COMPANY ANNOUNCEMENT

17 October 2025

No. 14-2025

ViroGates Receives FDA Feedback on 513(g) Request, confirming Regulatory Pathway for U.S. Market Entry

BIRKERØD, DENMARK—ViroGates A/S, a medical technology company developing blood tests for measuring chronic inflammation at health clinics and hospitals, today announce that it has received formal written feedback from the U.S. Food and Drug Administration (FDA) regarding its 513(g) submission for the suPARnostic® TurbiLatex product. The work is done in collaboration with Sobi as announced in Company announcement no 2/2025

The FDA has indicated that suPARnostic® TurbiLatex is "appropriate for classification through the De Novo pathway section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act[1]". This is the regulatory path through which ViroGates had expected suPARnostic® TurbiLatex to be assessed. The feedback gives ViroGates a defined regulatory pathway for advancing its U.S. market strategy for suPARnostic® TurbiLatex®.

ViroGates submitted the 513(g) request to obtain the FDA's view on product classification and applicable data requirements for U.S. clearance. Following the FDA's response, the company plans to complete the additional analytical and clinical validation work necessary to support a future submission. Depending on the outcome of the analytical and clinical validation process, the aim is to file an application for clearance for marketing with the FDA during Q4 2025 or Q1 2026.

Jakob Knudsen, CEO of ViroGates, says: "*We are pleased to have received this constructive feedback from the FDA. The agency's guidance provides a clear framework for the U.S. regulatory pathway for our suPARnostic® TurbiLatex product. We look forward to advancing toward FDA clearance and, ultimately, enabling broader U.S. access to our suPAR-based solutions that help clinicians identify patients at high or low risk of disease progression.*"

This announcement does not change ViroGates' financial guidance as previously communicated.

The announcement is available at ViroGates' website click here

For further information, please contact:
ViroGates A/S
Jakob Knudsen, Chief Executive Officer

[1] 21 U.S.C. § 360c(f)(2) — Section 513(f)(2) of the FD&C Act - https://www.govinfo.gov/content/pkg/USCODE-2010-title21/html/USCODE-2010-title21-chap9-subchapV-partA-sec360c.htm

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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 improve hospital patient care. 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 suPAR and suPARnostic®

suPAR is a biomarker detected by ViroGates' suPARnostic® products. It is a protein in plasma, measurable in every human being. suPAR is a general risk status biomarker indicating chronic inflammation, disease presence and severity. The suPARnostic® products can support healthcare professionals and individuals in leading healthier lives and making better clinical decisions.