COMPANY ANNOUNCEMENT

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ViroGates submits its De Novo application to the U.S. FDA for suPARnostic® TurbiLatex

BIRKERØD, DENMARK – ViroGates A/S ("ViroGates"), a medical technology company developing blood tests for measuring chronic inflammation at health clinics and hospitals, announces that it has submitted a De Novo marketing application, formally referred to as a "De Novo Classification Request", to the U.S. Food and Drug Administration (FDA) for its suPARnostic® TurbiLatex product.

The De Novo submission marks a significant regulatory milestone for ViroGates as it seeks U.S. market authorisation for a first-of-its-kind in vitro diagnostic product. This submission follows the FDA's formal confirmation in October 2025 (cf. Company announcement 14-2025) that the De Novo pathway is the appropriate regulatory route for suPARnostic® TurbiLatex.

The De Novo regulatory pathway

The De Novo application is a regulatory pathway for novel, low-to-moderate risk medical devices that does not have a predicate device for a 510(k) clearance. In preparing this submission, ViroGates has conducted multiple clinical studies to demonstrate the clinical utility of the suPARnostic® TurbiLatex assay, supported by comprehensive analytical validation. The submission has been developed in close collaboration with Sobi (Swedish Orphan Biovitrum AB (publ)) as outlined in the amended partnership agreement (cf. Company announcement 2-2025).

The De Novo application includes:

- Analytical validation data demonstrating the reliability and reproducibility of the assay
- Clinical data from the SAVE-MORE phase 3 study, which demonstrated that suPAR-guided anakinra treatment improves outcomes and reduces progression to severe respiratory failure and mortality in hospitalised COVID-19 patients requiring supplemental oxygen
- Additional clinical data supporting the clinical utility of suPARnostic® TurbiLatex for patient stratification in the U.S. market

FDA review process

The FDA will now begin its De Novo review, which evaluates the products' safety and effectiveness in the absence of a predicate device. This process may establish a new device classification and define special controls for similar future devices. The timeline for FDA

review of De Novo applications typically spans several months, during which the agency may request additional information or clarification from the applicant.

Commercial implications

The initial FDA clearance targets a narrow, high-need patient population, providing a de-risked commercial entry point. Beyond this indication, suPARnostic® TurbiLatex is inherently scalable, with a clear pathway for label expansion into significantly larger adjacent markets based on subsequent filings of clinical datasets. FDA clearance not only enables commercialisation but serves as a critical validation for hospital procurement and alignment with accreditation standards such as those from The Joint Commission and the Centres for Medicare & Medicaid Services. This positions ViroGates to drive both clinical adoption and mid- to long-term economic value.

Financial guidance unchanged

This announcement is consistent with ViroGates' strategic plan and does not change expectations for 2026. ViroGates restates its previously announced guidance and expects full-year revenue between DKK 6 and 7 million and an EBIT of DKK -10 to -12 million in 2026.

Jakob Knudsen, CEO of ViroGates, says:

"Submitting our De Novo request marks a major milestone in bringing our suPARnostic® technology to clinicians and patients in the United States. suPARnostic® TurbiLatex is a clinically proven biomarker with demonstrated impact on clinical decision-making, and we believe this automated assay can support improved patient stratification and clinical decisions in hospital settings. We appreciate the FDA's clear guidance on the regulatory pathway, which has enabled us to submit a robust and comprehensive application. We look forward to working closely with the FDA throughout the review process to make this important diagnostic tool available in the U.S."

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About ViroGates

ViroGates A/S is an international medical technology company that develops and markets blood tests to measure chronic inflammation at health clinics and hospitals. ViroGates markets its blood test products under the suPARnostic® brand.

The company was founded in 2000. Headquartered in Denmark, ViroGates' sales force covers Spain, France, and Benelux, while distributors serve other markets. ViroGates' shares (ticker "VIRO") are listed on Nasdaq First North Growth Market Denmark. For more information, please visit www.virogates.com.

About the suPARnostic® TurbiLatex Assay
The suPARnostic® TurbiLatex Assay is an in-vitro diagnostic, particle-enhanced turbidimetric immunoassay (PETIA) designed for the automated quantitative measurement of soluble urokinase plasminogen activator receptor (suPAR) in human EDTA plasma on the Roche Diagnostics Cobas® 6000 c501 systemE.

The assay consists of a reagents kit, calibrators and controls, enabling precise quantification of suPAR levels as part of laboratory workflow. suPAR is a well-established biomarker associated with systemic inflammation and disease severity. The Intended Use is as an aid in assessing the risk of progression to severe respiratory failure in hospitalized adult COVID-19 patients, identifying individuals who may benefit from targeted treatment such as anakinra under the FDA Emergency Use Authorization framework.

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.

About Emergency Use Authorisation status
Kineret (anakinra) has not been approved but has been authorised for emergency use by the FDA, 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 Sobi and Kineret® (anakinra)
Sobi (Swedish Orphan Biovitrum AB (publ)) is a global biopharma company unlocking the potential of breakthrough innovations, transforming everyday life for people living with rare diseases. Sobi has approximately 1,900 employees across Europe, North America, the Middle East, Asia and Australia. In 2025, revenue amounted to SEK 28 billion. Sobi's share (STO:SOBI) is listed on Nasdaq Stockholm. More about Sobi at sobi.com and LinkedIn.

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 U.S. prescribing information, please visit https://kineretrxhcp.com/pdf/Full-Prescribing-Information-English.pdf. For full EU prescribing information, please visit the EMA website.