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Rakovina Therapeutics Inc. Announces Q3 2022 Financial Results and Provides Corporate Update

VANCOUVER, British Columbia, Nov. 17, 2022 (GLOBE NEWSWIRE) -- Rakovina Therapeutics Inc. (TSX-V: RKV, the “Company”) a biopharmaceutical company committed to advancing new cancer therapies based on novel DNA-damage response technologies announced the financial results for the quarter ended September 30, 2022 and provided a corporate update.

Corporate Update

Rakovina Therapeutics has continued to communicate progress in the Company’s research and development programs through presentations at peer-reviewed scientific meetings and publications:

- On October 31, 2022, the Company announced our presentation at the 34th Annual AACR-NCI-EORTC Molecular Targets and Cancer Therapeutics Symposium;
- On November 14, 2022, the Company announced the preprint publication of a manuscript entitled ‘*A bi-functional PARP-HDAC inhibitor with activity in Ewing sarcoma*’. The manuscript reports research results of our kt-3000 dual PARP-HDAC inhibitor drug candidate in HR-proficient Ewing sarcoma models.

“Our data support advancing lead compounds from our kt-3000 PARP-HDAC inhibitor series as a novel approach in the treatment of Ewing sarcoma,” stated Prof. Mads Daugaard Rakovina Therapeutics’ president and chief scientific officer. “This concept will likely be relevant in the treatment of cancer indications beyond Ewing sarcoma and potentially offer an opportunity to overcome therapeutic resistance to PARP-inhibitor treatment.”

Rakovina Therapeutics’ kt-3000 series is a novel class of bi-functional small-molecule drug candidates that has been designed to combine inhibition of both poly(ADP)-ribose polymerase (PARP) and histone deacetylase (HDAC) in a single molecule as a novel approach to providing meaningful clinical benefit to cancer patients.

Data presented demonstrate that the kt-3000 prototype lead compound performs 30-40 times better than the FDA-approved PARP inhibitor olaparib (Lynparza®) and 5-10 times better than the FDA-approved HDAC-inhibitor vorinostat (Zolina®) in Ewing sarcoma 3D spheroid models. In an Ewing sarcoma metastasis model, a kt-3000 drug candidate prevented metastatic cancer growth in the lungs of mice inoculated with an aggressive Ewing sarcoma cell line. The Company believes that these data provide proof-of-concept validation of kt-3000 drug candidates to address significant unmet needs in the treatment of Ewing sarcoma and other solid tumors.

Ewing sarcoma is a cancer that occurs primarily in the bone or soft tissues and is the second most common type of bone cancer affecting children and young adults. The development of new and improved treatments for Ewing sarcoma represents a significant unmet medical need. Approximately thirty percent of patients will experience recurrence within five years following treatment. The prognosis for patients with recurrent or progressive Ewing sarcoma is poor with average survival from the time of relapse of only 14 months.

A kt-3000 series drug candidate for the treatment of recurrent Ewing sarcoma may qualify for an FDA priority review voucher. Under this program, a sponsor who receives an approval for a drug or biologic for a "rare pediatric disease" may qualify for a voucher that can be redeemed to receive a priority review of a subsequent marketing application for a different product.

If received, a priority review voucher could be used to accelerate the regulatory review of another Rakovina Therapeutics drug candidate or it could be sold to a third party. During 2022, multiple companies sold priority review vouchers at prices ranging from US$100 million to US$110 million.

“Based on our progress to date, we are confident that we may be in a position to file regulatory documentation to begin human clinical trials with a kt-3000 series drug candidate in the second half of 2023,” stated Prof. Daugaard. “Because early-stage clinical trials in the cancer field are often ‘open label’, we will have the opportunity to report continued progress of our future clinical trials at peer-reviewed scientific meetings.”

The Company also reported continued progress within its other research programs.

- kt-2000 series drug candidates are being optimized to achieve PARP-1 selectivity and therapeutically relevant brain penetration. Recent research has suggested an improved safety profile for PARP-1 selective compounds vs. PARP-1/2 inhibitors.

  Currently, the four FDA-approved PARPi are all PARP-1/2 inhibitors with limited brain penetration. Rakovina Therapeutics believes that a PARP-1 selective brain-penetrant drug candidate from our kt-2000 series will provide attractive opportunities to establish collaborations with leading pharmaceutical companies.

- kt-4000 series drug candidates combine a targeted DNA-damaging functionality with potent PARP inhibition in a single molecule. Earlier this year, the Company presented data at the American Association of Cancer Research Annual Meeting demonstrating that treatment with kt-4000 series candidates leads to G2/M cell cycle arrest and cell death in HR-proficient cancer cells, normally resistant to PARP inhibitor treatment.

Summary Financial Results for the quarter ended September 30, 2022

The Company commenced operations on March 25, 2021, concurrent with the closing of the qualifying transaction with Vincero Capital Corp. and began trading on the Toronto Venture Exchange under the symbol RKV on April 1, 2021. At September 30, 2022, the Company had positive working capital of approximately $1.4 million.

For the three and nine months ended September 30, 2022, the Company reported a net loss of $715,880 and $2,143,808 respectively. Research and development expenses were $541,447 and $1,427,949 for the three and nine months ended September 30, 2022, respectively. General and administrative expenses were $185,903 and $736,671 for the three and nine months ended September 30, 2022, respectively. Total cash expenses related to research and development and general and administrative expenses for the three months ended September 30, 2022 were $529,462.

Selected Financial Information	As at September 30, 2022 $
Cash & cash equivalents	1,346,760
Working capital	1,432,620
Intangible assets	5,186,289
Total Assets	6,865,680
Total liabilities	246,771
Deficit	7,664,960
Total equity	6,618,909

Statements of net loss and comprehensive loss data:	For the three months ended September 30, 2022 $	For the nine months ended September 30, 2022 $
Research & Development	541,447	1,427,949
General and administrative	185,903	736,671
Net loss and comprehensive loss	715,880	2,143,808
Basic and diluted income (loss) per share	(0.01)	(0.03)
Operating cash burn	529,462	1,547,336
Weighted average shares outstanding	69,829,500	69,828,555

Rakovina Therapeutics’ financial statements as filed with SEDAR can be accessed from the Company’s website at: https://www.rakovinatherapeutics.com/corporate-profile/

About Rakovina Therapeutics Inc.

Rakovina Therapeutics Inc. is focused on the development of new cancer treatments based on novel DNA-damage response technologies. The Company has established a pipeline of novel DNA-damage response inhibitors with the goal of advancing one or more drug candidates into human clinical trials and obtaining marketing approval for new cancer therapeutics from Health Canada, the United States Food and Drug Administration and similar international regulatory agencies. Further information may be found at www.rakovinatherapeutics.com.

Additional Information

The TSXV has neither approved nor disapproved the content of this press release. Neither the TSXV nor its Regulation Services Provider (as that term is defined in policies of the TSXV) accepts responsibility for the adequacy or accuracy of this release.

Notice regarding forward-looking statements:

This release includes forward-looking statements regarding the Company and its respective business, which may include, but is not limited to, statements with respect to the proposed business plan of the Company and other statements. Often, but not always, forward-looking statements can be identified by the use of words such as "plans", "is expected", "expects", "scheduled", "intends", "contemplates", "anticipates", "believes", "proposes" or variations (including negative variations) of such words and phrases, or state that certain actions, events, or results "may", "could", "would", "might" or "will" be taken, occur or be achieved. Such statements are based on the current expectations of the management of the Company. The forward-looking events and circumstances discussed in this release may not occur by certain specified dates or at all and could differ materially as a result of known and unknown risk factors and uncertainties affecting the Company, including risks regarding the medical device industry, economic factors, regulatory factors, the equity markets generally and risks associated with growth and competition. Although the Company has attempted to identify important factors that could cause actual actions, events, or results to differ materially from those described in forward-looking statements, there may be other factors that cause actions, events, or results to differ from those anticipated, estimated or intended. No forward-looking statement can be guaranteed. Except as required by applicable securities laws, forward-looking statements speak only as of the date on which they are made and the Company undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events, or otherwise. The reader is referred to the Company's most recent filings on SEDAR for a more complete discussion of all applicable risk factors and their potential effects, copies of which may be accessed through the Company's profile page at www.sedar.com.

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