

SAVE-MORE study on the effect of suPARnostic® guided anakinra treatment in patients with COVID-19 pneumonia published in Nature Medicine

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 reports that Nature Medicine has published the previously announced positive results from the investigator-driven phase III SAVE-MORE study evaluating the effect of suPARnostic® guided anakinra plus standard of care treatment (SOC) in patients with moderate-to-severe COVID-19 pneumonia. The study demonstrated that patients triaged based on high suPAR results, that were subsequently treated with anakinra, in addition to current SOC, experienced reduced risk of death, ICU admission and increased the likelihood of full recovery. The study was conducted by the Hellenic Institute for the Study of Sepsis.

KEY HIGHLIGHTS FROM THE STUDY

- Early triage with suPARnostic® for medical intervention using anakinra showed considerable efficacy and reduced risk of disease progression and death by 64 percent, according to day 28 results from the SAVE-MORE study.
- Relative decrease of mortality was 55%, reaching 80% for patients with cytokine storm.
- Proportion of patients who fully recovered exceeded 50 percent, and number of patients remaining with severe disease reduced by 54 percent. Average time until hospital and intensive care unit (ICU) discharge was reduced by one and four days.

[The SAVE-MORE study](#), conducted by the Hellenic Institute for the Study of Sepsis, is the first large, pivotal randomised controlled trial to specifically evaluate a patient population triaged at being at risk of progressing to critical state by the use of suPARnostic® and demonstrate considerable benefit of earlier intervention for the prevention of disease progression and death. Patients at low risk based on low suPAR results were excluded from the study. The study population had co-administered treatments that were similar between the two arms of the study and included dexamethasone, anticoagulants and remdesivir. The study results were [previously reported](#) in May.

“The results published in Nature Medicine provide the only data available on prevention from early stage progressing to critical status, indicating that the inflammatory disease

needs to be treated earlier with a specifically targeted approach to IL-1 alpha and IL-1 β ," said lead investigator **Evangelos J. Giamarellos-Bourboulis, Professor of Internal Medicine and Infectious Diseases, National and Kapodistrian University of Athens, President of the European Shock Society, and Chairman of the European Sepsis Alliance.**

Jakob Knudsen, CEO of ViroGates, said: "Publication of the SAVE-MORE study results in Nature Medicine demonstrates the clinical importance of the data achieved. Using suPARnostic[®] to guide the use of pharmaceutical intervention with anakinra demonstrates the ability to intervene in an important pathway, the IL-1 in COVID-19. The study further shows how physicians can use suPARnostic[®] to guide treatment and reserve intervention for patients that are benefitting from the dampening of their inflammatory response. We can see that this leads to more effective treatment and more effective use of scarce hospital resources. "

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.

About SAVE-MORE

SAVE-MORE ([NCT04680949](https://clinicaltrials.gov/ct2/show/study/NCT04680949)); suPAR-Guided Anakinra Treatment for Management of Severe Respiratory Failure by COVID-19, is a large, pivotal, confirmatory, phase III randomized controlled trial (RCT) in over 600 hospitalised patients. 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 2:1 across

37 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 sponsor.

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 sponsored by HISS. For more details visit www.sepsis.gr
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About Sobi

Sobi is a specialised international biopharmaceutical company transforming the lives of people with rare diseases. In 2020, Sobi's revenue amounted to SEK 15.3 billion. Sobi's share (STO:SOBI) is listed on Nasdaq Stockholm. You can find more information about Sobi at www.sobi.com.

About Kineret® (anakinra)

Kineret® is an interleukin-1 α and β receptor antagonist 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).

For full US prescribing information visit www.kineretrx.com and for full European prescribing information visit the EMA website. Anakinra has not been approved for the treatment of COVID-19.

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