ViroGates reports use of suPAR-guided anakinra treatment improved overall clinical outcome by 64% in hospitalised patients with COVID-19 pneumonia

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Hellenic Institute for the Study of Sepsis announces positive data from investigator-sponsored SAVE-MORE randomised controlled study, evaluating early and targeted use of suPAR-guided anakinra treatment in over 600 patients.

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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, and the Hellenic Institute for the Study of Sepsis announces positive top-line results from the SAVE-MORE study. SAVE-MORE is an investigator-sponsored study, which assessed the effect of suPAR-guided anakinra treatment in moderate to severe COVID-19 pneumonia patients.

The results show that early, suPAR-guided use of anakinra in addition to the current standard of care in hospitalised patients with poor prognosis, as demonstrated by an elevated suPAR level (above 6 ng/ml), prevented either death or progression to severe respiratory failure, whilst increasing the number of patients who were discharged from hospital with no evidence of COVID-19 infection.

SAVE-MORE is a multicenter, double-blinded, randomised controlled trial in over 600 hospitalised patients that specifically identifies those at risk of severe respiratory failure by the measurement of elevated suPAR (soluble urokinase plasminogen activator receptor), a plasma biomarker that reflects immune activation and has been previously associated with poor prognosis in a number of conditions. The study is sponsored by the Hellenic Institute for the Study of Sepsis (HISS) in Greece and led by its President and Chairman, Professor Evangelos J. Giamarellos-Bourboulis. Giamarellos-Bourboulis is Professor of Internal Medicine and Infectious Diseases at the National and Kapodistrian University of Athens, President of the European Shock Society and Chairman of the European Sepsis Alliance.

Analysis of the primary endpoint, the comparative 11-point WHO Clinical Progression ordinal Scale (CPS) [i], at day 28 demonstrated significant improvement in patients with elevated suPAR levels receiving standard-of-care treatment plus anakinra vs patients with elevated suPAR levels receiving standard-of-care plus placebo (Odds Ratio 0.36, $p<0.001$). There were reductions in the number of patients who died or who progressed to severe respiratory failure and an increase in the number of patients discharged from hospital with no evidence of COVID-19 infection. These changes were apparent at day 14 (Odds Ratio 0.59, $p= 0.001$). ViroGates intends to participate in discussions with regulatory authorities concerning the results.

Professor Evangelos J. Giamarellos-Bourboulis, President and Chairman of HISS, says: "*This is the first study to specifically evaluate an at-risk patient population before admission to intensive care unit (ICU). The results provide a significant step forward in the search for additional treatment options to prevent progression to a more critical state. My thanks go to the many patients and clinicians who have contributed across Greece and Italy*."

Jakob Knudsen, CEO of ViroGates, says: *"We are pleased that suPAR-guided anakinra treatment demonstrated a significant improvement in the overall clinical outcome for the affected COVID-19 patients. We have previously seen the effects of using suPARnostic® to guide early discharge of low-risk patients. However, we are pleased to see that suPARnostic® can also be extended to guide early intervention in high-risk patients in addition to standard-of-care. Furthermore, we are delighted that our products can help combat the negative outcomes of COVID-19. At ViroGates, we would like to congratulate and sincerely thank Professor Giamarellos-Bourboulis and his team for this valuable work conducted under challenging conditions in a short time."*

Jesper Eugen-Olsen, CSO of ViroGates, says: "*We are delighted to see that suPAR is a useful biomarker in guiding the treatment of COVID-19 patients. Identifying the right high-risk patients for treatment to improve overall clinical outcomes can be an important part of battling the global pandemic. We will now conduct additional data analyses and await the outcome of the ongoing dialogue with EMA led by Professor Giamarellos-Bourboulis*."

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About SAVE-MORE

SAVE-MORE (NCT04680949); suPAR-Guided Anakinra Treatment for Management of Severe Respiratory Failure by COVID-19) is a pivotal, confirmatory, phase III randomised controlled trial (RCT). The trial aims to evaluate the efficacy and safety of early start of anakinra guided by suPAR in patients with LRTI by SARS-CoV-2 in improving the clinical state of COVID-19 over 28 days, as measured by the ordinal scale of the 11-point World Health Organization (WHO) clinical progression scale (CPS). Anakinra was administered at a dose of 100mg/day SC for up to 10 days. Of 1,060 patients screened, 606 patients were randomised across 40 sites in Greece and Italy. SAVE-MORE is an investigator-sponsored study conducted independently by Professor Giamarellos-Bourboulis, with the Hellenic Institute for the Study of Sepsis being the regulatory sponsor. ViroGates has supported the study with suPARnostic® Quick Triage test kits and readers. ViroGates had no influence on the design or governance of the study.

About SAVE

In the SAVE study (NCT04357366), patients with lower respiratory tract infection with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) at high risk for progression to serious respiratory failure were detected using the suPAR biomarker. Early treatment began with anakinra 100 mg/day sc for up to 10 days in the effort to prevent progression in serious respiratory failure. The study is open label, single arm and will include a total of 1000 patients. 130 patients were included in a preliminary analysis. The analysis of the SAVE study at Day 14 showed that early treatment with anakinra as guided by the suPAR biomarker significantly decreased the incidence of severe respiratory failure in COVID-19 patients with pneumonia compared to a matched control cohort [ii]. The SAVE study is an investigator sponsored study conducted independently by Professor Giamarellos-Bourboulis, with the Hellenic Institute for the Study of Sepsis being the regulatory sponsor. ViroGates has supported the study through the Horizon Europe 2020 RISCinCOVID grant. ViroGates had no influence on the design or governance of the study [iii].

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 700 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 hospitalisation 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 and Alinity instruments. ViroGates works with partners to develop solutions for other platforms.

About Kineret® (anakinra)

Kineret® is a interleukin-1 receptor antagonist sold by Swedish Orphan Biovitrum AB (publ) (Sobi™) (STO:SOBI) that is indicated in the US for reduction in signs and symptoms and slowing the progression of structural damage in moderately to severely active rheumatoid arthritis, in patients 18 years of age or older who have failed one or more disease modifying antirheumatic drugs (DMARDs), for the treatment of neonatal-onset multisystem inflammatory disease (NOMID, a form of cryopyrin-associated periodic syndromes (CAPS)), and for the treatment of Deficiency of Interleukin-1 Receptor Antagonist (DIRA).

In Europe, Kineret is indicated in adults for the treatment of the signs and symptoms of rheumatoid arthritis (RA) in combination with methotrexate, with an inadequate response to methotrexate alone. In addition, Kineret is indicated in adults, adolescents, children and infants aged 8 months and older with a body weight of 10 kg or above for the treatment of cryopyrin-associated periodic syndromes (CAPS), including - neonatal-onset multisystem inflammatory disease (NOMID)/chronic infantile neurological, cutaneous, and articular syndrome (CINCA), Muckle-Wells syndrome (MWS) and familial cold auto inflammatory syndrome (FCAS). Kineret is indicated for the treatment of Familial Mediterranean fever (FMF). Kineret should be given in combination with colchicine, if appropriate. It is also indicated in adults, adolescents, children and infants aged 8 months and older with a body weight of 10 kg or above for the treatment of Still's disease, including Systemic Juvenile Idiopathic Arthritis (SJIA) and Adult-Onset Still's Disease (AOSD), with active systemic features of moderate to high disease activity, or in patients with continued disease activity after treatment with non-steroidal anti-

inflammatory drugs (NSAIDs) or glucocorticoids. Kineret can be given as monotherapy or in combination with other anti-inflammatory drugs and disease-modifying antirheumatic drugs (DMARDs).

For full US prescribing information visit www.kineretrx.com and for full European prescribing information visit the EMA website.

About the Hellenic Institute for the Study of Sepsis

The Hellenic Institute for the Study of Sepsis (HISS) is a non-profit organisation situated in Athens. HISS coordinates the research activities in sepsis and severe inflammatory disorders since 2010 of 58 departments of Internal Medicine and Intensive Care Units in Greece and abroad. HISS has sponsored the conduct of more than 30 clinical studies and has a track record of providing support for more than 100 publications. The phase II SAVE trial and the phase III SAVE-MORE trial were regulatory sponsored by HISS. For more details visit www.sepsis.gr

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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 the 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.

[i], [iii] Lancet Infect Dis 2020, Published Online June 12, 2020 https://doi.org/10.1016/S1473-3099(20)30483-7

[ii] Early suPAR-guided anakinra decreased SRF and restored the pro-/anti-inflammatory balance.

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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