COMPANY ANNOUNCEMENT

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ViroGates announces the emergency use authorisation of Kineret treatment for COVID-19 related pneumonia with a post-authorisation requirement on developing suPAR tests for commercial use in the US

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 United States Food and Drug Administration (FDA) has granted Emergency Use Authorisation (EUA) for the use of Sobi®'s medicine Kineret (anakinra) for the treatment of coronavirus disease 2019 (COVID-19) in hospitalized adults with pneumonia requiring supplemental oxygen (low- or high-flow oxygen) who are at risk of progressing to severe respiratory failure and likely to have an elevated plasma soluble urokinase plasminogen activator receptor (suPAR).

The authorisation is based on the results of suPAR-guided Kineret treatment from the SAVE-MORE phase 3 study, published in Nature Medicine on 3 September 2021. In this study, suPAR was used to identify patients at risk of progressing to more severe disease and thus being eligible for treatment. As ViroGates' suPARnostic® products are not presently commercially available in the US, the authorisation is based on an alternative patient identification method.

However, the FDA has issued a post-authorisation requirement related to the development of suPAR for commercial use in the US. ViroGates has agreed to collaborate with Sobi to identify the appropriate regulatory pathway and associated analytical and clinical requirements with the intention to submit a marketing application no later than 31 January 2025. ViroGates has required funding from Sobi for the regulatory, analytical and clinical work related to the submission with initiation in 2022 to meet the submission deadline. A contractual agreement is still pending.

COVID-19 can progress to severe respiratory failure and death due to an excessive inflammatory response[i]. Kineret is an anti-inflammatory medicine that neutralises the biological activity of both cytokines IL-1α and β, which play a role in COVID19-induced hyperinflammation[ii]. Blocking these cytokines early in the course of the hyperinflammatory phase can have an important impact on COVID-19 disease progression[iii].

suPAR-guided Kineret treatment was shown to improve outcomes, reduce progression to severe respiratory failure and mortality in patients hospitalised with COVID-19 pneumonia requiring supplemental oxygen, and the benefits were maintained long-term. This illustrates the benefit of measuring suPAR levels to stratify patients for treatment.

Jakob Knudsen, CEO of ViroGates, says: *"We congratulate Sobi on the EUA of Kineret for treating COVID-19 in the US. We appreciate the thoroughness of the FDA during the approval process, where ViroGates has been involved several times. We are happy to learn that the FDA considers suPARnostic® to be such an important tool for patient identification to include the commercial development of ViroGates' suPAR tests in the post-authorisation requirements. We are looking forward to collaborating with Sobi on developing our suPARnostic® products related to COVID-19 for commercial use in the US."*

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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 Spain, France, and Benelux, 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 850 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 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 and patient population identification

SAVE-MORE (NCT04680949); suPAR-Guided Anakinra Treatment for Management of Severe Respiratory Failure by COVID-19) was a pivotal, confirmatory, phase 3 double-blind randomised controlled study. The study evaluated the efficacy and safety of early start of Kineret guided by suPAR in patients with lower respiratory tract infection 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 clinical progression scale. Kineret 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 was an investigator-sponsored study conducted independently by Professor Evangelos J. Giamarellos-Bourboulis, with the Hellenic Institute for the Study of Sepsis being the regulatory sponsor. The study protocol and the full statistical analysis plan was developed after advice from the

COVID-Emergency Task Force of the EMA. Sobi has supported the study with study drug and funding. 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.

The suPAR assay is not commercially available in the US. In order to identify a comparable population as was studied in the SAVE-MORE trial, an alternative patient identification method was developed to select patients most likely to have suPAR ≥ 6 ng/mL based on commonly measured patient characteristics. Patients meeting at least three of the following eight criteria are considered likely to have suPAR ≥ 6 ng/mL at baseline.

1. Age ≥ 75 years
2. Severe pneumonia by WHO criteria[iv]
3. Current/previous smoking status
4. Sequential Organ Failure Assessment (SOFA)[v] score ≥ 3
5. Neutrophil-to-lymphocyte ratio (NLR) ≥ 7
6. Haemoglobin ≤ 10.5 g/dL
7. Medical history of ischemic stroke
8. Blood urea ≥ 50 mg/dL and/or medical history of renal disease

About Emergency Use Authorisation status

Kineret (anakinra) has not been approved but has been authorised for emergency use for the treatment of coronavirus disease 2019 (COVID-19) in hospitalised adults with positive results of direct SARS-CoV-2 viral testing with pneumonia requiring supplemental oxygen (low- or high-flow oxygen) who are at risk of progressing to severe respiratory failure and likely to have an elevated plasma soluble urokinase plasminogen activator receptor (suPAR). The emergency use of Kineret is only authorised for the duration of the declaration that circumstances exist justifying the authorisation of the emergency use of drugs and biological products during the COVID-19 pandemic under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb- 3(b)(1), unless the declaration is terminated or authorisation revoked sooner. See full fact sheet for healthcare providers for the justification for emergency use of drugs during the COVID-19 pandemic, information on available alternatives, and additional information on COVID-19.

About Kineret® (anakinra)

Kineret (anakinra) is an interleukin-1α 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 (RA), 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 the EU, 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). Kineret is indicated for the 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) ≥ 6 ng/ml.

For full US prescribing information please visit https://kineretrxhcp.com/pdf/Full-Prescribing-Information-English.pdf and for full EU prescribing information please visit the EMA website.

References

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