Portage Biotech Provides Update on Clinical-Stage and Development Programs

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Preliminary safety data suggests lead iNKT agonists, PORT-2 and PORT-3, are well tolerated supporting continued development

Company continues to work toward multiple clinical readouts in 2022

Portage is accelerating studies by expanding regions and clinical sites; continued advancement of pipeline beyond iNKTs

WESTPORT, Conn., March 31, 2022 (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 provided an update on its clinical development programs and announced its development goals for the remainder of 2022.

"We are pleased to report that as expected, Portage's invariant natural killer T cell (iNKT) agonists, PORT-2 and PORT-3, were well tolerated in initial clinical studies," said Dr. Ian Walters, chief executive officer of Portage. "We believe that robust randomized trial design approaches for both PORT-2 and PORT-3 will allow us to rapidly evaluate efficacy signals in Phase 2. With our unique drug development strategy, experienced management team, burgeoning collaborations with academic and pharma partners and financial resources secured in 2021, Portage is well prepared and funded to leverage our product engine to deliver on important clinical milestones through the end of 2023."

Q2-Q4 2022 Development Focus

The Company remains focused on advancing its pipeline of novel immuno-oncology therapeutics designed to prevent and overcome cancer treatment resistance. Clinical trials were initiated in 2021 for both of Portage's lead invariant natural killer T cell (iNKT) agonist programs, PORT-2 (a liposomal formulation iNKT agonist) and PORT-3 (a nanoparticle coformulation of Portage's iNKT agonist packaged with an antigen to establish immune priming and boosting).

Preliminary Phase 1 data received to date suggests PORT-2 was well tolerated when administered as a monotherapy, with no related adverse events. This has enabled a plan to accelerate opening of the combination safety cohort with Keytruda, in parallel with the ongoing high dose monotherapy cohort. Detailed data will be submitted to congresses later this year.

With the enhanced management team, efficient organization, and financial resources obtained in 2021, Portage has decided to expand the PORT-2 study beyond the UK to accelerate clinical studies while addressing COVID-19 headwinds. The Company has hired a global clinical research organization (CRO-Parexel) and is preparing for regulatory submissions in other countries. By expanding the regions and sites contributing to the study, Portage will be enabled to accelerate enrollment in the planned Phase 2 portion of this trial.

Preliminary safety data for repeat dosing of PORT-3, a nanoparticle co-formulation of PORT-2 and NY-ESO-1 immunogenic peptides developed for the treatment of NY-ESO-1 positive solid tumors, is also favorable. The Company expects to submit data to a scientific congress for PORT-3 later this year.

New Collaborations with Academic Partners to Enhance Strategic Goals

As part of its broader research and development strategy, Portage is partnering with experts and companies that could bring additional expertise and insights to help advance the science and open new avenues for development. New collaborations include a partnership with Dr. Francis Mussai and Dr. Carmela De Santo at University of Birmingham on iNKTs. Dr. Mussai and colleagues will be analyzing samples for immune markers and helping Portage to understand both the pro-inflammatory markers induced by iNKT agonists as well as the impact on suppressive cells that can impair immune based attacks.

Portage is also initiating a second collaboration with Dr. Robert Negrin and his team at Stanford University to evaluate the use of PORT-2 with iNKT cell therapies in animals. This work will evaluate if an agonist co-administered with expanded or transformed iNKT cells can further activate the transplanted and endogenous cells inside the patient. The Stanford collaboration will also study the impact iNKT agonists have on driving an adaptive immune response and correcting the suppressive tumor microenvironment.

Clinical Development Goals for the Remainder of 2022

- Generate safety and efficacy data on all products currently in clinical trials
  - PORT-2: iNKT agonist to treat melanoma and non-small cell lung cancer (NSCLC) (Phase 1/2); initial efficacy data anticipated by the end of 2022
  - PORT-3: iNKT agonist co formulated in a nanoparticle with NY-ESO-1 peptide vaccine in tumors that express NY-ESO-1 (Phase 1/2); preliminary efficacy data in patients expected year end, going into 2023
  - PORT-1: intratumoral amphiphilic formulation, developed in collaboration with our affiliate Intensity, being evaluated as a monotherapy and in combination with Keytruda and Yervoy to treat multiple solid tumors (Phase 2); multiple readouts expected in 2H 2022
- Prepare additional compounds to enter clinical studies
  - PORT-5: Systemically delivered STING agent developed in collaboration with our affiliate Stimunity, is progressing

towards the clinic. Preclinical data has been recently published and was selected for a late breaker presentation at the 2022 American Association of Cancer Research (AACR) annual meeting. This compound is a next generation, systemically delivered, targeted STING approach differentiated from others in this area.

- Continue to explore collaboration opportunities for all of our assets and evaluate new opportunities to expand immuno-oncology product portfolio

"We are grateful to the patients and families who have enrolled in our studies and are helping us to better understand cancer and ways to improve care. While the COVID pandemic has certainly created challenges for everyone, Portage is optimistic moving in to 2022 that we can resume more normal activities in our day-to-day business. The Company's focus for this year is on data generation and ways to accelerate the studies that were initially managed by third parties. With this lean structure, our current financial runway is sufficient to support progress through the end of 2023 including the release of many key data points from our ongoing trials," concluded Dr. Walters.

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 through the end of 2023. For more information, please visit 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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