



## Portage Biotech Highlights Promising Efficacy and Survival Data Presented on Intensity Therapeutics' INT230-6 (PORT-1) at November Scientific Conferences

November 15, 2021

- *Data presented at the Society for Immunotherapy of Cancer (SITC) 36th Annual Meeting and Connective Tissue Oncology Society (CTOS) Annual Meeting suggest INT230-6 (PORT-1) offers a promising approach to treating metastatic disease, including advanced soft tissue sarcomas. Data from Intensity Therapeutics' Phase 2 IT-01 clinical trial show that INT230-6 (PORT-1) is safe when administered both as a monotherapy and in combination with checkpoint inhibitors.*

WESTPORT, Conn., Nov. 15, 2021 (GLOBE NEWSWIRE) -- Portage Biotech Inc., (NASDAQ: PRTG) ("Portage" or the "Company"), a clinical-stage immuno-oncology company developing therapies to improve patient lives and increase survival by avoiding and overcoming cancer treatment resistance, today highlighted data being presented by Intensity Therapeutics during the Society for Immunotherapy of Cancer (SITC) 36<sup>th</sup> Annual Meeting and the Connective Tissue Oncology Society (CTOS) Annual Meeting. Data from the Phase 2 IT-01 trial shows that Intensity's lead asset, INT230-6 (PORT-1) is well tolerated with direct tumor-killing effects, both as a monotherapy and in combination with the approved checkpoint inhibitors pembrolizumab and ipilimumab. Highlights from the presentations are included below.

"The promising results showcased in these presentations validate the broad treatment potential of INT230-6 (PORT-1) in multiple treatment regimens – alone, in combination with a PD-1 antibody and in combination with a CTLA-4 antibody – and show substantially longer survival when compared to historical data," said Dr. Ian Walters, Chief Executive Officer of Portage Biotech and Chief Medical Officer of Intensity. "The company has amassed data in over 110 patients and the continual favorable safety and efficacy profile bodes well for this therapy's potential as a treatment for metastatic cancers that have been historically challenging to treat, including soft tissue sarcoma. We look forward to working with our collaborators at Intensity to initiate a randomized Phase 3 study in 2022 and to further exploring how INT230-6 (PORT-1) can impact survival and improve quality of life for these patients."

INT230-6 (PORT-1) is a novel intratumoral amphiphilic formulation developed by Intensity Therapeutics, a company affiliated with Portage. It delivers potent cancer-killing agents directly into the tumor to immediately reduce cancer burden, break down the cytokine wall and recruit immune cells to attack residual disease. The Phase 2 IT-01 trial is governed by joint development committees with Bristol Myers Squibb and Merck, in which Dr. Walters contributes as a representative of Intensity Therapeutics.

### SITC 2021

#### **Presentation Details:**

- **Poster #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
- **Poster #536:** 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]

#### **Data Highlights:**

- INT230-6 demonstrates direct tumor killing in injected lesions
- Immunohistochemistry analysis and abscopal results in non-injected lesions indicate dosing INT230-6 may also activate a T-cell mediated immune response
- INT230-6 injection into tumors appears to be a promising approach in treating metastatic disease alone and in combination with immunotherapies
- 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
- Exploratory analysis suggests promising survival for subjects receiving INT230-6 compared to historical standards

### CTOS 2021

#### **Presentation Details:**

- **Paper #33:** Safety and efficacy from a phase 1/2 study of intratumoral INT230-6 alone or in combination with ipilimumab [Intensity# it-01; BMS# ca184-592] in adult subjects with metastatic sarcomas (NCT 03058289)

#### **Data Highlights:**

- Preliminary data suggests that INT230-6 (PORT-1), as a monotherapy, demonstrates direct tumor killing in soft tissue sarcoma subjects that can elicit an anti-cancer immune response

- INT230-6 (PORT-1) was also shown to be well tolerated either as a monotherapy or in combination with checkpoint inhibitor ipilimumab
- Exploratory analysis suggests promising survival with dosing, based on total tumor burden, as compared to historic survival from historical sarcoma studies

To view the full announcement from Intensity Therapeutics, visit their website at [www.intensitytherapeutics.com](http://www.intensitytherapeutics.com).

#### **About PORT-1**

INT230-6 (PORT-1) contains amphiphilic molecules combined with anti-cancer payloads, offering a next-generation formulation to safely deliver up to three times the systemic dose of cancer-killing agents directly into tumors. PORT-1 breaks down the cytokine wall and stimulates immune cells to process tumor antigens and attack residual disease. Used alone or in combination with checkpoint inhibitors, PORT-1 may lead to improved survival with dramatically fewer unwanted side effects. PORT-1 has received Fast Track Designation from the U.S. Food and Drug Administration (FDA) for triple-negative breast cancer, demonstrating the importance of ongoing drug development and improved therapies for this aggressive type of cancer. Select members of the Portage management team contribute to the development efforts led by Intensity Therapeutics.

#### **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 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](http://www.intensitytherapeutics.com) and follow us on Twitter [@IntensityInc](https://twitter.com/IntensityInc).

#### **About Portage Biotech Inc.**

Portage is a clinical-stage immuno-oncology company advancing first-in-class therapies that target known checkpoint resistance pathways to improve long-term treatment response and quality of life in patients with evasive cancers. The Company's access to next-generation technologies coupled with a deep understanding of biological mechanisms enables the identification of the most promising clinical therapies and product development strategies that accelerate these medicines through the translational pipeline. Portage's portfolio consists of five diverse platforms, leveraging delivery by intratumorals, nanoparticles, liposomes, aptamers and virus-like particles. Within these five platforms, Portage has 10 products currently in development with multiple clinical readouts expected over the next 12-24 months. For more information, please visit [www.portagebiotech.com](http://www.portagebiotech.com), follow us on Twitter at @PortageBiotech, or find us on LinkedIn at Portage Biotech Inc.

#### **Forward-Looking Statements**

This news release contains statements about the Company's information that are forward-looking in nature and, as a result, are subject to certain risks and uncertainties. Although the Company believes that the expectations reflected in these forward-looking statements are reasonable, undue reliance should not be placed on them as actual results may differ materially from the forward-looking statements. The forward-looking statements contained in this news release are made as of the date hereof, and the Company undertakes no obligation to update publicly or revise any forward-looking statements or information, except as required by law.

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