COMPANY ANNOUNCEMENT

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ViroGates announces an amendment to its agreement with Sobi

BIRKERØD, DENMARK—ViroGates A/S ("ViroGates"), a medical technology company developing blood tests for measuring chronic inflammation in health clinics and hospitals, today announces the finalization of an amendment to its agreement with Swedish-based Sobi (Swedish Orphan Biovitrum AB (publ)) on developing suPARnostic® for commercial use in the US in combination with the pharmaceutical product Kineret® (anakinra).

The agreement was initially announced in June 2023 (cf. Company announcement 12-2023 of 2 June 2023), and the collaboration has been ongoing since then. In April 2024, the Parties held an initial Q-Submission meeting with the US FDA, gaining insight into the FDA's requirements for a marketing application for ViroGates' suPARnostic® TurbiLatex product (cf. Company announcement 3-2024 of 15 April 2024). The feedback received at the meeting laid the basis for proceeding with the regulatory process.

The amendment, which is announced today, extends the collaboration between the Parties to include not only making suPARnostic® TurbiLatex commercially available in the US but also supporting Sobi's post-approval commitment with EMA For the suPARnostic® TurbiLatex compliance with the new requirements of the EU IVDR[1].

Under the amendment, ViroGates, and Sobi will continue to fund the analytical development work required for both the US FDA and EU IVDR, while ViroGates will be responsible for conducting the work, and for additional clinical data to be obtained to support the applications. The amendment extends certain timelines and also specifies that Sobi will be allowed to recover its investments in the development by way of a royalty payment clause that will apply to sales in both the US and EU.

Sobi is also granted an option to engage in additional development efforts to apply suPARnostic® TurbiLatex to instrument platforms other than those initially targeted.

The agreement and amendment now entered into is based on the Emergency Use Authorisation granted to Sobi in November 2022 for Kineret® (cf. Company announcement 25-2022 of 10 November 2022) and the results of suPAR-guided Kineret® treatment from the SAVE-MORE phase 3 study, published in Nature Medicine on 3 September 2021. suPAR-guided anakinra 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.

Jakob Knudsen, CEO of ViroGates, says: *"We are happy to be working with Sobi to fulfil the post-authorisation and post-approval commitments in the US and EU. The work is ongoing within our Polish laboratory partner Nutopi Sp. z o. o. Much of the laboratory-oriented work will now be initiated, and we will also reach out to academic partners to see how we can supply additional clinical data that the FDA expects to see to potentially issue a market clearance in the US. We also look forward to conducting important work to prepare for the EU IVDR approvals of suPARnostic® TurbiLatex."*

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About ViroGates

ViroGates A/S is a medical technology company developing blood tests to measure the level of inflammation in individuals in health clinics and 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 1000 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 and individuals in making clinical decisions on hospitalization or discharge and on the risk of development of life style related diseases 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.

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[2]
3. Current/previous smoking status
4. Sequential Organ Failure Assessment (SOFA)[3] 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.

[1] Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices

[2] 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.

[3] 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.