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## **Volition presents study data at ASCO GI 2022 on circulating nucleosomes for the detection of colorectal cancer and high-risk advanced adenomas**

AUSTIN, Texas, Jan. 20, 2022 /PRNewswire/ --VolitionRx Limited (NYSE AMERICAN: VNRX) ("Volition"), a multi-national epigenetics company, has announced the results of two large scale clinical studies, which show that the company's Nu.Q® assays, when used in conjunction with the Fecal Immunochemical Test (FIT), can detect colorectal cancer and all high-risk advanced adenomas in symptomatic patients, and thereby reduce unnecessary colonoscopies. The studies also demonstrated that the company's Nu.Q® assays can improve the detection of high-risk adenomas in asymptomatic patients.

Principal Investigator, Professor Han-Mo Chiu, National Taiwan University, said "We are enormously encouraged by the findings of these two studies. Not only do they show that using Nu.Q® assays in combination with FIT can potentially reduce unnecessary colonoscopies by up to 28% in patients with gastrointestinal symptoms, the studies also show that this dual approach could be used more widely to improve the effectiveness of FIT-based screening programs targeting asymptomatic patients. We look forward to presenting our findings to colleagues at ASCO GI 2022."

Dr. Marielle Herzog, Research and Development Director at Volition, said "Early diagnosis is key to improving outcomes for patients with colorectal cancer, and cancer screening programs are critical to every public health system. The results of our studies, using Volition's Nu.Q® assays in conjunction with FIT, are incredibly encouraging, not only in reducing unnecessary colonoscopies but also in detecting high-risk adenomas, both proximal and distal, which FIT, when used alone can miss. We are excited about the next stage, facilitating an independent, prospective validation study later this year."

The studies were undertaken by Volition and the Department of Internal Medicine at the National Taiwan University Hospital and findings will be presented at the 2022 ASCO Gastrointestinal Cancers Symposium, later this week.

Volition is developing simple, easy to use, cost-effective blood tests to help diagnose and monitor a range of life-altering diseases including cancer.

Colorectal cancer is the fourth most common cancer worldwide, with 1.9 million new cases in 2020, and accounts for over 9% of all cancer-related deaths each year<sup>1</sup>. Population-based colorectal cancer screening programs are in place in many healthcare systems globally, and the most commonly recommended screening method<sup>2</sup> is the FIT, followed up with colonoscopy, an invasive visual examination. However, approximately 60% of FITs provide false-positive results<sup>3</sup>, leading to unnecessary and costly colonoscopies.

Posters to be presented at ASCO GI 2022 can be downloaded here:

- 1) [Circulating nucleosomes levels improve FIT performance for detecting high-risk colorectal neoplasms in a symptomatic population.](#)
- 2) [Circulating nucleosomes for detection of colorectal cancer and high-risk advanced adenomas.](#)

For more information about Volition's Nu.Q® technology go to: [www.volition.com](http://www.volition.com)

#### **Notes to editors:**

#### **References:**

<sup>1</sup> World Health Organization International Agency for Research on Cancer (IARC). GLOBOCAN 2020: estimated cancer incidence, mortality and prevalence worldwide in 2020.

<sup>2</sup> Schliemann, D., Ramanathan, K., Matovu, N. *et al.* The implementation of colorectal cancer screening interventions in low-and middle-income countries: a scoping review. *BMC Cancer* 21, 1125 (2021).

<sup>3</sup> Chiu HM, Chen SL, Yen AM, et al. Effectiveness of fecal immunochemical testing in reducing colorectal cancer mortality from the One Million Taiwanese Screening Program. *Cancer*. 2015;121(18):3221-3229.

#### **About the studies**

- 476 patients referred for surveillance colonoscopy or secondary to bowel symptom were enrolled: (i) CRC (n= 67), (ii) advanced adenoma (AA) (n=60), non-AA (n=123); (iv) non-neoplastic polyps (n=29); (vi) colonoscopy negative (controls) (n=197).
- 520 average-risk asymptomatic patients: (i) CRC (n= 33), (ii) advanced adenoma (AA) (n=123, including 18 with AA>2cm); (iii) non-AA (n=168); (iv) non-neoplastic polyps (n=30); (vi) colonoscopy negative control (n=166).
- Plasma and stool samples were obtained prior to colonoscopy.
- Circulating Nucleosome levels measured using Volition's Nu.Q® quantitative immunoassays.
- FIT: OC-SENSOR (Eiken Chemical Co., Ltd., Tokyo, Japan) using a positive cut-off of 20ug/g feces.

#### **About Volition**

Volition is a multi-national epigenetics company that applies its Nucleosomics™ platform through its subsidiaries to develop 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 to 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 is primarily focused on human diagnostics and monitoring but also has a subsidiary focused on animal diagnostics and monitoring.

Volition's research and development activities are centered in Belgium, with a small laboratory in California and additional offices in Texas, London, and Singapore, as the company focuses on bringing its diagnostic and disease monitoring products to market.

For more information about Volition, visit Volition's website [volition.com](http://volition.com) or connect with us via:

- Twitter: <https://twitter.com/volitionrx>
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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," "can," "could," "would," "should," "may," "will" and similar expressions identify forward-looking statements. These forward-looking statements relate to the effectiveness of Volition's blood-based diagnostic, prognostic and disease monitoring tests, 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, and the timing of product launches and publications. 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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