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Intensity Therapeutics Reports Promising Overall Survival Results Using INT230-6 as a Monotherapy or in Combination with Pembrolizumab or Ipilimumab to Treat Solid Tumors, at The Society for Immunotherapy of Cancer's (SITC) 36th Annual Meeting

Clinical Data Suggests that INT230-6 has Potential to Prolong Survival When Compared to Historical Results

INT230-6 Alone Demonstrates Direct Tumor Necrosis and Abscopal Effects

INT230-6 Alone or as Combination Therapy Was Well Tolerated with No Dose Limiting Toxicity

WESTPORT, Conn., Nov. 13, 2021 /PRNewswire/ --**Intensity Therapeutics, Inc.** ("Intensity"), a clinical-stage biotechnology company focused on the discovery and development of proprietary immune-based intratumoral cancer therapies designed to kill tumors and increase immune system recognition of cancers, today announced the Company made two presentations on novel lead asset, INT230-6, at the Society for Immunotherapy of Cancer's 36th Annual Meeting (SITC) in Washington, D.C.

"Patients with metastatic and refractory cancers continue to have poor survival. Response rates remain low in most tumor types even with the use of immunotherapies such as checkpoint inhibitors," said Jacob S. Thomas, M.D., Assistant Professor of Clinical Medicine, Keck School of Medicine at the University of Southern California (USC) and oncologist at USC's Norris Comprehensive Cancer Center, part of Keck Medicine of USC. "INT230-6 demonstrates direct tumor killing in injected lesions. In addition, analysis shows increases of immune cells in tumors and the shrinkage of uninjected tumors or abscopal results. These data suggest dosing INT230-6 may activate a T-cell mediated immune response. Results presented at SITC indicate that use of intratumoral INT230-6 appears to be a viable approach in treating metastatic disease alone or in combination with immunotherapies."

"Sarcoma continues to be a very challenging cancer to treat and has proven resistant to checkpoint blockade. Novel immunotherapy-based approaches are still needed, and

sarcoma is an attractive cancer for intratumoral injection of INT230-6, which is a direct tumor killing agent," said Matthew Ingham, M.D., Assistant Professor of Medicine in the Division of Hematology and Oncology, Columbia University Irving Medical Center. "Biopsies from tumors treated using INT230-6 showed substantial tumor necrosis, reduction of viable cancer, a decreased cancer proliferation as measured by Ki67, and increased tumor infiltrating lymphocytes such as CD4 and CD8 T-cells. An exploratory analysis suggests promising survival for subjects receiving INT230-6 compared to historical standards."

"Our Phase 1/2 data show INT230-6 alone or in combination with checkpoint inhibitors was well tolerated with no severe toxicities," remarked Dr. Ian Walters, Intensity's Chief Medical Officer. "We now have promising early results from 115 patients with this drug, and the safety remains favorable even with injections into multiple deep tumors. The most common adverse event related to the drug is pain at the injection site. We have also demonstrated rapid tumor necrosis and promotion of systemic immune responses."

These presentations illustrate three different treatment regimens of INT230-6; as monotherapy, with pembrolizumab, or with ipilimumab. The results showcase the broad treatment potential of our locally-delivered anti-cancer product candidate in a variety of tumor types," stated Lewis H. Bender, President and Chief Executive Officer of Intensity Therapeutics. "Extended survival is the goal of any new cancer treatment, and these data show the potential for longer survival using INT230-6 when compared to historical results. Survival also appears to be improved with higher INT230-6 loading into tumors and treating more tumors over the course of therapy. Based on these encouraging early results, we are planning to initiate a randomized Phase 3 study with INT230-6 in patients with advanced soft tissue sarcomas next year."

The posters are accessible on the "Publications, Papers and Posters" section of Intensity's website at: https://intensitytherapeutics.com/news/publications-papers-and-posters/.

Highlights from the presentations are as follows:

Abstract Number: 501 **"*Survival and Immune Response Data from Intratumoral INT230-6 Alone (IT-01) and with Pembrolizumab [KEYNOTE-A10] in Subjects with Locally Advanced, Unresectable and Metastatic Solid Tumors"***

Authors: Jacob Thomas, MD; Anthony El-Khoueiry, MD; Anthony J. Olszanski, MD, RPh; Nilofer Azad, MD; Giles F. Whalen, MD; Diana Hanna, MD; Matthew Ingham, MD; Syed Mahmood, MD; Lewis H. Bender, MS, MA, MBA; Ian B. Walters, MD, MBA; Lilian L. Siu, MD

- This presentation reports results from 78 subjects summarizing the preliminary efficacy and safety of either INT230-6 alone (n=60) or in combination with the anti-PD-1 therapy, pembrolizumab (n=18) from an ongoing open-label, multi-arm Phase 1/2 clinical trial. Patients had a variety of relapsed, refractory metastatic solid tumors and progressed following a median of four prior therapies. INT230-6 was administered at doses of 0.3 to 175mL (86 mg CIS, 17.2 mg VIN) in a single session, which are higher amounts than typical IV doses, with repeated intratumoral injections in multiple tumors.
- The median overall survival (mOS) of 373 days for all monotherapy (n=53) patients compares favorably to results seen in studies with similar Phase 1 solid tumor populations. An exploratory analysis of dose relative to total tumor burden (TTB) showed that subjects receiving a dose of INT230-6 to <40% of their reported TTB had

a mOS of 96 days, while in subjects receiving a dose of INT230-6 to ≥40% of TTB, had a mOS of 570 days (HR=0.104, 95% CI(0.038, 0.29)). Patients receiving the pembrolizumab combination had a mOS of 376 days (n=16). Comparison of the survival data of INT230-6 monotherapy to the pembrolizumab combo was not made due to different cancer types in the two cohort populations.

- As of July 31, 2021, six patients in the monotherapy arm who received an INT230-6 dose of ≥40% of the TTB demonstrated abscopal effects (i.e., shrinkage of multiple non-injected tumors), further emphasizing the importance of dosing sufficient amounts to cause substantial tumor necrosis. Together with the immunohistochemistry biomarker findings, the results suggest a systemic immune system activation.
- INT230-6, either as monotherapy or in combination with pembrolizumab, was well tolerated. The most common adverse events (AEs) were localized tumor-related pain, nausea, fatigue and vomiting. AEs were mainly mild to moderate with no Grade 4 or 5 AEs.

Abstract Number: 16284 **"*Intratumoral INT230-6 Shows a Favorable Safety Profile and Early Signs of Efficacy in Advanced Soft Tissue Sarcoma with Monotherapy and in Combination with Ipilimumab [Intensity IT-01; BMS#CA184-592]"***

Authors: Matthew Ingham, MD; James Hu, MD; Giles F. Whalen, MD; Jacob Thomas, MD; Anthony El-Khoueiry, MD; Diana Hanna, MD; Anthony J. Olszanski, MD, RPh; Christian F. Meyer; Nilofer Azad, MD; Syed Mahmood, MD; Lewis H. Bender, MS, MA, MBA; Ian B. Walters, MD, MBA; Lilian L. Siu, MD; Albiruni R. Razak

- The poster reports preliminary efficacy and safety results from 19 subjects treated with either INT230-6 alone (n=10) or in combination with checkpoint inhibitors primarily ipilimumab from an ongoing Phase 1/2 clinical trial. Patients had a variety of relapsed, refractory sarcoma types and progressed following a median of three prior therapies. Demographics were similar in subjects enrolled in monotherapy and checkpoint inhibitor combination arm. The cumulative dose of INT230-6 injections given every 2 weeks over 56 days ranged from 20 to 530mL with repeated intratumoral injections in multiple tumors. Pharmacokinetic (PK) profile analysis from 18 sarcoma subjects were analyzed for cisplatin, SHAO and vinblastine and showed that greater than 95% of the active drugs remains in the tumor.
- Kaplan Meier estimates that approximately 60% of those of sarcoma subjects receiving INT230-6 monotherapy a dose volume greater than 40% of their total tumor burden will be alive at 1 year. These results compare favorable to results of survival data in studies of mixed refractory sarcoma patients with similar prognostic factors scores (ECOG, LDH, # of metastatic sites) where the median survival is estimated to be 3 to 8 months
- Biopsies showed substantial tumor necrosis, reduction of viable cancer, a decreased cancer proliferation as measured by Ki67, and increased Tumor Infiltrating Lymphocytes (CD4 and CD8 T-cells). Monotherapy patients had abscopal effects (i.e., shrinkage of multiple non-injected tumors).
- INT230-6 safety data showed that INT230-6 is well tolerated as monotherapy and preliminary data suggests that INT230-6 is well tolerated in combination with ipilimumab in sarcoma subjects. Most adverse events were low grade and transient. There were no grade 4 or 5 treatment emergent AEs and no events that were dose limiting.

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 the drugs throughout tumors for diffusion into cancer cells. In addition to local disease control, direct killing of the tumor by INT230-6 creates neoantigens leading to engagement of the immune system and systemic anti-tumor effects in the tumor. Importantly, these effects are mediated without the immunosuppression of concomitant systemic chemotherapy.

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 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 Company to evaluate the combination of INT230-6 with Bristol-Myers Squibb's anti-CTLA-4 antibody, Yervoy® (ipilimumab), in patients with advanced liver, breast and sarcoma cancers. In 2021, the Company executed agreements with the Ottawa Hospital Research Institute and the Ontario Institute of Cancer Research 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 privately held, 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 systemic 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 has partnerships with Merck and Bristol-Myers Squibb. For more information, please visit www.intensitytherapeutics.com.

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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View original content:https://www.prnewswire.com/news-releases/intensity-therapeutics-reports-promising-overall-survival-results-using-int230-6-as-a-monotherapy-or-in-combination-with-pembrolizumab-or-ipilimumab-to-treat-solid-tumors-at-the-society-for-immunotherapy-of-cancers-sitc-36th-a-301423313.html

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