November 11, 2020

Intensity Therapeutics Reports Favorable Data of INT230-6 from the Ongoing Phase 1/2 Study (IT-01/KEYNOTE A10) in Patients with Advanced Solid Tumors at SITC 2020 (Abstract 411)

- Kaplan Meier analysis shows a 79.1% survival probability estimate at 1 year when dosing a volume of INT230-6 of ≥50% of the baseline tumor burden
- Several subjects had regression in untreated tumors with INT230-6 monotherapy
- Increased infiltration of activated CD4 and CD8 T-cells observed in tumors
- Safety remains favorable, majority low grade adverse events with no additional safety signals seen when dosing INT230-6 in combination pembrolizumab

WESTPORT, Conn.--(BUSINESS WIRE)-- Intensity Therapeutics, Inc., a clinical-stage biotechnology company developing proprietary intratumoral immunotherapy products to kill tumors and increase immune system recognition of cancers, today announced new efficacy and safety data from the ongoing Phase 1/2 clinical study of INT230-6, the Company's lead product candidate. These data will be shared November 11th and 13th in a poster presentation at the Society for Immunotherapy of Cancer's (SITC) 35th Annual Meeting.

"The preliminary data generated supports the hypothesis that dosing a substantial proportion of patient's tumor burden with INT230-6 may cause enough tumor killing and immune activation to provide the patient with extended survival," said poster presenter and study investigator Anthony El-Khoueiry, MD, Associate Professor of Clinical Medicine, Keck School of Medicine of the University of Southern California and Director of the phase I program at the USC Norris Comprehensive Cancer Center. "The emerging data shows that the treatment is well tolerated with no patients having to discontinue therapy due to treatment-related toxicities. Observations of tumor shrinkage, tumor necrosis and the regression of uninjected lesions in several patients provide early signs of anti-cancer efficacy. We are looking forward to the emerging data in combination with checkpoint inhibitors."

"We are excited to share this interim clinical data of intratumoral INT230-6. There have been over 225 deep tumor injections without complications to date including dosing directly into the lung, liver, and pancreas. We and our investigators are increasing our understanding of a suitable dosing regimen needed to improve patient outcomes," said Ian B. Walters, MD, Chief Medical Officer of Intensity Therapeutics. "Having the ability to safely reduce tumor cell burden and prime an immune response is an important advance in our ability to manage refractory cancers that often are non-immunogenic. We look forward to evaluating the combination of INT230-6 with Keytruda® as well as with Yervoy® in our on-going phase 2

studies and to advancing INT230-6 into registrational studies as soon as possible."

The presentation includes survival analysis on heavily pretreated patients with 19 different types of advanced or metastatic solid tumors. Enrolled patients progressed following a median of three prior lines of therapy (range 0 to 10) including all approved, appropriate therapies for a subject's particular cancer. Patients enrolled into the study's cohorts with random baseline tumor burden ranging from less than 2 cm^3 to greater than 11,000 cm^3. Four subjects who had total tumor burden below 2 cm^3 or above 1300 cm^3 were censored from the survival analysis. Thirty (30) patients received a cumulative dose volume of INT230-6 greater than or equal to 50% of their total tumor burden (target dose). Twenty-six (26) patients received a total dose of INT230-6 to less than 50% of their total tumor burden. These two groups were reasonably balanced with respect to age, gender, ethnicity, tumor types and mean baseline tumor burden (243 cm^3 vs. 270 cm^3 ($p = 0.7045$)). Other prognostic factors have yet to be evaluated. Median survival was 162 days for patients receiving cumulative doses of INT230-6 less than 50% of their tumor burden. Whereas median survival for subjects receiving cumulative doses of INT230-6 greater than or equal to 50% of their tumor burden has not yet been reached after a median follow-up of over 385 days. Cox Model analysis shows a hazard ratio of 0.272 (95% Confidence Interval; 0.152, 0.592).

A pharmacokinetic (PK) analysis revealed greater than 95% of the active drugs (cisplatin (CIS) and vinblastine (VIN)) remain in the tumor. There was no clinically meaningful difference in the rate or severity of treatment emergent adverse events reported between the monotherapy and pembrolizumab combination arms. Only 12.7% of subjects in the monotherapy cohorts and 14.7% in the KEYNOTE A10 pembrolizumab cohort had treatment emergent grade 3 adverse events. There have been no grade 4 or 5 treatment emergent adverse events and no events that were dose limiting.

Local delivery of INT230-6 as monotherapy into tumors induced an immune response with increases of activated CD4+ and CD8+ T-cells in the tumor without any immune-related adverse events. These clinical results are consistent with immune findings from *in vivo* models.

Presentation Information

Title: Intratumoral INT230-6 increases tumor T cell infiltration and results in durable benefit as monotherapy and in combination with pembrolizumab in refractory patients.

Abstract Number: 411

Date/Time: Wednesday, November 11, 5:15-5:45 p.m. EST and Friday, November 13 4:40-5:10 p.m. EST. Additionally, posters will remain on display in the virtual poster hall from Monday, November 9 to Thursday, December 31.

Session: Clinical Trial In Progress

Presenter: Anthony El-Khoueiry, MD, Associate Professor of Clinical Medicine, University of Southern California's Keck School of Medicine

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^{SM} 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, release of tumor antigens and recruitment of immune cells to the tumor. Results generated by both the Company and 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 Company's research published in the International Journal of Molecular Sciencesearlier this year and joint research with the NCI published in July 2019 in the Journal OncoImmunology as part of Intensity's awarded CRADA , also showed strong synergy when INT230-6 was combined with anti-PD-1 and anti-CTLA-4 antibodies.

Clinical Studies

INT230-6 is currently being evaluated in Phase 2 clinical studies (NCT03058289) in patients with various advanced solid tumors. Phase 1 dose escalation cohorts completed in 2020. There have been no dose limiting adverse events observed in patients to date, even when dosing into deep tumors in the lung, pancreas or liver. In 2019, the Company executed 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 solid malignancies. In 2020, the Company executed a clinical collaboration agreement with Bristol Myers Squibb (BMS) to evaluate the combination of the Company's lead product, INT230-6, with BMS's anti-CTLA-4 antibody, Yervoy® (ipilimumab), in patients with advanced solid malignancies. Clinical data reported improved survival at higher doses of INT230-6 per total tumor burden. Several patients demonstrated tumor shrinkage, symptomatic improvement, and evidence of cancer cell death and immune cell activation on tumor biopsy. In the combination cohort with pembrolizumab the Company reported that the safety of the combination was comparable to INT230-6 monotherapy.

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 DfuseRx^{SM} 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 and partnerships with Merck and BMS. For more information, please visit www.intensitytherapeutics.com and follow us 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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