

ViroGates announces a delay in the development and launch of its pipeline product suPARnostic® POC+

BIRKERØD, DENMARK – ViroGates A/S, a medical technology company developing blood tests for better triaging in hospitals to improve patient care and reduce healthcare costs, announces that the development of the company's new point-of-care product, suPARnostic® POC+, will be delayed to the first half of 2022.

suPARnostic® POC+ is co-developed with Austrian-based GENSPEED Biotech GmbH and will enable the measurement of both suPAR and CRP in a blood sample from a fingerprick. The product will expand the addressable market for ViroGates to pre-hospital customers, general practitioners, and others.

The product was previously scheduled for launch in the second half of 2021. The product launch is now expected in the first half of 2022, following a clinical validation study and an expected CE-IVD approval.

The reason for the delay is related to general analytical performance parameters. The final steps of the product development and manufacturing are pivotal and required from a regulatory point to have completed before a clinical validation study can be initiated.

This announcement does not affect the strategic objectives of ViroGates.

Jakob Knudsen, Chief Executive Officer of ViroGates, says: "Today we announce a further delay of the launch of our suPARnostic® POC+ product. The delay follows a detailed revision of our development plans with our Austrian partner GENSPEED Biotech and today's final approval of our revised development plan here at ViroGates. The quality of all our products is pivotal to us since clinical decisions are taken based on the performance of our products. We decided that we wanted to optimise parameters associated with the analytical performance of the product, before running the final clinical performance study. We remain excited about the suPARnostic® POC+ product and the opportunity it will have in the acute care, pre-hospital, and patient transportation segments of the market and further on potential screening of healthy individuals to assess general inflammatory status."

The announcement can be found at
<https://www.virogates.com/investor/announcements>

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About ViroGates

ViroGates A/S is an international medical technology company developing and marketing blood test products under the suPARnostic® brand for better triaging in hospitals to improve patient care, reduce healthcare costs and empower clinical staff.

The company was founded in 2000. Headquartered in Denmark, ViroGates' sales force covers the Nordics, Spain, and France, while distributors serve other markets.

ViroGates' shares (VIRO) are listed on Nasdaq First North Growth Market Denmark. For more information, please visit www.virogates.com.

About suPAR and suPARnostic®

suPAR is the biomarker detected by ViroGates' suPARnostic® products and is a protein in plasma, measurable in every human being. suPAR is considered a general risk status biomarker indicating disease presence, disease severity and progression, organ damage and mortality risk across disease areas such as cardiovascular diseases, kidney diseases, type 2 diabetes, cancer, etc. Strong scientific evidence from more than 750 clinical trials and studies show that the higher the level of suPAR, the worse the prognosis for the patient.

The suPARnostic® products can be used to support healthcare professionals in making clinical decisions on hospitalization or discharge of acute care patients. The increasing demands on health systems globally and tightening healthcare budgets necessitate efficiency improvements and innovative solutions in hospitals. The use of suPAR in clinical routine in emergency departments can improve patient care and reduce healthcare costs by increasing the number of discharges by up to 34% and reducing the average hospital length-of-stay by up to 6% without affecting mortality. suPARnostic® TurbiLatex is currently available on Roche Diagnostics' cobas® instruments, Siemens Healthineers ADVIA® XPT and Atellica® instruments and the Abbott Labs Architect™ and Alinity™ instruments. ViroGates works with partners to develop solutions for other platforms.