Portage Biotech Summarizes Data Presented at ASCO 2022 Annual Meeting Including Updates from Ongoing PORT-2 Study

June 6, 2022

Preliminary data from the Phase 1/2 trial of PORT-2 demonstrates favorable safety and tolerability as a monotherapy with translational data supporting its mechanism of action

WESTPORT, Conn., June 06, 2022 (GLOBE NEWSWIRE) -- Portage Biotech Inc. (NASDAQ: PRTG), a clinical-stage immuno-oncology company developing therapies to improve patient lives and increase survival by avoiding and overcoming cancer treatment resistance, today announced that the Company presented early data from its Phase 1/2 study of PORT-2 (IMM60), an invariant natural killer T cell (iNKT) agonist for patients with melanoma and non-small cell lung cancer (NSCLC), at the 2022 American Society of Clinical Oncology (ASCO) meeting. Portage also presented three posters on INT230-6 (PORT-1) in collaboration with Intensity Therapeutics.

“We are encouraged by the preliminary safety profile of PORT-2, which is well tolerated when administered intravenously as a monotherapy at all doses tested, including demonstrating single agent activity in one of the two heavily pre-treated patients treated at the mid dose level,” said Dr. Ian Walters, Chief Executive Officer of Portage Biotech. “Additionally, translational analysis confirms that PORT-2 activates iNKT cells, NK cells and dendritic cells, supporting the mechanism of action to stimulate both the adaptive and innate immune system. We plan to continue to evaluate PORT-2 both as a monotherapy and in combination with pembrolizumab and look forward to sharing additional data later in 2022.”

Dr. Walters added, “We are also pleased to share ongoing progress from our collaborators at Intensity Therapeutics including further proof-of-concept in a randomized Phase 2 study for patients with neoadjuvant breast cancer, as well as updates on the ongoing Phase 2 combination studies with Keytruda and Yervoy in collaboration with Merck and BMS.”

The presentation abstracts are available to registrants through the conference platform. The PORT-2 poster will be added to Portage’s website following the conference.

Presentation Details:

PORT-2 Poster Presentation

Track: Developmental Therapeutics – Immunotherapy
Abstract Title: A Phase 1 first-in-human dose finding/randomized phase 2 study of IMM60 and pembrolizumab (PEM) in advanced melanoma and non-small-cell lung cancer (NSCLC) (IMP-MEL).
Presenter/First Author: Nicholas Coupe, MBBS Oxford University Hospital Oxford, United Kingdom
Abstract Number: 382017
Poster: 237

PORT-1 Presentations

Track: Sarcoma
Abstract Title: INT230-6 monotherapy and in combination with ipilimumab (IPI) across a broad spectrum of refractory soft tissue sarcomas (STS) [Intensity IT-01; BMS#CA184-592].
Presenter/First Author: Matthew Ingham, MD
Abstract Number: 11515
Poster: 420

Track: Developmental Therapeutics – Immunotherapy
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
Abstract Number: 2520
Poster: 176

Track: Breast Cancer – Local/Regional/Adjuvant
Abstract Title: Intratumoral (IT) INT230-6 can cause tumor necrosis In Vivo: Preliminary results of a phase II randomized presurgical window-of-opportunity study in early breast cancers (the INVINCIBLE study).
First Author: Angel Arnaout, MD, FACS
Abstract Number: 605
Poster: 376

About PORT-2
PORT-2 is a liposomal formulation of IMM60, an invariant natural killer T cell (iNKT) agonist developed by the University of Oxford. iNKT cells are a distinct class of T lymphocytes which play an important role in anti-tumor immune responses by recognizing lipid antigens on the surface of the tumor. Our synthetic iNKT agonists are designed to optimally engage the T cell receptor on the iNKT and facilitate its binding to dendritic cells, resulting in the secretion of a large amount of pro-inflammatory cytokines. This leads to the activation and expansion of important immune system components and primes and boosts an adaptive immune attack against cancer. We see that monotherapy treatment with iNKT agonists shows a heightened immune

response and better cancer control in animal models that are resistant to PD-1 antibody treatment. Additionally, combination therapy with PD-1 antibodies is synergistic with iNKT agonists and restores sensitivity to PD-1 blockade.

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, and is being evaluated in several ongoing clinical trials in collaboration with Merck and Bristol Myers Squibb. Select members of the Portage management team contribute to the development efforts led by Intensity Therapeutics.

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, follow us on Twitter at @PortageBiotech, or find us on LinkedIn at Portage Biotech Inc.

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 and further details on the data being presented by Intensity Therapeutics at ASCO 2022, please visit www.intensitytherapeutics.com.

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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