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VolitionRx Publishes Study Confirming Stability of Circulating Cell-Free Nucleosomes as Biomarkers for Cancer Diagnostic Blood Tests

Full results published in the *Scandinavian Journal of Clinical and Laboratory Investigation*

NAMUR, Belgium, June 14, 2016 /PRNewswire/ -- [VolitionRx Limited](#) (NYSE MKT: VNRX), today announced full results from a prospective assessment of pre-analytical variables contributing to the accuracy of its NuQ[®] blood test that confirm the stability of circulating cell-free nucleosomes (cfnucleosomes) as biomarkers in cancer. The findings were published on 13th June 2016 in the article, "Pre-analytical variables of circulating cell-free nucleosomes containing 5-methylcytosine DNA or histone modification H3K9me3" in the *Scandinavian Journal of Clinical and Laboratory Investigation*, an international scientific journal focused on clinically-orientated biochemical and physiological research.

(<http://www.tandfonline.com/doi/full/10.1080/00365513.2016.1190862>)

VolitionRx's proprietary NuQ[®] blood tests are based on biomarker assays that can identify fragments of chromosomes, called nucleosomes, circulating in the blood and analyze them for epigenetic modifications that signal that cancer is present.

The study, led by VolitionRx lead scientist Dr. Marielle Herzog working with the Department of Surgical Gastroenterology, Hvidovre Hospital, University of Copenhagen, Denmark and the Institute of Clinical Medicine, University of Copenhagen, Denmark evaluated sampling and handling factors of the blood draw and storage process of the NuQ[®] tests that can impact the tests' stability and fragility. For accurate results in any blood test, it is important to confirm that the results of the test are the same regardless of when and how the blood sample is taken.

VolitionRx Chief Scientific Officer Dr. Jake Micallef commented, "The findings of this study are very good news for us, especially as we head to market in the EU, as no nucleosome stability or fragility issues were found and no special blood draw requirements were needed. What this means for patients is that our NuQ[®] test will be relatively easy to complete, with no need to fast or limit testing to a specific time of day. The test will also be easy, convenient and cost-effective for both the doctor and the lab since it can be done during a regular blood draw with no special collection, separation, handling or storage requirements."

The study investigated the influence of the following six elements which could affect cfnucleosome blood test stability and/or fragility:

- Stasis at blood collection: blood was collected with and without a tourniquet stasis and [white cells and platelets] were separated in the samples
- Within-day variation: blood was collected at 3 different time points during the same day from the same subject
- Day-to-day variation: blood was collected at day 1, 8, 15, 22 and 29 from the same subject
- Variation in temperature and time to centrifugation: blood samples were kept at room temperature or on ice before centrifugation, the time to centrifugation varied also from 30 minutes to 72 hours
- Effect of colonoscopy: blood was collected pre- and post-colonoscopy
- Effect of surgical trauma: blood was collected pre- and post-surgical resection of primary rectal cancer

The study concluded that the levels of circulating cf nucleosomes appear stable in most pre-analytical settings, including the processes of sampling and handling blood samples at room temperature prior to centrifugation.

VolitionRx Chief Executive Officer Cameron Reynolds, added, "The validation of our stability study with the publication of this article represents yet another important step toward providing an accurate and easy to use NuQ[®] diagnostic blood tests to physicians and their patients for the early detection of cancer. This result is key to making our tests low cost and easy to use, as eating, time of day and time of month of sample collection had no meaningful difference in the results for an individual person's biomarker result."

Results from clinical trials demonstrating the effectiveness of VolitionRx's NuQ[®] biomarker assays include:

Colorectal cancer and pre-cancerous colorectal adenomas

- Interim results from a 4,800 patient retrospective symptomatic population study (Hvidovre Hospital, University of Copenhagen, Denmark), released September 9, 2015: Panel of four NuQ[®] biomarker assays detected 81% of colorectal cancers at 78% specificity and 67% of high-risk adenomas. (<http://www.volitionrx.com/news/press-releases/detail/531/volitionrx-demonstrates-nuqr-blood-test-detects-81-of>)
- Results from a completed prospective study of 121 patients referred for colonoscopy (CHU Dinant Godinne - UCL Namur, in Belgium), released December 8, 2015: Panel of four NuQ[®] biomarker assays detected 91% of colorectal cancer cases at 90% specificity and also detected 67% of high-risk adenomas. (<http://www.volitionrx.com/news/press-releases/detail/542/volitionrx-demonstrates-more-than-90-accuracy-for>)
- Results from a retrospective study of 430 patients referred for colonoscopy (Hvidovre Hospital, University of Copenhagen, Denmark), released February 17, 2016: Panel of five NuQ[®] biomarker assays demonstrated 75% accuracy in detecting highest-risk pre-cancerous colorectal adenomas and also detected 86% of early (stage I) colorectal cancers at 78% specificity. (<http://www.volitionrx.com/news/press-releases/detail/550/volitionrx-demonstrates-75-accuracy-in-detecting>)

Pancreatic cancer

- Results from a 59-patient retrospective study (Lund University, Sweden) published in Clinical Epigenetics online journal (<http://www.clinicalepigeneticsjournal.com/content/pdf/s13148-015-0139-4.pdf>), October 7, 2015: Panel of four NuQ[®] biomarker assays plus CA 19-9 classical biomarker detected 92% of pancreatic cancers at 100% specificity. (<http://www.volitionrx.com/news/press-releases/detail/534/volitionrx-announces-publication-of-results-from-pancreatic>)
- Interim results from a 4,800 patient retrospective symptomatic population study (Hvidovre Hospital, University of Copenhagen, Denmark), released October 22, 2015: Panel of two NuQ[®] biomarker assays and the classical cancer marker CEA (carcino-embryonic antigen) detected 95% of pancreatic cancers at 84% specificity. (<http://www.volitionrx.com/news/press-releases/detail/535/volitionrx-demonstrates-nuq-blood-test-detects-95-of>)

Prostate Cancer

- Results from a 537-patient retrospective study (Surrey Cancer Research Institute at University of Surrey, United Kingdom), released April 20, 2016 at the AACR Annual Meeting: A single NuQ[®] biomarker assay detected 71% of early stage I prostate cancer cases and 86% of late stage IV prostate cancer at 93% specificity, which is significantly higher than the commonly-used PSA test reported to detect 53% of prostate cancers at 73% specificity. (<http://www.volitionrx.com/news/press-releases/detail/561/volitionrx-announces-study-results-showing-nuq-blood-test>)

Lung cancer

- Interim results (73 of 240 patients collected and assessed) from a prospective study (Liège University Hospital, Belgium), released November 19, 2015: Panel of four NuQ[®] biomarker assays detected 93% of lung cancers at 91% specificity and differentiated lung cancer from the common lung disease, COPD. (<http://www.volitionrx.com/news/press-releases/detail/540/volitionrx-demonstrates-nuq-blood-test-detects-lung>)

Idiopathic Pulmonary Fibrosis

- Results from a retrospective study of 78 patients referred for colonoscopy (Liège University Hospital, Belgium), released March 9, 2016: Preliminary data demonstrated 86% accuracy in detecting Idiopathic Pulmonary Fibrosis, a fatal lung disease, at 80% specificity. (<http://www.volitionrx.com/news/press-releases/detail/551/preliminary-data-demonstrates-86-accuracy-in-detecting>)

About VolitionRx

VolitionRx is a life sciences company focused on developing diagnostic tests for cancer and other conditions. 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.

VolitionRx's goal is to make the tests as common and simple to use, for both patients and

doctors, as existing diabetic and cholesterol blood tests. VolitionRx's research and development activities are currently centered in Belgium as the company focuses on bringing its diagnostic products to market first in Europe, then in the U.S. and ultimately, worldwide.

Visit VolitionRx's website (<http://www.volitionrx.com>) or connect with us via [Twitter](#), [LinkedIn](#), [Facebook](#) or [YouTube](#).

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Safe Harbor Statement

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 the effectiveness of the Company's bodily-fluid-based diagnostic tests as well as the Company's ability to develop and successfully commercialize such test platforms for early detection of cancer. The Company's actual results may differ materially from those indicated in these forward-looking statements due to numerous risks and uncertainties. For instance, if we fail to develop and commercialize diagnostic products, we may be unable to execute our plan of operations. Other risks and uncertainties include the Company's failure to obtain necessary regulatory clearances or approvals to distribute and market future products in the clinical IVD market; a failure by the marketplace to accept the products in the Company's development pipeline or any other diagnostic products the Company might develop; the Company will face fierce competition and the Company's intended products may become obsolete due to the highly competitive nature of the diagnostics market and its rapid technological change; and other risks identified in the Company's most recent Annual Report on Form 10-K and Quarterly

Reports on Form 10-Q, as well as other documents that the Company files with the Securities and Exchange Commission. These statements are based on current expectations, estimates and projections about the Company'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, the Company does not undertake an obligation to update its forward-looking statements to reflect future events or circumstances.

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To view the original version on PR Newswire, visit <http://www.prnewswire.com/news-releases/volitionrx-publishes-study-confirming-stability-of-circulating-cell-free-nucleosomes-as-biomarkers-for-cancer-diagnostic-blood-tests-300284212.html>

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