COMPANY ANNOUNCEMENT

15 April 2024

No. 03-2024 – Inside information

ViroGates announces the outcome of its Q-Submission filing for suPARnostic® TurbiLatex with the US FDA and the overall timeline for filing a submission of a 510k/"*De Novo*" application with the FDA

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, announces the outcome of today's meeting with the Center for Devices and Radiological Health (CDRH) of the US Food and Drug Administration (FDA).

As previously announced in Company announcement 12-2023, ViroGates is supported by Sobi® to gain market clearance/approval for suPARnostic® TurbiLatex to be available in the US market to identify patients who may be eligible for treatment with Sobi's drug Kineret®.

ViroGates has filed for a consultation with the CDRH division of the FDA under the Q-Submission scheme. ViroGates sought advice from the FDA regarding several aspects of its analytical method and clinical data packages. FDA has certain requirements for data supplied to support that products are reliable, reproducible, and consistent, which differs from those applied in ViroGates current CE-IVD file.

Today, the FDA has provided input on the additional data that needs to be presented for the FDA to clear suPARnostic® TurbiLatex for commercial use in the US market.

The data comprise additional US data, and ViroGates will now seek to establish the data from available biobanks. The data will complement the clinical data from three European sites that used suPARnostic® TurbiLatex during the pandemic for the SAVE-MORE Study.

A more detailed plan for obtaining and analyzing the data will be compiled and will depend on biobank sample availability. ViroGates preliminarily estimates that it will be able to submit the required data sometime during the second half of 2025.

ViroGates will communicate further once the obtaining of samples has been finalized.

Jakob Knudsen, Chief Executive Officer of ViroGates, says: *"We are happy about the outcome of today's meeting with the FDA. We had consulted regulatory guidelines in advance, but getting better insight into the exact situation is invaluable. We look forward*

to continuing our work with Sobi® to file for commercial clearance of our products in the US. We have established via the SAVE-MORE study that suPARnostic® can play an important role in selecting patients that will benefit from Kineret®, and we look forward to establishing the remaining data for the FDA review".

This message does not change ViroGates' financial guidance as communicated in Company announcement 24-2023.

A downloadable PDF version is available on the company's website.

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 900 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. The increasing demands on health systems globally and tightening healthcare budgets necessitate efficiency improvements and innovative solutions in hospitals. The use of suPAR in triage in emergency departments can identify patients in low risk of disease progression (supports discharge) and high risk patients that can benefit from early treatment to lower the risk of disease progression. 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 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://www.kineretrx.com and for full EU prescribing information please visit the EMA website.