COMPANY ANNOUNCEMENT

16 December 2021

No. 24-2021

ViroGates announces a positive opinion from the CHMP of the EMA for suPAR-guided anakinra treatment of patients with COVID-19 pneumonia

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 the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion of Kineret® (anakinra) for suPAR-guided treatment of coronavirus disease 2019 (COVID-19) in adult patients with pneumonia requiring supplemental oxygen (low- or high-flow oxygen) who are at risk of progressing to severe respiratory failure determined by plasma concentration of soluble urokinase plasminogen activator receptor (suPAR) ≥ 6ng/ml. EMA has recommended approval for use of Kineret® in COVID-19 to the European Commission which will issue a final decision.

COVID-19 infection can lead to death due to an overreaction of the infected person's inflammatory response, often referred to as a 'cytokine storm'[i]. Based on previous trial results, suPARnostic® was chosen as the tool to identify patients at risk of progressing to severe respiratory failure to guide anakinra treatment. Anakinra is an anti-inflammatory therapy that targets the cytokines IL-1α/β, which play a role in COVID-19-induced hyperinflammation. Blocking IL-1α/β before the hyperinflammatory phase can have an important impact on COVID-19 disease progression[ii].

The positive opinion is based on results from the SAVE-MORE phase 3 trial which found that early identification of candidate patients with suPAR followed by treatment with anakinra resulted in a 64% relative reduction of patients progressing into severe disease and death, in a 55% relative decrease in mortality, which reached 80% relative decrease in mortality for patients with cytokine storm. Results were published in *Nature Medicine* on 3 September 2021.

The SAVE-MORE study used learning from previous trials and demonstrated the effectiveness of anakinra therapy in patients who had not yet progressed to severe respiratory failure but had a poor prognosis, identified by suPARnostic®.

Jakob Knudsen, CEO of Virogates, says: "*We are pleased with the positive opinion from the CHMP for suPAR-guided anakinra treatment of COVID-19 patients. The strong phase 3 trial results show that treating patients with high suPAR levels is an important tool for healthcare professionals in battling the global pandemic.*"

Jesper Eugen-Olsen, CSO of ViroGates, says: "Once again, we would like to congratulate and sincerely thank *Professor Giamarellos-Bourboulis and his team for this important work conducted under challenging conditions. We will continue to support subsequent dialogues with the EMA and initiate dialogues with other regional and national health authorities to ensure suPAR is widely available to patients with COVID-19 pneumonia and clinicians.*"

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. 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.

SAVE-MORE

SAVE-MORE (NCT04680949); suPAR-Guided Anakinra Treatment for Management of Severe Respiratory Failure by COVID-19) is a pivotal, confirmatory, phase III randomized controlled trial (RCT). The trial aimed 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 ProfessorGiamarellos-Bourboulis, with the Hellenic Institute for the Study of Sepsis being the regulatory sponsor. Sobi has supported the study with study drug and funding.

SAVE-MORE found that suPAR-guided treatment with Kineret in addition to standard of care showed considerable efficacy, reducing the risk of disease progression and death by 64 per cent compared to standard of care alone. Overall, there was a significant improvement of the clinical status by Day 28 compared to placebo (OR: 0.36 [95% CI 0.26 to 0.50] P<0.001) and this improvement was seen by Day 14.

The suPAR-guided treatment benefit of Kineret was supported by increase in the number of patients fully recovered (50.4% and 26.5%) and significantly reduction of risk of death by 55% by day 28 compared to placebo (HR: 0.45, 95% CI 0.21–0.98, P = 0.045). No new safety signals or safety concerns were observed from the use of Kineret for treatment of COVID-19.

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 III SAVE-MORE trial were regulatory sponsored by HISS. For more details visit www.sepsis.gr.

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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).

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. Anakinra has not been approved for the treatment of COVID -19. Kineret is owned by Sobi, a specialised international biopharmaceutical company transforming the lives of people with rare diseases.

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[i] https://www.frontiersin.org/articles/10.3389/fimmu.2020.570993/full.

[ii] Kyriazopoulou, E., Poulakou, G., Milionis, H. et al. Early treatment of COVID-19 with anakinra guided by soluble urokinase plasminogen receptor plasma levels: a double-blind, randomized controlled phase 3 trial. Nat Med 27, 1752–1760 (2021). https://doi.org/10.1038/s41591-021-01499-z.