

May 12, 2016



# VolitionRx Initiates Clinical Trial with German Cancer Research Center (DKFZ) to Evaluate NuQ(R) Blood Test for Pancreatic Cancer

## 750-patient study will assess VolitionRx's proprietary Nucleosomics® platform for non-invasive detection of pancreatic cancer

NAMUR, Belgium, May 12, 2016 /PRNewswire/ --[VolitionRx Limited](#) (NYSE MKT: VNRX) today announced that it is initiating a study with DKFZ, the German Cancer Research Center, to evaluate VolitionRx's NuQ® blood tests for the detection of pancreatic cancer.

This collaboration follows VolitionRx's announcements last year of highly encouraging data from two preliminary studies for pancreatic cancer detection. Results from a 59-patient trial with [Lund University in Sweden](#), published in the journal *Clinical Epigenetics*, demonstrated a detection rate of 92% (23 of 25) of pancreatic cancer cases at 100% specificity using a panel of four NuQ® biomarker assays and the classical CA19-9 cancer biomarker. A second study with [Hvidovre Hospital, University of Copenhagen in Denmark](#) demonstrated that a panel of two NuQ® biomarker assays and the classical cancer marker CEA (carcino-embryonic antigen) in an age and gender adjusted panel detected 95% (19 out of 20) of pancreatic cancers at 84% specificity.

Professor Hermann Brenner, epidemiologist at DKFZ said, "VolitionRx has demonstrated some very encouraging early results for pancreatic detection using the Company's NuQ® blood-based diagnostic tool. This larger trial with DKFZ will provide a more extensive opportunity to evaluate the effectiveness of Nucleosomics® technology for pancreatic cancer diagnosis, a high-unmet medical need worldwide."

Dr. Mark Eccleston, VolitionRx's Business Development Director, said, "We are delighted to be working with a world class institution such as DKFZ to advance our pancreatic cancer tests. Our preliminary studies indicate that NuQ® tests can identify disease-associated nucleosomes in the blood of patients with pancreatic cancer, and differentiate those from healthy populations as well as those with other benign pancreatic diseases. Our goal at VolitionRx is to complete this trial by the end of this year and if successful, to begin the regulatory work to sell clinically in 2017, starting in Europe."

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 five-year survival rate for pancreatic cancer is currently just 7.7%<sup>1</sup>, due to late diagnosis

and the aggressive nature of the cancer. Screening for this cancer is only currently recommended for individuals considered at high risk of developing pancreatic cancer, as the only available methods are expensive or invasive techniques.<sup>2</sup> CA19-9, the only blood based biomarker for pancreatic cancer, has relatively low accuracy and is therefore used mainly for monitoring treatment response and disease progression. Despite this limitation, there are still over 46 million CA 19-9 tests performed in the US, UK, Germany, France, Italy, Spain and Japan annually.<sup>3</sup> Either replacing or augmenting this test would be the first target for VolitionRx in bringing a pancreatic blood test to market.

VolitionRx's Chief Executive Officer, Cameron Reynolds, added, "VolitionRx plans to launch its first commercial product, a blood test for colorectal cancer, later this year. Because our two preliminary trials for pancreatic cancer have produced such outstanding results, we anticipate this will be followed soon after by a NuQ<sup>®</sup> panel test for pancreatic cancer. This trial with DKFZ allows us to expand our analysis very quickly, with results expected by the end of the year, in a large sample set with a world class institution. If successful, this would be a game changing breakthrough in the diagnosis of this very deadly cancer."

Results from on-going clinical trials assessing the effectiveness of VolitionRx's 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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>)

## **References**

1. National Cancer Institute. "SEER Stat Fact Sheets: Pancreas Cancer." April 2016 . Accessed April 26, 2016. Canto MI, Harinck F, Hruban RH, Offerhaus GJ, Poley JW, Kamel I, et al. International Cancer of the Pancreas Screening (CAPS) Consortium summit on the management of patients with increased risk for familial pancreatic cancer. *Gut*. 2013 Mar. 62(3):339-47
2. Research and Markets. CA 19-9: 2013-2018 Test Volume and Sales Forecasts by Country and Market Segment: Hospitals, Commercial Labs, POC Locations -- France, Germany, Italy, Japan, Spain, UK, USA. November 2014.
- 3.

## **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<sup>®</sup>, 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](#).

## **About DKFZ**

Deutsches Krebsforschungszentrum, or DKFZ, is the largest biomedical research institute in Germany. It is a world-renowned research institute engaged in basic and clinical research aimed at developing effective methods for cancer detection, prevention and therapy. With access to trial samples across clinical centers in Germany, DKFZ performs multiple Government funded and collaborative research projects with corporate partners.

Visit DKFZ's website (<https://www.dkfz.de>) for more information.

## **Media Contacts**

Louise Day, VolitionRx  
[L.day@volitionrx.com](mailto:L.day@volitionrx.com)  
+44 (0) 7557 774620

Kirsten Thomas, The Ruth Group  
[kthomas@theruthgroup.com](mailto:kthomas@theruthgroup.com)  
+1 (508) 280-6592

## **Investor Contacts**

Scott Powell, VolitionRx  
[S.Powell@volitionrx.com](mailto:S.Powell@volitionrx.com)  
+1 (646) 650-1351

Lee Roth, The Ruth Group  
[lroth@theruthgroup.com](mailto:lroth@theruthgroup.com)  
+1 (646) 536-7012

## **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.

Nucleosomics<sup>®</sup>, NuQ<sup>®</sup> and HyperGenomics<sup>®</sup> and their respective logos are trademarks and/or service marks of VolitionRx Limited and its subsidiaries. All other trademarks, service marks and trade names referred to in this press release are the property of their respective owners.

To view the original version on PR Newswire, visit <http://www.prnewswire.com/news-releases/volitionrx-initiates-clinical-trial-with-german-cancer-research-center-dkfz-to-evaluate-nuqr-blood-test-for-pancreatic-cancer-300267550.html>

SOURCE VolitionRx Ltd