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VolitionRx to Initiate Study with University Hospital Bonn to Confirm NuQ® Test Accuracy in Lung Cancer

Confirmatory study will assess VolitionRx's proprietary Nucleosomics® platform for non-invasive diagnosis of lung cancer as part of larger ongoing, prospective clinical trial

Initiation based on findings from pilot study that demonstrated NuQ® tests able to detect lung cancer in 76% of patients using blood

NAMUR, Belgium, Dec. 17, 2014 /PRNewswire/ --VolitionRx Limited (OTCQB: VNRX), a life sciences company focused on developing diagnostic tests for cancer and other conditions, today announced that the University Hospital Bonn in Germany will initiate a clinical confirmatory study to assess VolitionRx's proprietary Nucleosomics® platform technology for the diagnosis of lung cancer through a blood test in individuals.

The confirmatory study will be conducted as a separate trial in conjunction with VolitionRx's larger 4,000-subject prospective study evaluating VolitionRx's NuQ® assays in the 20 most prevalent cancers with the University Hospital Bonn, in which hospital researchers are currently collecting blood samples from healthy individuals, patients with cancers and patients with other conditions and for which analysis will begin in 2015.

The confirmatory study will include a portion of the samples from the 4,000-subject trial, with both studies being led by Priv-Doz. Dr. Stefan Holdenrieder at the Institute of Clinical Chemistry and Clinical Pharmacology, University Hospital Bonn. In the confirmatory study, approximately 600 blood samples will be analyzed, including approximately 400 samples from patients with lung cancer with different histological subtypes and diverse stages of disease; 100 from patients with benign lung diseases that are relevant for differential diagnosis; as well as 100 samples from healthy subjects tested to determine distribution of nucleosome modifications compared to those modifications in malignant samples.

Priv-Doz. Dr. Stefan Holdenrieder, remarked, "Following the encouraging results reported from VolitionRx's pilot lung cancer study in both blood and sputum at the BioWin Day 2014 in Belgium last month, I am looking forward to conducting a subsequent study in blood to further validate the accuracy of the Nucleosomics® technology in lung cancer. Early detection of lung cancer remains a high unmet medical need across the globe and the use of promising biomarkers such as modifications of nucleosomes – which play an important role in the development and progression of lung cancer – may offer the potential to enhance the accuracy of early cancer detection."

Chief Scientific Officer Dr Jake Micallef commented, "The confirmatory study led by Dr.

Holdenrieder at University Hospital Bonn serves as further validation of the data we have shown to date demonstrating the accuracy and sensitivity of our NuQ® test not only lung cancer, but also in other prevalent cancers including colorectal and prostate. We look forward to initiating the confirmatory study and hope that the results will confirm the accuracy of the test in detecting lung cancer, this time in a larger number of subjects."

VolitionRx's pilot lung cancer study assessed the ability of the NuQ® platform to detect lung cancer in both blood and sputum (airway secretions, or mucus coughed up from the lower respiratory tract). Samples were collected from 46 individuals with either non-small cell lung cancer (NSCLC), chronic obstructive pulmonary disease (COPD) or with no disease (healthy).

Overall, the NuQ® technology was able to detect both early and late stage lung cancer with high sensitivity and specificity in both blood and sputum samples.

In sputum samples, the NuQ® test was able to detect 85% of lung cancer cases, with no false positive results for healthy subjects, and discriminate lung cancer from COPD. The sputum assay data is age and smoking independent.

In blood samples from the same patients adjusted for age and smoking risk, the NuQ® assays were able to detect 76% of patients with cancer, with a single false positive result for a healthy subject, and to also discriminate lung cancer from COPD.

The NuQ® tests utilize the Company's proprietary Nucleosomics® platform, which identifies and measures circulating nucleosome structures for the presence of epigenetic cancer and signals within the blood, and now within sputum.

In addition to the confirmatory lung cancer study, other clinical trials assessing the effectiveness of VolitionRx's assays include:

- A 4,800 patient retrospective symptomatic population study in colorectal cancer at Hvidovre Hospital, University of Copenhagen, Denmark
- A 14,000 patient prospective screening study in colorectal cancer at Hvidovre Hospital, University of Copenhagen, Denmark
- A 4,000 patient prospective study that involves patients with the 20 most prevalent cancers at University Hospital in Bonn, Germany
- A 250 patient prospective study in colorectal cancer at CHU-UCL Mont Godinne Hospital, Belgium
- A retrospective study with MD Anderson, Texas, 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.
- A prospective study with the University of Oxford, United Kingdom, to assess VolitionRx's NuQ® tests for the diagnosis of endometriosis.

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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 centred in Belgium as the company focuses on bringing its diagnostic products to market first in Europe, then in the US and ultimately, worldwide.

Visit VolitionRx's website (www.volitionrx.com) or connect with us viaTwitter, LinkedIn or Facebook.

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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," "believes," "seeks," "estimates," "optimizing," "potential," "goal," "suggests" 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 Report 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-to-initiate-study-with-university-hospital-bonn-to-confirm-nuq-test-accuracy-in-lung-cancer-300011029.html

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