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Volition Presents Breakthrough Liquid Biopsy Blood Test Method for Early-stage Cancer

HENDERSON, Nev., Oct. 23, 2023 /PRNewswire/ -- VolitionRx Limited (NYSE AMERICAN: VNRX) ("Volition"), a multi-national epigenetics company, has unveiled what it believes to be an entirely new cancer detection method at ESMO 2023¹, the annual congress of the European Society for Medical Oncology.

In early-stage cancer, it is difficult to detect cancer-derived circulating tumor DNA (ctDNA) in the blood because it may comprise only 0.01% of the DNA present among a background of 99.99% normal DNA. Moreover, most of the cancer DNA has exactly the same sequence as normal DNA.

As physical separation of tumor derived and healthy circulating DNA has never before been achieved, current ctDNA detection methods involve DNA extraction, sequencing of all (cancer and normal) circulating DNA and analysis of the sequencing data using sophisticated computer bioinformatics, to tell them apart.

Volition has developed a novel method for liquid biopsy involving the first reported physical isolation of a class of tumor-derived ctDNA fragments from blood. Cancer derived ctDNA fragments are then extracted after removal of all normal background DNA of the same sequence for detection with a simple, low cost PCR test.

Dr. Jake Micallef, Chief Scientific Officer at Volition, explains:

"Based on our 13 years of work on the chemistry of circulating chromatin fragments, we have developed a transformational wet chemistry pathway that identifies and physically isolates chromatin fragments that we know are tumor-derived from background DNA of the same sequence, using Chromatin Immunoprecipitation (ChIP), followed by quantitative real-time PCR (qPCR) testing to establish whether cancer is present. Removal of normal DNA obviates expensive and time-consuming DNA sequencing and bioinformatics allowing for rapid, cost-effective detection in a routine blood test."

Volition's proof of concept data, presented at ESMO 2023, demonstrates the isolation of tumor derived ctDNA fragments from plasma. Volition tested the new method in a first small clinical experiment and detected a range of liquid and other cancers, including at early stage I disease. For example, 74% of leukemias were detected at 96% specificity and 77% of colorectal cancers were detected at 92% specificity with 2-qPCR assays.

Dr. Micallef added: "These early assays were developed using a leukemia model, but surprisingly also detected many other cancers including detecting colorectal cancer in a blood test with an accuracy approaching that of current Fecal Immunochemical Tests (FIT). The results to date are exciting and may pave the way for a whole new class of

undiscovered biomarkers, with hundreds or thousands of possible targets. We are now developing a range of cancer-specific assays which we expect to be more accurate and look forward to sharing our progress beginning in Q1 2024."

Dr Michael Hubank, Professor of Translational Genomics at the Institute of Cancer Research, and Scientific Director of Clinical Genomics at The Royal Marsden NHS Foundation Trust, said: "The novel CTCF-ChIP/qPCR method developed by Volition shows great promise for the accurate, rapid, low-cost detection of cancer. The test complements existing approaches and has the potential to reach the high levels of sensitivity and specificity required to detect early-stage disease. It may also be suitable for automation, enabling application in hospital laboratories. We look forward to working with Volition on further research and development in this important and exciting area."

Volition has organized a data insights webinar on Thursday 26th October at 10.30 AM U.S. Eastern to provide more information about the new cancer detection method. Click [HERE](#) to register. The event will be recorded and available afterward on-demand.

Notes:

1. 'A novel immunoprecipitation/PCR method for detection of plasma cfDNA fragments selectively occupied by CTCF in cancer.' D Pamart et al. [ESMO 2023](#)
2. In 2020 there were 19.3 million new cancer cases diagnosed worldwide – this is set to grow to 30.2 million by 2040. ([Globocan Today](#) and [Globocan Tomorrow](#))
3. In 2020, just under 10 million deaths were cancer-related (9.96m) which is also expected to increase to 16.3 million by 2040. ([Globocan Today](#) and [Globocan Tomorrow](#))

About Volition

Volition is a multi-national epigenetics company powered by Nu.Q®, its proprietary nucleosome quantification platform. Through its subsidiaries, Volition is developing simple, easy to use, cost effective blood tests to help diagnose and monitor a range of life-altering diseases including some cancers and diseases associated with NETosis such as sepsis and COVID-19. Early diagnosis and monitoring have the potential to not only prolong the life of patients but also improve their quality of life. The tests are based on the science of Nucleosomics™, which is the practice of identifying and measuring nucleosomes in the bloodstream or other bodily fluid - an indication that disease is present.

Volition's research and development activities are centered in Belgium, with an innovation laboratory and office in the U.S. and additional offices in London and Singapore.

For more information about Volition's Nu.Q® technology go to:www.volition.com

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Statements in this press release may be "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, that concern matters that involve risks and uncertainties that could cause actual results to differ materially from those anticipated or projected in the forward-looking statements. Words such as "expects," "anticipates," "intends," "plans," "aims," "targets," "believes," "seeks," "estimates," "optimizing," "potential," "goal," "suggests," "could," "would," "should," "may," "will" and similar expressions identify forward-looking statements. These forward-looking statements relate to, among other topics, Volition's estimated market opportunity, the effectiveness of Volition's blood-based diagnostic, prognostic and disease monitoring tests, and Volition's ability to develop and successfully commercialize such test platforms for early detection of cancer and other diseases as well as serving as a diagnostic, prognostic or disease monitoring tools for such diseases. Volition's actual results may differ materially from those indicated in these forward-looking statements due to numerous risks and uncertainties, including, without limitation, results of studies testing the efficacy of its tests. For instance, if Volition fails to develop and commercialize diagnostic, prognostic or disease monitoring products, it may be unable to execute its plan of operations. Other risks and uncertainties include Volition's failure to obtain necessary regulatory clearances or approvals to distribute and market future products; a failure by the marketplace to accept the products in Volition's development pipeline or any other diagnostic, prognostic or disease monitoring products Volition might develop; Volition's failure to secure adequate intellectual property protection; Volition will face fierce competition and Volition's intended products may become obsolete due to the highly competitive nature of the diagnostics and disease monitoring market and its rapid technological change; downturns in domestic and foreign economies; and other risks identified in Volition's most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, as well as other documents that Volition files with the Securities and Exchange Commission. These statements are based on current expectations, estimates and projections about Volition's business based, in part, on assumptions made by management. These statements are not guarantees of future performance and involve risks, uncertainties and assumptions that are difficult to predict. Forward-looking statements are made as of the date of this release, and, except as required by law, Volition does not undertake an obligation to update its forward-looking statements to reflect future events or circumstances.

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