date. These statements include, but are not limited to, statements relating to the expected trading commencement and closing dates. We have based these forward-looking statements on our current expectations and projections about future events, nevertheless, actual results or events could differ materially from the plans, intentions and expectations disclosed in, or implied by, the forward-looking statements we make. These risks and uncertainties, many of which are beyond our control, include: the risk that the initial public offering of common stock may not close, and other risks described in the section entitled "Risk Factors" in the prospectus, which can be obtained on the SEC website at www.sec.gov. Readers are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date on which they are made and reflect management's current estimates, projections, expectations and beliefs. The company does not plan to update any such forward-looking statements and expressly disclaims any duty to update the information contained in this press release except as required by law.

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