Portage Biotech Announces First Patient Dosed in Phase 1a Trial of PORT-6 in Select Solid Tumors

June 26, 2023

WESTPORT, Conn., June 26, 2023 (GLOBE NEWSWIRE) -- Portage Biotech Inc. (NASDAQ: PRTG), a clinical-stage immuno-oncology company advancing novel multi-targeted therapies for use as single agents and in combination, announced today that it has dosed the first patient in its Phase 1a trial, ADPORT-601 (NCT04969315). The trial is evaluating Portage's adenosine 2A receptor (A2AR) antagonist candidate, PORT-6, in patients with solid tumors including prostate cancer, renal and non-small cell lung cancer.

"We are excited to announce the first patient dosed in the Phase 1a safety portion of the ADPORT-601 trial in collaboration with our academic partners. This trial is a critical next step in our comprehensive exploration of how targeting the adenosine pathway could improve outcomes in multiple cancer types," said Dr. Ian Walters, CEO and Chairman of Portage Biotech. "Adenosine pathway blockade has shown safety and monotherapy activity in numerous solid tumors, and PORT-6 represents a next-generation approach which we believe is, based on our pre-clinical studies, more potent, durable and selective than other agents. We are continuing to advance this program along with the ongoing development of our iNKT engager, PORT-2, giving us multiple potential product candidates for patients in need."

ADPORT-601 is an adaptive Phase 1a/1b trial evaluating the safety and efficacy of PORT-6 (A2AR). The trial also plans to evaluate Portage's adenosine 2B receptor (A2BR) antagonist (PORT-7) and integrate proprietary biomarkers to select patients with high A2A and A2B expression. This approach is expected to allow for customization of treatment for any given tumor type to identify patients that are more likely to respond and have potential to benefit most from treatment.

"Preclinical, translational, and clinical trials have demonstrated the critical role of the adenosine signaling pathway in contributing to tumor evasion of the immune system. Portage appears to have the best-in-class A2AR and A2BR antagonists to target this immunosuppressive pathway," said Dr. Sumit Subudhi of MD Anderson Cancer Center, one of the investigators in the ADPORT-601 trial.

Dr. Lawrence Fong of the Hellen Diller Family Comprehensive Cancer Center at the University of California, San Francisco remarked, "The PORT-6 A2AR antagonist and PORT-7 A2BR antagonist trial should provide insight into understanding the therapeutic implications of targeting each pathway alone or in combination together at optimum biologic doses in multiple cancer types, something we have not been able to do before in this field. We look forward to evaluating the potential of Portage's adenosine antagonists in this clinical trial, which should also provide insights into potentially improving on current patient selection strategies by selecting patients whose tumors have a high level of adenosine expression."

In March 2023, Portage Biotech hosted both Dr. Subudhi and Dr. Fong to review the current preclinical and clinical data in the field on targeting the adenosine pathway and its potential impact on the future of cancer treatment. A replay of the KOL event is available here.

About Adenosine
A critical mechanism of cancer immune evasion is the generation of high levels of immunosuppressive adenosine within the tumor microenvironment (TME). Research suggests that the TME has significantly elevated concentrations (100-500 fold) of extracellular adenosine. Engagement with adenosine receptors A2A and A2B triggers a dampening effect on the immune response, suppressing effector cell function and stabilizing immunosuppressive regulatory cells. Over-expression of the A2A and A2B receptors leads to poor prognosis in multiple cancers, including prostate cancer, colorectal cancer and lung adenocarcinoma, driven by a reduced ability to generate an immune response against the tumor. These findings have made A2A and A2B high-priority targets for immunotherapeutic intervention. Portage is advancing four first-in-class adenosine antagonist which together represent the full suite of adenosine-targeting approaches and will enable a comprehensive exploration of how targeting the adenosine pathway could improve response in multiple cancer and non-cancer indications.

About ADPORT-601
The ADPORT-601 adaptive Phase 1a/1b study will explore Portage Biotech's small molecule adenosine antagonists, PORT-6 and PORT-7, as monotherapies, in combination with one another and potentially in combination with other Portage assets. Phase 1a will evaluate the safety of PORT-6 and PORT-7 both as monotherapy and in combination with immune checkpoint inhibitors, with the goal of identifying a recommended Phase 2 dose. Phase 1b is designed to explore PORT-6 and PORT-7 monotherapies in an enriched population and in randomized trials vs. standard of care. To learn more about the study, visit clinicaltrials.gov.

About Portage Biotech Inc.
Portage is a clinical-stage immuno-oncology company advancing multi-targeted therapies to extend survival and significantly improve the lives of patients with cancer. Lead programs in the Portage portfolio include first-in-class invariant natural killer T cell (iNKT) small molecule engagers and best-in-class adenosine antagonists. These programs are being advanced using innovative trial designs and translational data to identify the patient populations most likely to benefit from treatment. The Company's unique business model leverages a strong network of academic experts and large pharma partners to rapidly and efficiently advance multiple products. 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

All statements in this news release, other than statements of historical facts, including without limitation, statements regarding about the Company's information that are forward-looking in nature and, business strategy, plans and objectives of management for future operations and those statements preceded by, followed by or that otherwise include the words "believe," "expects," "anticipates," "intends," "estimates," "will," "may," "plan," "potential," "continue," or similar expressions or variations on such expressions are forward-looking statements. For example, statements regarding the Company's belief that targeting the adenosine pathway could improve outcomes in multiple cancer types; the Company's belief that PORT-6 is more potent, durable and selective than other agents; the Company's commitment to advancing the PORT-6 program along with its ongoing development of

its iNKT agonist; the Company's plan to evaluate PORT-7 as part of the ADPORT Phase 1a/1b trial; the Company's expectation that PORT-7 will allow for customization of treatment for any given tumor type to identify patients that are likely to respond and have potential to benefit most from treatment; the ability of the PORT-6 A2AR inhibitor and PORT-7 A2BR inhibitor trial should provide insight into understanding of the therapeutic implications of targeting each pathway alone or in combination at optimum biologic doses in multiple cancer types; the ability of such trial to provide insights into potentially improving patient selection strategies by selecting patients whose tumors have a high level of adenosine expression; expected benefits of adenosine and its potential impact on the future of cancer treatment are forward-looking statements. As a result, forward-looking statements are subject to certain risks and uncertainties, including, but are not limited to: the Company's plans and ability to develop and commercialize product candidates and the timing of these development programs; the Company's clinical development of its product candidates, including the results of current and future clinical trials; the benefits and risks of the Company's product candidates as compared to others; the Company's maintenance and establishment of intellectual property rights in its product candidates; the Company's need for financing and its estimates regarding its capital requirements and future revenues and profitability; the Company's estimates of the size of the potential markets for its product candidates; its selection and licensing of product candidates; and other factors set forth in "Item 3 - Key Information-Risk Factors" in the Company's Annual Report on Form 20-F for the year ended March 31, 2022. 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 these 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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