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VolitionRx Demonstrates More Than 90% Accuracy for Colorectal Cancer NuQ(R) Blood Test in Completed Prospective Study

NAMUR, Belgium, Dec. 8, 2015 /PRNewswire/ --VolitionRx Limited (NYSE MKT: VNRX) today announced results demonstrating that its NuQ® blood tests accurately detected 91% of colorectal cancer cases in a clinical study.

The study included 121 patients referred for colonoscopy at the university hospital, CHU Dinant Godinne - UCL Namur, in Belgium, who either presented with symptoms suggesting the presence of colorectal cancer or were high-risk subjects. Of these, 23 were found to have colorectal cancer. Investigators in the prospective study tested blood samples collected according to VolitionRx's standard procedures, taken from subjects prior to their colonoscopy, to determine whether a NuQ® test could accurately predict the subsequent findings of the colonoscopy.

Analysis of the results revealed that a panel test of four NuQ® biomarker assays, adjusted for age, detected 91% of colorectal cancer cases at 90% specificity. In addition the results showed equally accurate detection of early- and late-stage cancers. The analysis also revealed that the same panel test detected 67% of the type of polyps most likely to develop into cancer, demonstrating a potential for NuQ® tests to accurately detect the complete spectrum of cancer development from pre-cancerous polyps through early-stage to late-stage colorectal cancer.

Colorectal cancer is one of the most preventable cancers, yet there are still 50,000 deaths and more than 130,000 new cases diagnosed every year in the U.S. alone[1]. Colonoscopy examinations provide a high percentage of detection, yet due to their invasive and costly nature, more than one third of adults of screening age in the U.S. are not screened with such a procedure[2]. The five-year survival rate for colorectal cancer is 90% when detected at stage I but only 13% if detected at stage IV.

Professor Lionel D'Hondt, Head of the Department of Oncology at CHU Dinant Godinne - UCL Namur, remarked, "The development of better methods for the early detection of colorectal cancer is critical for the improvement of patients' survival rates. We have found that a NuQ® panel test detects colorectal cancer and pre-cancer, with high accuracy, indicating it may be useful as a routine clinical colorectal cancer blood test."

VolitionRx Chief Scientific Officer, Dr. Jake Micallef, Ph.D., added, "Current screening options for colorectal cancer are limited to invasive endoscopy procedures and fecal tests. Neither of these methods is patient-friendly and their uptake by the population at large is

poor. In contrast, a NuQ® panel test uses a tiny amount of blood and could be added to a routine medical check-up along with cholesterol, blood sugar, liver function, and other commonly administered blood tests. The study results demonstrate detection of 91% of colorectal cancer cases using an age-adjusted panel of four NuQ® assays. Moreover, 87% of colorectal cancer cases and 67% of high-risk dysplastic pre-cancerous polyps were detected using an unadjusted panel of five NuQ® assays alone, and no patient information. The study data provide evidence of the significant potential of our diagnostic NuQ® tests for detecting colorectal cancer."

Cameron Reynolds, Chief Executive Officer of VolitionRx, commented, "To detect colorectal cancer and pre-cancerous polyps with such high accuracy in an affordable blood test is a notable development. VolitionRx has demonstrated detection rates of 90% or higher in pancreatic cancer, lung cancer and now colorectal cancer, showing our unique proprietary platform technology can accurately detect a variety of cancers. Even more encouraging is the accuracy in detecting early-stage cancers and pre-cancers; finding tumours before they spread is a truly crucial breakthrough that will improve the outcomes for cancer patients."

Detailed findings from the 121-patient prospective study on colorectal cancer (CRC) at CHU Dinant Godinne - UCL Namur include:

	4 NuQ® biomarker assays*		5 NuQ® biomarker assays**	
	% detected	Number cases	% detected	Number cases
CRC (all stages)	91%	21 of 23 cases	87%	20 of 23 cases
CRC stage I	100%	4 of 4 cases	75%	3 of 4 cases
CRC stage II	83%	5 of 6 cases	83%	5 of 6 cases
CRC stage III	86%	6 of 7 cases	86%	6 of 7 cases
CRC stage IV	100%	4 of 4 cases	100%	4 of 4 cases
CRC unknown stage	100%	2 of 2 cases	100%	2 of 2 cases
Dysplastic pre-cancers	67%	6 of 9 cases	67%	6 of 9 cases

At 90% specificity against healthy subjects.

*age adjusted

**not age adjusted

Other results from ongoing clinical trials assessing the effectiveness of VolitionRx's assays, include:

Colorectal cancer and pre-cancerous colorectal polyps

- 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 and 67% of high-risk adenomas at 78% specificity.

Pancreatic cancer

- Results from a 59-patient retrospective study (Lund University, Sweden) published in *Clinical Epignetics* 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.

Lung cancer

- Interim results (73 of 240 patients collected and assessed) from a prospective study (Liege University Hospital, Belgium), released November 19 2015: Panel of four NuQ® biomarker assays detected 93% of lung cancers at 91% specificity.

References

1. National Cancer Institute. "SEER Stat Fact Sheets: Colon and Rectum Cancer." April 2015. Available online at: http://seer.cancer.gov/statfacts/html/colorect.html . Accessed September 8, 2015.

2. American Cancer Society. "Colorectal Cancer Facts & Figures 2014-2016." March 2014. Available online at: http://www.cancer.org/acs/groups/content/documents/document/acspc-042280.pdf . Accessed September 8, 2015.

About VolitionRx

VolitionRx is a life sciences company focused on developing blood-based diagnostic tests for different types of cancer. The tests are based on the science of Nucleosomics which is the practice of identifying and measuring nucleosomes in the bloodstream – an indication that cancer 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 centred 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 (www.volitionrx.com) or connect with us on Twitter, LinkedIn, Facebook or YouTube.

An animation introducing VolitionRx's Nucleosomics® technology can be found at: https://www.youtube.com/watch?v=38dodCpyXf0.

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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," "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.

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/volitionrx-demonstrates-more-than-90-accuracy-for-colorectal-cancer-nuqr-blood-test-in-completed-prospective-study-300189560.html

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