Portage Biotech Provides Research and Development Update

September 14, 2022

--The Company Highlights its Clinical Strategy for its Adenosine and iNKT Platforms--

--Clinical Development Goals are Focused on Producing Phase 1b/Phase 2 Efficacy Readouts in Multiple Tumor Types Over the Next two Years--

WESTPORT, Conn., Sept. 14, 2022 (GLOBE NEWSWIRE) -- Portage Biotech Inc. (NASDAQ: PRTG), a clinical-stage immuno-oncology company developing therapies to improve patient lives and increase survival, today provided an update on its research and development programs for its expanded portfolio of immuno-oncology assets, and outlined its forward-looking clinical development goals for the next two years.

“Following the transactions we executed over this past summer, we are focusing our research and development priorities on 1) converting our investigator-initiated PORT-2 study into a company-sponsored study and 2) launching our company-sponsored adenosine trial (PORT-6 and PORT-7) in the U.S.,” said Dr. Ian Walters, Chief Executive Officer and Chairman of Portage. “The reception from major academic centers and thought leaders for both of these trials, now named IMPORT and ADPORT, respectively, has been positive. Given the potential for broad immune targeting, both trials and all agents are being tested as single agents as well as in combination with other drugs. These trials are also designed to potentially enrich for patients that may be more likely to respond to treatment, including patients with high expression of adenosine receptors A2A and A2B. Utilizing our adaptive drug development strategy, we are confident that we can continue to build on our fundamental understanding of immuno-oncology treatments and deliver on multiple catalysts within our current cash runway, which potentially extends into 2024.”

Development Focus
The company remains focused on advancing two broad platforms, its invariant natural killer T cell (iNKT) agonists and its newly acquired adenosine antagonists, PORT-6 (A2AR inhibitor) and PORT-7 (A2BR inhibitor). COVID-related backlogs for activating clinical trial sites and staff shortages have made expansion of the PORT-2 study in the United Kingdom challenging. As a result, the company has prepared a parallel company-sponsored study, IMPORT-201, to be launched in the United States and European Union to mitigate the slowdown in the United Kingdom. This will enable more control of progress on the trials and will also impact timing of data readouts.

Ongoing development programs are as follows:

iNKT Portfolio - *Activating the innate, adaptive immune systems and correcting the tumor microenvironment*

- **PORT-2:** The newly designated IMPORT-201 study is a multi-arm study Phase 1/2 trial evaluating PORT-2 in non-small cell lung cancer (NSCLC) and refractory melanoma
  - Data presented at the 2022 American Society of Clinical Oncology (ASCO) meeting in June confirmed MOA and demonstrated preliminary safety , tolerability and single agent activity.
  - During ongoing discussions with melanoma thought leaders in the U.S. and EU, it became clear that the front-line standard of care for melanoma is different in the U.S. than in the UK. As a result, the Company has made a strategic decision to drop the front-line randomized melanoma arms of this study and recruit more patients into the front-line NSCLC randomized comparison portion of the study.
  - The Company anticipates four Phase 2 efficacy readouts from the IMPORT-201 study in both NSCLC and melanoma in 2023 and 2024.
- **PORT 3:** The Horizon grant that was funding the PRECIOUS study has ended. The Company is waiting for additional data to determine next steps for development.

Adenosine Portfolio - *Modulating adenosine pathway in four different ways to determine the optimal approach to maximize the impact mechanism of action on different tumors*

- The Company believes that leveraging the A2A and A2B pathways, alone or in combination, holds the potential for customized treatment for specific patients and/or tumor types. PORT-6 is a potent, selective and durable A2A antagonist while PORT-7 is a highly selective and potent A2B antagonist.
  - The ADPORT-601 adaptive Phase 1a/1b study will explore PORT-6 and PORT-7 as monotherapies, in combination with one another and possibly in combination with other Portage assets. Phase 1b is designed to explore PORT-6 and PORT-7 monotherapies in an enriched population and in randomized trials vs. standard of care.
  - There is strong interest from academic collaborators in the upcoming ADPORT-601 study and the Company is in the process of setting up multiple collaborations on the platform.
- The Company also recently announced that the U.S. National Cancer Institute (NCI) has amended its Cooperative Research and Development Agreement to test the products targeting the adenosine pathway.

Clinical Development Goals & Anticipated Readouts

- Q4 2022

    - Data from IMPORT-201 study to be presented at a major scientific conference in November
    - Activation of the ADPORT-601 adaptive Phase 1a/1b study of PORT-6 in multiple tumor types
- 2023
    - Initiation of IMPORT-201 Phase 2 trial (Q1)
    - Submission to a major oncology conference with update on IMPORT-201 data (Q2)
    - Addition of PORT-7 in the ADPORT-601 Phase 1a/1b study in multiple tumor types (1H)
    - ADPORT-601 data and IMPORT-201 data presented at a major medical conference (Q4)
- 2024
    - IMPORT Phase 2 ORR data submitted to a medical conference (1H)
    - ADPORT-601 Phase 1b trial initiation (2H)
    - IMPORT Phase 2 PFS data submitted to a medical conference (2H)

Dr. Walters concluded, “2022 has been both a challenging and successful year on many fronts for Portage. Despite the tumultuous market environment, we expanded our pipeline with synergistic assets, setting up opportunities for future growth and success. Execution and data generation are our key priorities, and we will continue to provide timely updates as our clinical trials progress.”

About Portage Biotech Inc.
Portage is a clinical-stage immuno-oncology company advancing first-in-class therapies to improve long-term treatment response and quality of life in patients with evasive cancers. Portage’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 six diverse platforms, with lead programs including invariant natural killer T cell (iNKT) agonists and a suite of therapeutics targeting the adenosine pathway. Portage expects to report multiple clinical readouts through the end of 2024. 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 Portage’s information that are forward-looking in nature and, as a result, are subject to certain risks and uncertainties. Although Portage 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 Portage undertakes no obligation to update publicly or revise any forward-looking statements or information, except as required by law.

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