



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

7.1.2021 17:13:25 CET | ViroGates | Company Announcement

COMPANY ANNOUNCEMENT - No. 1-2021 - 7 January 2021

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 second half of 2021.

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.

As previously announced, the product launch was expected in Q1, 2021. The product launch is now expected in the second half of 2021, following a clinical validation study in Q2, 2021, and an expected CE-IVD approval.

The reason for the delay is related to QC/QA specification development that has been delayed as a result of the COVID-19 pandemic in Austria during the second half of 2020. The final steps of the product development and manufacturing is 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: *"In close collaboration with our Austrian partner, we have decided to delay the clinical validation study of our suPARnostic® POC+ product as we do not want to compromise the quality of this promising product opportunity. Obviously, we need to adhere to the CE-IVD development regulations. Therefore, we will postpone our launch of the product until the second half of 2021, and pending a successful clinical validation 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>

For further information, please contact:

ViroGates A/S:

CEO, Jakob Knudsen

Tel. (+45) 2226 1355, email: jk@virogates.com

Certified Advisor:

Västra Hamnen Corporate Finance

Per Lönn

Tel. (+46) 40 200 250, email: per.lonn@vhcorp.se

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 based on the discovery that suPAR was predictive of outcome in HIV-infections and subsequently in many other disease areas. 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 measured 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 600 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 34% and reducing the average hospital length-of-stay by 6% without affecting mortality. suPARnostic® TurbiLatex is currently available on Roche Diagnostics' cobas, instruments, Siemens ADVIA XPT instruments and the Abbott Labs Architect instruments. ViroGates works with partners to develop solutions for other platforms.

Disclosure regulation

Prospects about the future reflect ViroGates' current expectations for future events and results. The statements are by nature inherent in risks, uncertainties and other matters that are difficult to predict or out of control. The actual results may therefore differ from the expectations expressed.

Contacts

- Jakob Knudsen, CEO, +45 2226 1355, jk@virogates.com

Attachments

- [20210107-ViroGates Company announcement 1.pdf](#)