

VolitionRx Initiates Prostate Cancer Study in Collaboration with the Surrey Cancer Research Institute, University of Surrey, UK

NAMUR, Belgium, Feb. 2, 2016 /PRNewswire/ --<u>VolitionRx Limited</u> (NYSE MKT: VNRX) today announced that it has initiated a study to assess the feasibility of using the Company's NuQ[®] blood tests to detect prostate cancer. The study is in collaboration with the Surrey Cancer Research Institute of the University of Surrey in the UK.

In the retrospective study, 550 blood samples collected from patients attending the hospital will be analyzed using a panel of VolitionRx's NuQ[®] biomarker assays. Three groups of patients will be assessed: those with aggressive prostate cancer; those with indolent or slow-growing prostate cancer; and age-matched healthy controls. In addition to determining the NuQ[®] blood test's accuracy in detecting prostate cancer, the study will also assess the tests' ability to distinguish among the different prostate conditions and healthy samples.

Approximately 14% of men will be diagnosed with prostate cancer at some point during their lifetime and nearly 3 million men are estimated to be living with prostate cancer in the United States alone¹. While more than 80% of all prostate cancers are detected at the local stage, and nearly 100% of men diagnosed and treated at this stage will be disease-free after five years, a small percentage of men experience more rapidly growing, aggressive forms of prostate cancer².

VolitionRx Chief Scientific Officer, Dr. Jake Micallef, commented, "I am pleased that we have been able to commence this work in collaboration with Professor Hardev Pandha from the University of Surrey, who is very experienced and well-known in the field of prostate cancer diagnostics. Early detection and the ability to differentiate men with aggressive tumors requiring immediate treatment from men with slow-growing tumors that do not require aggressive treatment are important goals in the field of prostate cancer research. This new study with the University of Surrey will investigate the use of NuQ[®] blood tests both for cancer detection and for selection of patients requiring aggressive treatment. This trial of our NuQ[®] biomarker assays for more general prostate cancer detection complements the study we have underway in collaboration with MD Anderson, in which we are focusing on anaplastic prostate cancer – one of the most aggressive forms."

Professor Hardev Pandha, Director of the Surrey Cancer Research Institute and Professor of Urological Oncology at the University of Surrey, remarked, "There is an unmet medical need for better diagnostics in prostate cancer. In particular, patient monitoring and selection for treatment currently relies predominantly on the invasive prostate biopsy. Based on the analysis we will conduct in this study and further evaluation in larger studies, it is our hope

that VolitionRx's NuQ[®] tests will enable non-invasive and cost-effective blood-testing that will result in better diagnosis and treatment, and improved outcomes, for patients with prostate cancer."

Cameron Reynolds, Chief Executive Officer of VolitionRx, added, "We have now developed and manufactured a large suite of NuQ[®] biomarker assays which can be run rapidly using our high throughput ELISA robots at low cost. This allows us to investigate an expanding number of disease applications for our NuQ[®] tests while continuing to focus on the development and commercialization of regulatory approved products for colorectal cancer at very little extra cost."

In addition to this study, other clinical trials assessing the effectiveness of VolitionRx's biomarker assays in detecting prostate cancer include the following:

- A retrospective study to establish the efficacy of VolitionRx's NuQ® tests to distinguish anaplastic prostate cancer, a particularly aggressive form of the disease, from typical castration resistant prostate cancer (CRPC), the less aggressive form (MD Anderson Cancer Center, Texas)
- A 120-patient prospective feasibility study (ImmuneHealth, Belgium)

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: <u>Panel of four NuQ® biomarker assays detected 81% of colorectal cancers and 67% of</u> <u>high-risk adenomas at 78% specificity</u>
- Results from a prospective study of 121 patient referred for colonoscopy (CHU Dinant Godinne - UCL Namur, in Belgium), released December 8 2015: <u>Panel of four NuQ®</u> <u>biomarker assays detected 91% of colorectal cancer cases at 90% specificity</u>

Pancreatic cancer

- Results from a 59-patient retrospective study (Lund University, Sweden) published in Clinical Epignetics online journal (<u>http://www.clinicalepigeneticsjournal.com/content/pdf/s13148-015-0139-4.pdf</u>), October 7 2015: <u>Panel of four NuQ[®] biomarker assays plus CA 19-9 classical</u> biomarker detected 92% of pancreatic cancers at 100% specificity
- Interim results from a 4,800 patient retrospective symptomatic population study (Hvidovre Hospital, University of Copenhagen, Denmark), released October 22 2015: <u>Panel of two NuQ[®] assays and the classical cancer marker CEA (carcino-embryonic antigen) distinguished 95% of pancreatic cancer cases from healthy subjects at 84% specificity
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Lung cancer

• Interim results (73 of 240 patients collected and assessed) from a prospective study

(Liege University Hospital, Belgium), released November 19 2015: <u>Panel of four NuQ[®]</u> <u>biomarker assays detected 93% of lung cancers at 91% specificity</u>

References

1. National Cancer Institute. "SEER Stat Fact Sheets: Prostate Cancer." November 2015. Available online at: <u>http://seer.cancer.gov/statfacts/html/prost.html</u>. Accessed January 25, 2016.

2. Prostate Cancer Foundation. "What is Prostate Cancer?" Available online at: <u>http://www.pcf.org/site/c.leJRIROrEpH/b.5802045/k.6D36/What_Is_Prostate_Cancer.htm</u> . Accessed January 25, 2016.

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 (<u>www.volitionrx.com</u>) or connect with us on<u>Twitter</u>, <u>LinkedIn</u>, <u>Facebook</u> or <u>YouTube</u>.

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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-fluidbased 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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About the University of Surrey

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The University of Surrey is one of the UK's leading professional, scientific and technological universities with a world-class research profile and a reputation for excellence in teaching. Ground-breaking research at the University is bringing direct benefit to all spheres of life – helping industry to maintain its competitive edge and creating improvements in the areas of health, medicine, space science, the environment, communications, defence and social policy. Programmes in science and technology have gained widespread recognition and it also boasts flourishing programmes in dance and music, social sciences, management and languages and law.

In addition to the campus on 150 hectares just outside Guildford, Surrey, the University also owns and runs the Surrey Research Park, which provides facilities for 110 companies

employing 2,750 staff. The University of Surrey was recently named University of the Year by the Times and Sunday Times, both overall and for 'Student Experience', and has achieved a top-ten ranking in all three major national university league tables.

For more information about the University and its work, visit<u>www.surrey.ac.uk</u>

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