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VolitionRx Announces First CE Mark for NuQ(R) Blood Assay for Detection of Colorectal Cancer

CE Mark Enables European Clinical Use/Sale in 33 Countries with nearly 600 million people

NAMUR, Belgium, Sept. 22, 2015 /PRNewswire/ --VolitionRx Limited (NYSE MKT: VNRX) today announced the Company's first CE Mark for its blood-based diagnostic assay, NuQ®X001S, for detection of colorectal cancer. The NuQ® test utilizes the Company's proprietary Nucleosomics® technology platform, which identifies and analyses fragments of chromosomes, called nucleosomes, circulating within the blood for the presence of epigenetic cancer signals.

The NuQ®X001S assay is the first to be CE Marked out of a suite of NuQ® assays developed by VolitionRx targeting different epigenetic modifications that indicate that cancer is present. The Company plans to offer a commercial test consisting of a panel of 4-6 individual ELISA assays; it is currently conducting ongoing clinical trials and following the CE compliance process on further assays in order to refine the make-up of the panel and produce the highest accuracy detection rates. VolitionRx anticipates launching its panel of CE Marked assays for clinical use in Europe during 2016.

This announcement follows the presentation earlier this month of interim data of a 4,800-subject trial, which demonstrated that VolitionRx's NuQ® blood tests detected 81% of colorectal cancers at 78% specificity equally well for both for early- and late-stage cancers, as well as 63% of potentially pre-cancerous adenomas and 67% of high-risk adenomas - the most likely to become cancerous.

Gaetan Michel, PhD, Chief Executive Officer of Belgian Volition SA, commented, "Our recent results showed that a panel test of 4 NuQ® assays successfully detected both early- and late-stage cancer well, which is critical for improving five-year survival rates. Achieving the first CE mark for our NuQ®X001S diagnostic assay demonstrates VolitionRx's clear commitment to deliver these first-class quality products to physicians and their patients. The CE Mark means that this NuQ® product is compliant with EU legislation and meets EU in-vitro diagnostic medical device requirements for clinical use in the European market. Due to

the non-invasive, low-cost and patient friendly nature of NuQ® blood tests, we believe our technology has the potential to gain market acceptance and save lives in Europe and worldwide."

Cameron Reynolds, President and Chief Executive Officer of VolitionRx, added, "This is yet another very important milestone for the Company on our path to making our blood tests available to patients. We are now able to sell this assay clinically in the 28 member states of the European Union, as well as Switzerland, Turkey, Iceland, Norway and Liechtenstein - an area with a total population of nearly 600 million people including over 150 million of screening age. We are currently in the process of CE marking other assays to finalise the panel for the anticipated European launch of our tests in 2016. We are proud of the thorough scientific and operational development of our NuQ® colorectal cancer tests and I would particularly like to thank our whole team who, through years of dedication and commitment, have made this key milestone possible. We also aim to continue to progress in 2016 towards our goal of making our assays available for clinical use in the U.S. and the rest of the world."

VolitionRx currently has several ongoing clinical trials assessing the effectiveness of its NuQ® assays. The full list includes:

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)

VolitionRx has applied the CE Mark to its blood-based diagnostic assay,NuQ®X001S, in agreement with the IVD Directive 98/79/EC and the Company has notified the product to the Competent Authorities.

Animation:

Animation showing how VolitionRx's NuQ® tests work. Credit: VolitionRx Ltd: https://www.youtube.com/watch?v=38dodCpyXf0

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 centered in the wholly owned subsidiary, Belgian Volition SA, 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 viaTwitter, LinkedIn, Facebook or YouTube.

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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" 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-announces-first-ce-mark-for-nuqr-blood-assay-for-detection-of-colorectal-cancer-300146876.html

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