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VolitionRx Engages Specialty Clinical Research Organization to Support Initial Entry of its NuQ(R) Colorectal Cancer Tests via U.S. CLIA Labs

Global Specimen Solutions, Inc. to Support U.S. Access through Select CLIA Labs and Medical Universities

Target to Enable Initial NuQ® U.S. Availability in 2016

NAMUR, Belgium, July 27, 2015 /PRNewswire/ --VolitionRx Limited (NYSE MKT: VNRX), a life sciences company focused on developing blood-based diagnostic tests for a broad range of cancer types and other conditions, today announced that it has engaged the services of a specialty specimen management clinical research organization, Global Specimen Solutions, Inc. (GSS), to support initial U.S. market entry of its NuQ® colorectal cancer tests.

Under the agreement, GSS will target and select U.S. medical universities and U.S. commercial clinical laboratories providing diagnostic testing services regulated under the Clinical Laboratory Improvement Amendments (CLIA) as strategic collaboration partners for testing of VolitionRx's NuQ® colorectal cancer tests. GSS will also develop a strategic market access plan for implementing relationships with select CLIA regulated labs, including licensing and royalty modeling from CLIA Laboratory Developed Tests (LDT) development, and strategic regulatory and clinical development for Premarket Approval (PMA) submission with the Food and Drug Administration (FDA).

Through partnership with GSS, VolitionRx aims to license its Nucleosomics® biomarker panels to CLIA labs for LDT development in the U.S. in 2016.

Cameron Reynolds, Chief Executive Officer of VolitionRx, commented, "With world-class expertise in collecting and managing specimens for research, and a strong understanding of the technology trends, regulatory environment and competitive situation, GSS is an ideal partner to support VolitionRx's strategy to enter the U.S. market and gain FDA approval of our NuQ® colorectal cancer tests. By first partnering with GSS to enter CLIA-certified labs and medical universities in the U.S., we believe that we will be well-positioned to initiate a bridging U.S. FDA-endorsed trial with our ongoing large trials in Europe, which will be designed to provide the clinical data to support PMA submission for the potential FDA approval of our NuQ® tests for the early detection of colorectal cancer. In parallel, we aim to license our Nucleosomics® biomarker panels in the US for development as an LDT in 2016, and provide VolitionRx with early revenue, while proceeding with the FDA approval process."

Gerald J. Vardzel, Vice President of Corporate Development at Global Specimen Solutions, commented, "VolitionRx's innovative blood-based cancer tests offer a potentially viable solution for detecting cancer early to allow more effective treatments. We look forward to supporting VolitionRx regarding strategic decisions to assess the value of its Nucleosomics® platform; providing insights on our understanding of technology trends, regulatory environment and competitive situation; and introducing VolitionRx to select medical universities and CLIA labs for collaborations aimed at initial entry into the U.S."

Mark Eccleston, PhD, MBA, Business Development Director at VolitionRx, added, "Collaborating with GSS in the U.S. augments our primary commercialization strategy to gain approvals in both Europe and the U.S. in alignment with swift market entry across these regions. Our objective is to work with GSS to identify and select key U.S. partners to develop our Nucleosomics biomarkers as an LDT and we look forward to providing further updates on this process."

Amelia Warner, PharmD, RPh, CEO and Founder of GSS, commented, "We are extremely excited about collaborating with VolitionRx on this promising technology. GSS is looking forward to building a long-term relationship with VolitionRx to help roll out their disruptive technology platform into the clinic where we hope to impact current patient care."

The NuQ® tests will utilize VolitionRx's proprietary Nucleosomics® technology platform, which identifies and measures circulating nucleosome structures as epigenetic biomarkers of cancer within the blood. The results from several large ongoing clinical trials in the EU will provide the basis for application for a CE Mark application, the European equivalent of the FDA approval in the U.S. In support of its PMA submission to the FDA, VolitionRx plans to bridge its European trials with trials in the U.S. to evaluate the NuQ® tests with patient populations representative of U.S. ethnicity.

Ongoing clinical trials assessing the effectiveness of VolitionRx's 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 prospective 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)

About Global Specimen Solutions, Inc. (GSS)

Global Specimen Solutions, Inc. (GSS) is a clinical research organization that specializes in integrated specimen management. The Company provides products and operational service expertise for human specimen research across the pharmaceutical and diagnostic sectors and others who are designing future use specimen collection, collecting specimens at one site, multiple sites, or sites around the world, and managing large specimen inventories. http://www.globalspecimensolutions.com

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 centered 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 (http://www.volitionrx.com) or connect with us viaTwitter, LinkedIn, Facebook or YouTube.

About the Clinical Laboratory Improvement Amendments (CLIA)

The Centers for Medicare & Medicaid Services (CMS) regulates all laboratory testing (except research) performed on humans in the U.S. through the Clinical Laboratory Improvement Amendments (CLIA). In total, CLIA covers approximately 251,000 laboratory entities. The Division of Laboratory Services, within the Survey and Certification Group, under the Center

for Clinical Standards and Quality (CCSQ) has the responsibility for implementing the CLIA Program. The objective of the CLIA program is to ensure quality laboratory testing.

https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html?redirect=/clia/

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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-engages-specialty-clinical-research-organization-to-support-initial-entry-of-its-nuqr-colorectal-cancer-tests-via-us-clia-labs-300118892.html

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