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VolitionRx Demonstrates NuQ® Blood Test Detects Lung Cancers with more than 90% Accuracy

NAMUR, Belgium, Nov. 19, 2015 /PRNewswire/ --VolitionRx Limited (NYSE MKT: VNRX) today announced interim data demonstrating its NuQ® blood tests have accurately detected more than 90% of lung cancer cases in a study of 73 patients.

The clinical study is part of an ongoing larger prospective study of 240 subjects conducted with the Liege University Hospital (Belgium). The results were the outcome of an interim analysis of the first subjects recruited, including 29 subjects diagnosed with Non-Small Cell Lung Cancer, 22 diagnosed with another pulmonary disease (COPD) and 22 with healthy lungs.

The analysis revealed that, when combined with details of smoking history, a panel of four NuQ® biomarker assays detected 93% of lung cancer cases (27 of 29), with 91% specificity (2 false positive results among 22 healthy subjects).

Lung cancer is the second most common cancer in men and women, with around 220,000 new cases diagnosed each year and 158,000 deaths in the U.S. alone[1]. Lung cancer is the leading cause of cancer-related death in the U.S.[2]. Smoking history is the most important of the known and proven risk factors for lung cancer. While there are several types of lung cancer, Non-Small Cell Lung Cancer represents about 80% of those detected[3]. Typically, symptoms of lung cancer do not appear until the disease is already in an advanced stage, and they can be confused with others conditions. VolitionRx believes that there remains a high, unmet medical need for non-invasive and easy-to-use tests that detect early-stage cancer.

Professor Renaud Louis, Head of the Pneumology Department at Liege University Hospital (Belgium), said, "These data show that Lung Cancer is detected by a NuQ® blood test and confirm the findings of our previous pilot study, which we presented at BioWin Day in November 2014. We look forward to the results of the completed study."

VolitionRx Chief Scientific Officer, Dr. Jake Micallef, Ph.D., remarked, "The NuQ® blood test not only differentiates lung cancer from healthy subjects but also from the common lung disease, COPD, which is related to tobacco consumption. The best current test for lung cancer is a scan that has high accuracy but does not distinguish well between cancerous and non-cancerous fibrous nodules in the lung, leading to a high false positive rate[2]. Our interim data are exciting because they show both high sensitivity and very few false positives, indicating that a simple NuQ® blood test, used alone or in conjunction with current standards, may detect lung cancer and distinguish it from other lung diseases."

Cameron Reynolds, Chief Executive Officer of VolitionRx, added, "To be detecting more than 90% of cancers in this blinded trial is extremely exciting. VolitionRx's studies in colorectal cancer, pancreatic cancer and now lung cancer have consistently shown that our Nucleosomics® technology accurately detects cancers and is able to correctly distinguish among different diseases with a simple blood test. Using only a drop of blood, our NuQ® tests aim to be affordable, patient friendly, and to be as easy to use as they are simple to perform on existing hospital laboratory instruments."

VolitionRx expects to make full results of this ongoing lung cancer study available in 2016, as well as the results of another 600-subject lung cancer study conducted with the University Hospital Bonn in Germany.

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

Colorectal cancer

- A 4,800 patient retrospective symptomatic population study (Hvidovre Hospital, University of Copenhagen, Denmark)
- A 14,000 patient prospective screening study (Hvidovre Hospital, University of Copenhagen, Denmark)
- A 250 patient prospective study (CHU-UCL Mont Godinne Hospital, Belgium)

Pre-cancerous colorectal adenomas

- A 800 patient retrospective study (Hvidovre Hospital, University of Copenhagen, Denmark)

27 most prevalent cancers

- A 4,200 patient prospective study that involves patients with the 27 most prevalent cancers (University Hospital, Bonn, Germany)

Lung cancer

- A 600 patient prospective confirmatory study (University Hospital, Bonn, Germany)

Prostate cancer

- 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)

Ovarian cancer

- A 40-patient retrospective feasibility study (Singapore General Hospital, Singapore)

Endometriosis

- A prospective study to assess VolitionRx's NuQ® tests for the diagnosis of endometriosis (the University of Oxford, United Kingdom)

References

(1) American Cancer Society. "Lung and Bronchus Cancer." September 2015. Available online at: http://seer.cancer.gov/statfacts/html/lungb.html . Accessed November 18, 2015.

(2) Moyer, VA. "Screening for Lung Cancer: U.S. Preventive Services Task Force Recommendation Statement." Annals of Internal Medicine Vol.160; page 330 (2014). Available online at: http://annals.org/article.aspx?articleid=1809422 . Accessed 18 November 2015

(3) NHS. "Lung Cancer." November 2015. Available online at: http://www.nhs.uk/conditions/cancer-of-the-lung/Pages/Introduction.aspx . Accessed 18 November 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.

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