ViroGates announces the receipt and handling of a customer complaint regarding suPARnostic® ELISA

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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, today announces that it has received a complaint regarding the quality of the suPARnostic® ELISA product. The clinical customer has informed ViroGates that it has seen a drift concerning reported suPAR results in the magnitude of 40% over several lots. The complaint has also been filed with regulatory authorities (Lægemiddelstyrelsen).

ViroGates has conducted a thorough investigation of the complaint and has performed both in-house and external analyses including in a close collaboration with the customer to evaluate the reported issue. The external analysis has been conducted with an American university laboratory.

Based on findings from these analyses, ViroGates concludes that the reported complaint currently can be isolated to the use on a specific automated ELISA robot, the Siemens BEP 2000 System, which is being used by the customer. Manual re-testing on the same kits provides consistent and satisfactory results over time, thus the suPARnostic® ELISA product is not experiencing general quality issues.

Although the suPARnostic® ELISA product is approved for diagnostic use under the CE-IVD standards, it is almost exclusively applied by clinical research teams across the world for research applications. As most diagnostic customers prefer to use products for point of care or products amenable to automation, ViroGates offers the CE-IVD approved products suPARnostic® Quick Triage and suPARnostic® TurbiLatex products, respectively. These products are unaffected by this complaint.

ViroGates is currently working with the customer to implement the suPARnostic® Quick Triage test in the Emergency Department for point of care use.

The answer to the complaint has been filed with the regulatory authorities (Lægemiddelstyrelsen) and ViroGates is awaiting the response from the authorities.

During the time of the investigation, the clinical customer will not be using suPARnostic® ELISA for clinical decision making. This is expected to have a negative impact on revenues in the first quarter of 2020.

CEO Jakob Knudsen, says in a comment: *"We take quality complaints very seriously at ViroGates. We have worked with the customer to come up with an explanation for the drift in results they observed over time. It is a serious matter to report data for clinical patients and we wanted to make sure that our investigation was performed as thoroughly as possible. We have included data from the internal analysis, data from re-testing of samples at the customers site as well as data from a highly accredited American university laboratory, all arriving at the same conclusion that ViroGates has had no quality issue related to the suPARnostic® ELISA product when performed as a manual analysis. However, when analysed on a specific robot the results show a slight increase for the last batch. We will continue to work with the customer to find a solution to this problem. Due to the historic high volume of testing at this site there will be a negative impact on revenues in the first quarter of 2020, but our plans for placing suPARnostic® with other clinical customers remain unaffected as these efforts are based on the two other product lines we market."*

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 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 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 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 Siemens ADVIA XPT instruments and Roche Diagnostics' cobas 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.

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Attachments

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