COMPANY ANNOUNCEMENT

2 June 2023

No. 12-2023 – Inside information

ViroGates announces an agreement with Sobi for the development of suPARnostic® for commercial use in the US in combination with Sobi's Kineret® treatment for COVID-19-related 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 an agreement with Swedish-based Sobi™ for the development of suPARnostic® for commercial use in the US in combination with the pharmaceutical product Kineret® (anakinra).

The agreement is related to the development and regulatory work associated with approaching the United States Food and Drug Administration (FDA) to make suPARnostic® available to US hospitals in connection with Kineret® (anakinra) for the treatment of COVID-19 in hospitalised 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).

Under the agreement, Sobi will fund the work requested by the FDA, to be carried out by ViroGates to make suPARnostic® commercially available in the US. The agreement provides for a stepwise approach to the initiation of work packages. Sobi has the exclusive right to decide upon initiating work packages based on the outcome of meetings with the FDA and the achievement of previous development steps. The funding to ViroGates will be repaid to Sobi through subsequent capped royalties based on US sales.

The agreement is based on the Emergency Use Authorisation granted to Sobi in November 2022 for Kineret® as reported in ViroGates company announcement 25-2022 and the results of suPAR-guided Kineret treatment from the SAVE-MORE phase 3 study, published in Nature Medicine on 3 September 2021.

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 COVID-19-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 and 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.

The parties will not disclose the financial aspects of the agreement.

The agreement will not have implications for ViroGates' financial expectations for 2023, and ViroGates maintains its guidance for 2023 of full-year revenue between DKK 8 to 11 million and earnings before tax and interest (EBIT) of approximately DKK -10 to -13 million.

Jakob Knudsen, CEO of ViroGates, says: *"We are happy to continue our relationship with Sobi to fulfil the post-authorisation commitment to make suPARnostic® available to US hospitals and patients. We will commence the work immediately with our Polish laboratory partner Nutopi Sp. z o. o. and expect to approach the FDA with Sobi and regulatory consultants shortly. We already know some of the data that we need to produce for the FDA, but we look forward to gaining a better understanding of the full development package. We will report on the progress once we know more about the duration of the full development package."*

For further information, please contact:

ViroGates A/S:
CEO, Jakob Knudsen
Tel. (+45) 2226 1355, email: jk@virogates.com

Certified Advisor:
Västra Hamnen Corporate Finance
Per Lönn
Tel. (+46) 40 200 250, email: per.lonn@vhcorp.se

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 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, the Abbott Labs Architect™ and Alinity™ instruments and the Beckmann Coulter AU 5800 instrument. ViroGates works with partners to develop solutions for other platforms. ViroGates has recently launched its Point of Care suPARnostic® POC+ product, a platform that

uses only a few drops of finger-prick blood instead of plasma for full quantitative suPAR results in less than 20 minutes.

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

[i] Tang L, et al. Controlling Cytokine Storm Is Vital in COVID-19. Front Immunol 2020;11:570993. doi: 10.3389/fimmu.2020.570993.

[ii] Renieris G, et al. IL-1 Mediates Tissue-Specific Inflammation and Severe Respiratory Failure in COVID-19. J Innate Immun 2022;1-14. doi: 10.1159/000524560.

[iii] Kyriazopoulou E, 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 2021;27(10):1752-1760. doi: 10.1038/s41591-021-01499-z.

[iv] World Health Organization. (2020, March 13). Clinical management of severe acute respiratory infection (SARI) when covid-19 disease is suspected. Interim Guidance. https://www.who.int/docs/default-source/coronaviruse/clinical-management-of-novel-cov.

[v] HHS Technical Resources, Assistance Center and Information Exchange. (2020, December 21). SOFA score: What it is and how to use it in triage - hhs.gov. https://files.asprtracie.hhs.gov/documents/aspr-tracie-sofa-score-fact-sheet.pdf.