Portage Biotech Announces Results for Fiscal Quarter Ended December 31, 2022

March 1, 2023

- Enrollment ongoing in IMPORT-201 Phase 1/2 trial of PORT-2 in Melanoma and Non-Small Cell Lung Cancer

- Company on track to initiate Phase 1 portion of ADPORT-601 trial by end of 2Q23

- Company to Host a Key Opinion Leader Event on Targeting Adenosine Pathway in Cancer

WESTPORT, Conn., March 01, 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, today announced financial results for the fiscal quarter ended December 31, 2022.

“During the quarter and in recent weeks we continued to progress our clinical programs. Building on the favorable data presented from our lead program – invariant natural killer T cell (iNKT) agonist, PORT-2 – at the 2022 annual meeting of the Society of Immunotherapy of Cancer (SITC), we announced a new clinical collaboration agreement with Merck to evaluate PORT-2 in combination with KEYTRUDA® (pembrolizumab),” said Dr. Ian Waters, Chief Executive Officer and Chairman of Portage Biotech. “We are expanding this trial internationally and are pleased to announce that our Investigational New Drug application is approved in the U.S., and we are activating U.S. sites. We anticipate establishing the recommended Phase 2 dose shortly and commencing the Phase 2 portion of the IMPORT-201 trial in the second quarter of 2023.

“We also are continuing to advance our company-sponsored ADPORT-601 adenosine trial for PORT-6 and PORT-7 in the U.S.,” continued Dr. Walters. “This trial is designed to adapt over time and include safety and efficacy cohorts for these two agents alone and with other immune activating agents, including others from Portage’s internal pipeline. The potential of our unique approach of enhancing immune response with next-generation small molecule adenosine inhibitors will be discussed in the Key Opinion Leader event we will be hosting on March 9. We look forward to building on the progress made during this past quarter, advancing our clinical programs, and presenting trial data at multiple congresses later this year.”

Pipeline & Clinical Program Highlights for Fiscal Quarter Ended December 31, 2022 and Recent Weeks

- Presented updates from ongoing Phase 1/2 clinical trial of PORT-2 (IMM60) iNKT agonist for patients with non-small cell lung cancer (NSCLC) and advanced melanoma at SITC 37th Annual Meeting
    - The poster presentation included updated data from the IMPORT-201 clinical trial, a multi-arm Phase 1/2 trial evaluating PORT-2 in multiple settings including first-line and refractory NSCLC and refractory melanoma, both as a monotherapy and in combination with Merck’s anti-PD-1 therapy (programmed death receptor-1), KEYTRUDA® (pembrolizumab)
    - Data built on previous results shared at the 2022 American Society of Clinical Oncology (ASCO) meeting in June 2022 and presented additional safety and tolerability of PORT-2, along with the mechanistic potential to activate both the adaptive and innate immune systems and reduce the suppressive cells in the tumor microenvironment.
    - The presented data are available here.

- Entered into a clinical collaboration agreement with Merck for the evaluation of Portage’s lead iNKT agonist, PORT-2, in combination with KEYTRUDA® (pembrolizumab), Merck’s anti-PD-1 therapy, for patients with first-line as well as PD-1 refractory NSCLC.

- The Company will host a key opinion leader webinar on targeting the adenosine pathway in cancer on Thursday, March 9, 2023 at 10:30 am Eastern Time. Featuring Lawrence Fong, M.D., from The University of California, San Francisco (UCSF) Helen Diller Family Comprehensive Cancer Center, and Sumit Subudhi, M.D., Ph.D., from MD Anderson Cancer Center, this event will cover the immunologic rationale and current clinical landscape that set the foundation for Portage’s development approach. A live question and answer session will follow the formal presentations.

  To register for the event, please click here.

Financial Results from Quarter Ended December 31, 2022

The Company generated a net loss of approximately $7.5 million and other comprehensive loss of approximately $11.5 million during the three months ended December 31, 2022 (the “Fiscal 2023 Quarter”), compared to a net loss and other comprehensive loss of approximately $4.2 million during the three months ended December 31, 2021 (the “Fiscal 2022 Quarter”), an increase in net loss of $3.3 million and an increase in other comprehensive loss of $7.3 million.

Operating expenses, which include research and development (“R&D”) and general and administrative (“G&A”) expenses, were $4.8 million in the Fiscal 2023 Quarter, compared to $4.2 million in the Fiscal 2022 Quarter, an increase of $0.6 million, which is discussed more fully below.

R&D costs increased by approximately $0.6 million, or approximately 32%, from approximately $1.9 million in the Fiscal 2022 Quarter, to approximately $2.5 million in the Fiscal 2023 Quarter. The increase was primarily attributable to clinical trial costs of $0.6 million associated with the iNKT clinical trial and the start-up and manufacturing costs associated with the adenosine assets (PORT-6 and PORT-7) acquired in the Tarus acquisition of $0.8 million. There were no such costs incurred in the Fiscal 2022 Quarter. The Fiscal 2023 Quarter also included $0.1 million in other R&D costs relating to outside services and an increase in compensation of $0.1 million for consultants involved in R&D activities. The Fiscal 2022 Quarter included $0.6 million for bonuses to employees and consultants, reflected in payroll-related expenses, which was approved and paid in the Fiscal 2022 Quarter. There was no such amount in the Fiscal 2023 Quarter. Additionally, the Fiscal 2022 Quarter included a higher amount of non-cash share-based compensation expense of $0.4 million, which was primarily attributable to (a) the continued vesting over time of grants; and (b) the decrease in the fair value of grants made after the Fiscal 2022 Quarter.

G&A expenses were substantially the same in the year-over-year periods, as they decreased by approximately $0.02 million, or approximately 0.9%, from approximately $2.24 million in the Fiscal 2022 Quarter, to approximately $2.22 million in the Fiscal 2023 Quarter. Professional fees increased by $0.2 million due to legal fees and audit related fees associated with the updating of public filings and payroll-related expenses increased by $0.3 million due to the continued build-up of the Company's infrastructure. The Fiscal 2023 Quarter also included director's fees of $0.1 million (director's fees were approved and commenced January 2022). These increases were partially offset by a decrease in non-cash share-based compensation expense of $0.5 million attributable to the vesting of certain options granted in prior years and lower fair value associated with more recent grants and the decrease of $0.1 million associated with directors and officers ("D&O") insurance due to a decrease in the D&O premium market year-over-year.

The other principal components of the change in net loss and total comprehensive loss were as follows:

Other items of income and expense - Other items were substantially non-cash in nature and aggregated approximately $0.54 million net loss in the Fiscal 2023 Quarter, compared to approximately $0.08 million net income in the Fiscal 2022 Quarter, a change in other items of income and expense of approximately $0.62 million, quarter-over-quarter. The primary reason for the quarter-over-quarter difference in other items of income and expense was the difference in the fair value of warrants outstanding recognized in the quarter-over-quarter period, which expired in October 2022, and a loss from the change (increase) in fair value of the deferred purchase price payable – Tarus and deferred obligation – iOx milestone.

Net deferred income tax expense – Additionally, the Company reflected a net deferred income tax expense of $2.2 million in the Fiscal 2023 Quarter, compared to a net deferred income tax expense of $0.1 million in the Fiscal 2022 Quarter. The Fiscal 2023 Quarter includes the foreign currency effect on deferred tax liability balance settleable in British pound sterling of $2.5 million partially offset by the recognition of current period losses in the U.K. of $0.2 million and the related tax rate change effect of $0.1 million.

Fair value analysis – At December 31, 2022, the Company performed a fair value analysis of its investment in Intensity Therapeutics, Inc. ("Intensity") and determined the fair value was less than the its carrying value. Accordingly, the Company recognized an unrealized loss in value in Intensity of $4.046 million through other comprehensive income in the Fiscal 2023 Quarter.

As of December 31, 2022, the Company had cash and cash equivalents of approximately $13.1 million.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co. LLC., Rahway, N.J., USA.

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 plans to advance first-in-class therapies to improve long-term treatment response and quality of life in patients with evasive cancers; the Company's plan to commence the Phase 2 portion of the IMPORT-201 trial in the second quarter of 2023; the Company's plan to augment an immune response with its next-generation small molecule adenosine 2A and adenosine 2B inhibitors; the Company's plans to identify the most promising clinical therapies and product development strategies that accelerate these medicines through innovative trial designs and the translational pipeline; the Company's plans to report multiple clinical readouts through the end of 2024; the safety and tolerability profile of PORT-2; the Company's collaboration agreement with Merck to evaluate PORT-2 in combination with KEYTRUDA® (pembrolizumab) for the treatment of patients with front-line and refractory NSCLC; the Company's preparations to launch of ADPORT-601 adenosine trial for PORT-6 and PORT-7 in the U.S.; advancing the Company's broader strategy of de-risked clinical development; and the Company's ability to deliver on multiple catalysts in the coming months and 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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Portage Biotech Inc.
Condensed Consolidated Interim Statements of Operations and Other Comprehensive Income (Loss)
(U.S. Dollars in thousands, except per share amounts)
(Unaudited – see Notice to Reader dated February 28, 2023)

	Three months ended December 31,		Nine months ended December 31,	
	2022	2021	**2022**	**2021**
	In 000'$	In 000'$	**In 000'$**	In 000'$
Expenses				
Research and development	**$ 2,535**	$ 1,928	**$ 5,976**	$ 4,804
General and administrative expenses	**2,224**	2,241	**6,523**	6,288
Loss from operations	**(4,759)**	(4,169)	**(12,499)**	(11,092)
Change in fair value of deferred purchase price payable - Tarus and deferred obligation - iOx milestone	**(498)**	–	**(428)**	–
Share of loss in associate accounted for using equity method	**(152)**	(261)	**(268)**	(363)
Change in fair value of warrant liability	**8**	342	**33**	726
Foreign exchange transaction gain (loss)	**50**	–	**(60)**	–
Depreciation expense	**(1)**	–	**(1)**	–
Interest income	**50**	–	**115**	–
Interest expense	**–**	(1)	**(9)**	(42)
Loss before provision for income taxes	**(5,302)**	(4,089)	**(13,117)**	(10,771)
Income tax (expense) benefit	**(2,199)**	(117)	**2,906**	465
Net loss	**(7,501)**	(4,206)	**(10,211)**	(10,306)
Other comprehensive income (loss)				
Net unrealized loss on investments	**(4,017)**	–	**(4,017)**	–
Total comprehensive loss for period	**$ (11,518)**	$ (4,206)	**$ (14,228)**	$ (10,306)
Net loss attributable to:				
Owners of the Company	**$ (7,485)**	$ (3,512)	**$ (10,163)**	$ (9,553)
Non-controlling interest	**(16)**	(694)	**(48)**	(753)
Net loss	**$ (7,501)**	$ (4,206)	**$ (10,211)**	$ (10,306)
Comprehensive loss attributable to:				
Owners of the Company	**$ (11,502)**	$ (3,512)	**$ (14,180)**	$ (9,553)
Non-controlling interest	**(16)**	(694)	**(48)**	(753)
Total comprehensive loss for period	**$ (11,518)**	$ (4,206)	**$ (14,228)**	$ (10,306)
Loss per share				
Basic and diluted	**$ (0.44)**	$ (0.26)	**$ (0.65)**	$ (0.74)
Weighted average shares outstanding				
Basic and diluted	**17,039**	13,344	**15,719**	12,966

Portage Biotech Inc.
Condensed Consolidated Interim Statements of Financial Position
(U.S. Dollars in thousands)
(Unaudited – see Notice to Reader dated February 28, 2023)

As of,	December 31, 2022	March 31, 2022 (Audited)
Assets		
Current assets		
Cash and cash equivalents	**$ 13,104**	$ 23,352
Prepaid expenses and other receivables	**1,786**	1,480
Convertible note receivable	**642**	–
Total current assets	**15,532**	24,832
Long-term assets		
Investment in associate	**1,405**	1,673
Investment in private company	**3,363**	7,409
Goodwill	**43,862**	43,324
In-process research and development	**145,588**	117,388
Deferred commitment fee	**894**	–
Other assets, including equipment, net	**39**	36
Total long-term assets	**195,151**	169,830
Total assets	**$ 210,683**	$ 194,662
Total assets		
Liabilities and Equity		
Current liabilities		
Accounts payable and accrued liabilities	**$ 2,422**	$ 750
Warrant liability	**–**	33
Total current liabilities	**2,422**	783
Non-current liabilities		
Deferred tax liability	**25,515**	28,445
Deferred purchase price payable - Tarus	**8,876**	–
Deferred obligation - iOx milestone	**5,568**	–
Total non-current liabilities	**39,959**	28,445
Total liabilities	**42,381**	29,228
Shareholders' Equity		
Capital stock	**216,630**	158,324
Stock option reserve	**20,542**	16,928
Accumulated other comprehensive (loss) income	**(3,059)**	958
Accumulated deficit	**(65,168)**	(55,005)
Total equity attributable to owners of the Company	**168,945**	121,205
Non-controlling interest	**(643)**	44,229
Total equity	**168,302**	165,434
Total liabilities and equity	**$ 210,683**	$ 194,662

Source: Portage Biotech, Inc.