COMPANY ANNOUNCEMENT

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ViroGates announces initiation of a clinical trial with HISS to clinically validate its commercial biomarker test for guiding early anakinra treatment of COVID-19 patients across 42 hospitals

- ***suPARnostic® can become the first companion diagnostic device to aid in selecting and excluding COVID-19 patient groups for drug treatment***
- ***The product is already deployed for risk stratification and patient management of COVID-19 patients in European hospitals***

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 it has initiated a clinical study to be conducted in collaboration with HISS (Hellenic Institute for the Study of Sepsis) to clinically validate suPARnostic® for guiding early anakinra treatment of COVID-19 patients.

suPAR is a naturally occurring protein measurable in all humans reflecting immune activation and is associated with inflammation and adverse outcomes across life-threatening diseases[1] [2]. suPAR can be measured as a biomarker using the suPARnostic® TurbiLatex and Quick Triage products and is currently being used in existing hospital workflows and instruments across Europe. suPARnostic® TurbiLatex is validated for use on clinical chemistry analysers from Roche Diagnostics, Siemens Healthineers, and Abbott.

An exploratory study from October 2020[3], currently undergoing peer review, shows initial positive results using suPAR-guided anakinra treatment to prevent severe respiratory failure (SRF) for COVID-19 patients. The reported data include 130 COVID-19 patients with suPAR levels above 6 ng/mL undergoing anakinra treatment and 130 matched controls who did not receive anakinra treatment. Results showed that the incidence of SRF among treated patients was 22.3% compared to 59.2% among untreated comparators. Mortality after 30 days was 11.5% and 22.3%, respectively.

HISS has initiated a study to clinically validate the exploratory study's findings. The study is an interventional, confirmatory, phase III randomized clinical trial (RCT) aiming to evaluate the efficacy and safety of early start of anakinra treatment guided by suPAR in COVID-19 patients in improving the clinical outcome for COVID-19 patients over 28 days. The study will enrol 600 patients across 42 hospitals in Greece and Italy. The primary outcome is measured by the ordinal scale of the 11-point WHO clinical progression scale ranging from the best outcome (asymptomatic) to the worst outcome (death). Secondary outcomes such as cost of hospitalization, time until discharge and rate of adverse events will also be measured. ViroGates will provide suPARnostic® test kits for the clinical trial.

[1] Hayek SS. et al (2020) Soluble urokinase receptor and acute kidney injury. New England Journal of Medicine (NEJM) 382:416–426
[2] Backes Y. et al. Usefulness of suPAR as a biological marker in patients with systemic inflammation or infection: a systematic review. Intensive Care Med. 2012;38(9):1418-1428. doi:10.1007/s00134-012-2613-1
[3] Anakinra To Prevent Respiratory Failure In COVID-19. Kyriazopoulou et al. https://medrxiv.org/cgi/content/short/2020.10.28.20217455v1

Since 2019, the suPARnostic® TurbiLatex and Quick Triage products have been deployed across various hospitals in Europe, including for COVID-19 patients since March 2020. ViroGates has recently scaled up the production to meet the expected increased demand from customers using the product for COVID-19 patient management.

Evangelos Giamarellos-Bourboulis, MD, Ph.D., Hellenic Institute for the Study of Sepsis, said: "*Our interim analysis of 130 patients using suPAR-guided anakinra treatment of COVID-19 patients showed promising results in significantly decreasing mortality, the incidence of severe respiratory failure, and the median cost of hospitalization. If the interim results are validated in the randomized clinical trial, the implication for healthcare professionals working with the management of COVID-19 patients can be significant.*"

Jakob Knudsen, Chief Executive Officer of ViroGates, said: *"We are delighted to enter a partnership with HISS to clinically validate our suPARnostic® product as potentially the first companion diagnostic device used in the process to assess patients eligible for treatment for COVID-19 disease. The hospital systems currently face severe crowding in acute and intensive care functions. The ability to identify COVID-19 patients for early treatment can potentially save lives, reduce costs, and ease the burden on national health care systems."*

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 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.