

**VarmX receives Phase 1 waiver from Japanese regulator PMDA**

**for lead asset VMX-C001**

* **Japanese regulator, the PMDA, waived the requirement for a Phase 1 trial in Japanese subjects for lead asset VMX-C001, enabling it to go straight to Phase 3 development**
* **Rare waiver recognizes the global dataset already generated for VMX-C001 and streamlines the path to the important Japanese market**
* **Japan to be included in global EquilibriX-S Phase 3 trial of VMX-C001 in patients taking FXa DOACs undergoing urgent surgery**
* **Raises the prospect of faster access for Japanese FXa DOAC patients needing urgent surgery or facing severe bleeding**
* **Reduces cost and de-risks development of VMX-C001 in Japan**

**Leiden, The Netherlands, 25 September 2025** -VarmX, a biotech company developing innovative approaches for the bypass of direct oral anticoagulants targeting factor Xa (FXa DOACs) and inherited coagulation disorders, announces that the Japanese medicines regulator, the Pharmaceuticals and Medical Devices Agency (PMDA), has waived the requirement for a Japanese Phase 1 trial of lead asset, VMX-C001, a novel bypass agent which restores blood coagulation in patients receiving a FXa DOAC.

The PDMA has recognized the global dataset already generated for VMX-C001 and the unmet need for treatments that can enable urgent surgery in patients on FXa DOACs, and removed the requirement for a Phase 1 (ethnic bridging) study of a drug candidate in the Japanese population before entering further clinical studies in the country. It is very rare for this requirement to be waived entirely and this will enable VarmX to proceed directly to include Japanese patients in its global Phase 3 EquilibriX-S study of VMX-C001. The PMDA has also offered earlier interactions in the development process, potentially leading to an accelerated submission for drug approval in Japan.

This news follows VarmX’s announcement in July 2025, confirming that the FDA had cleared its Investigational New Drug (IND) application for VMX-C001. Also, VarmX announced in August 2025 that the FDA has given VMX-C001 Fast Track Designation. Both events enable the initiation of

EquilibriX-S, a landmark clinical trial evaluating the ability of a FXa DOAC bypassing agent to rapidly and durably restore coagulation in patients taking any FXa DOAC undergoing urgent surgery. VarmX recently entered a partnership with CSL in a strategic collaboration and option agreement to develop this molecule.

By 2030, approximately 30 million patients in the US, Europe and Japan are expected to receive FXa DOACs as a chronic anticoagulation therapy, including stroke prevention in atrial fibrillation and the prevention of deep vein thrombosis. Each week, more than 30,000 of these patients will experience severe life-threatening bleeding or require emergency surgery, where the risk of bleeding poses a critical challenge.

**John Glasspool, CEO of VarmX,** said:

*“We are proud that we can include Japan in our global Phase 3 EquilibriX-S study. Being granted a Phase 1 waiver by the Japanese PMDA is a rare example of a drug candidate being allowed to go directly into Phase 3 studies in Japan, enabling a truly global program.*

*“This recognition highlights both the real unmet need for treatments that  rapidly restore coagulation and enable urgent surgery in patients on Factor Xa direct oral anticoagulants, as well as the robustness of our existing clinical data package. Also, it significantly de-risks our development of VMX-C001 in Japan and potentially allows access for Japanese patients at the same time as Europe and the United States.*

*“This is another global milestone in the development of our novel bypass agent, building on the momentum already achieved with US FDA IND approval in July and Fast Track Designation earlier this month.”*

**ENDS**

**Notes to Editors**

**About VarmX**

VarmX is a spin-off from the Leiden University Medical Center (LUMC), founded in 2016 by Professor Pieter Reitsma, a world leading expert in hemostasis and thrombosis. VarmX’s lead compound VMX-C001 is a modified recombinant blood factor X. The compound is being developed for the treatment of severe spontaneous bleeding and for the prevention of bleeding during urgent surgery in patients taking oral factor Xa inhibitors (FXa DOACs) as anticoagulation therapy. The Company is supported by a strong syndicate of investors including Sound Bioventures, EIC, EQT Life Sciences (formerly LSP), Inkef, Lundbeckfonden BioCapital, Ysios Capital, BioGeneration Ventures and InnovationQuarter. For more information, please visit [www.varmx.com](file:///C%3A%5CUsers%5Cmnegen%5CDownloads%5Cwww.varmx.com).

**About VMX-C001**

VMX-C001 is a modified, human, factor X protein, designed to be insensitive to FXa DOACs, effectively bypassing their anticoagulant activity and swiftly restoring the coagulation cascade.VMX-C001 has been developed with significant clinical advantages, including universal dosing regardless of the specific FXa DOAC used, rapid and easy administration, compatibility with common anticoagulants like heparin, and crucially, no additional thrombotic risk.

**For further information, please contact:**

**Vigo Consulting (media enquiries)**

Rozi Morris

+44 20 7390 0230

VarmX@vigoconsulting.com