Veritas In Silico

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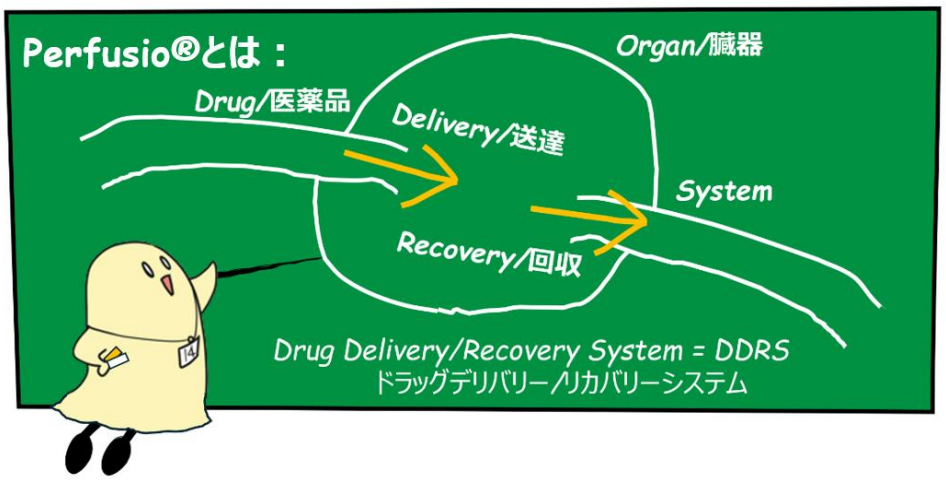
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Completion of Pre-development Consultation with PMDA and Future Prospects for Proprietary Drug Delivery System "Perfusio®"

Veritas In Silico Inc. (Headquarters: Shinagawa-ku, Tokyo; Representative Director and CEO: Shingo NAKAMURA, hereinafter referred to as "the Company") is advancing the development of "Perfusio®," a proprietary drug delivery system (DDS)[*1] designed to selectively deliver pharmaceuticals to target organs for therapy while concurrently withdrawing them, thereby minimizing systemic drug exposure.

Throughout its development process, the Company has filed multiple patent applications. As announced in its press release dated December 15, 2025 and titled "Completion of Patent Examination and Patent Grant Procedures for Drug Delivery System 'Perfusio'", several of these patents have already been granted. Furthermore, as part of its initiatives toward commercialization, trademark registrations for both "Perfusio®" and "パーフュージオ®" (Japanese Katakana representation) were successfully completed, as announced on October 28, 2026 and titled "Notice of Trademark Registration Completed for Drug Delivery System 'Perfusio®'".

In August 2026, the Company held a Pre-development Consultation[*2] with the Pharmaceuticals and Medical Devices Agency (PMDA). The Company is pleased to announce that the consultation minutes have recently been finalized as an official record. With this milestone, development policy for Perfusio® has been clearly defined as follows:



(Figure) Conceptual illustration of Perfusio®

● Outline of Perfusio®

Perfusio® is the Company's proprietary Drug Delivery System designed to administer and concurrently recover pharmaceuticals by inserting catheters into both the arterial and venous sides of the target organ. It is intended for application in anatomical sites and organs where blood flow can be temporarily occluded, such as upper limbs, lower limbs, kidneys, bladder, and uterus. The system aims to minimize systemic drug dissemination while selectively delivering high concentrations of therapeutics to the targeted site. Utilizing a relatively simple catheter-based mechanism, Perfusio® has the potential to reduce physical burden compared to traditional surgical procedures. Thanks to these advantageous features, broad applications across a wide variety of pharmaceutical agents are anticipated.

● Conclusion of PMDA Pre-Development Consultation and Development Policy

On August 28, 2026, the Company held a Pre-development Consultation with the Pharmaceuticals and Medical Devices Agency (PMDA). The official consultation minutes have recently been finalized, successfully concluding the process. Through this consultation, the regulatory requirements for the development and marketing approval application of the catheters used in Perfusio® have been successfully clarified.

During the consultation, the PMDA largely concurred with the development plan proposed by the Company. Furthermore, it was confirmed that additional non-clinical (animal) studies or clinical trials will not be required for the development of Perfusio® as a general-purpose medical device. Consequently, the Company will proceed with preparations for submitting the application for marketing approval in accordance with its original plan.

● Unlocking New Therapeutic Horizons with Perfusio®

In general systemic drug administration, therapeutic agents reach normal tissues outside the intended target site, often making side effects a key limiting factor regarding dosage and treatment duration.

Perfusio® is a technology engineered to minimize adverse impacts on healthy surrounding tissues by delivering pharmaceuticals selectively to the targeted site while simultaneously recovering drug-containing blood. Once commercialized, this technology holds the promise of offering more proactive treatment options to patients who previously could not receive sufficient therapeutic doses due to concerns over severe side effects. Moreover, mitigating treatment-induced side effects is expected to substantially enhance patients' quality of life (QOL). For instance, in the treatment of osteosarcoma affecting the limbs, enabling concentrated chemotherapy to the localized lesion could broaden therapeutic choices aimed at preventing limb amputation. Additionally, preventing the systemic circulation of chemotherapeutic agents may alleviate debilitating side effects such as alopecia, empowering patients to undergo treatment while maintaining their daily lives.

"Maximizing therapeutic efficacy while minimizing adverse side effects."

Perfusio® strives to deliver an innovative solution to this critical and enduring challenge in modern medicine.

● Future Outlook and Commercialization Roadmap

The Company remains committed to advancing the development and commercialization of Perfusio®, aiming for market launch within fiscal year 2027 as originally scheduled.

Currently, the Company's baseline target is to secure regulatory approval and initiate sales within fiscal year 2027 as a general-purpose medical device without organ-specific limitations, under the regulatory category of a "improved medical device". The review period from application to approval is estimated to be approximately six months; however, the precise timing of the submission will be determined based on ongoing development progress. On the other hand, should the Company prioritize co-marketing Perfusio® directly alongside specific pharmaceutical products, it may opt not to pursue standalone approval and sales as a general-purpose medical device.

The Company's primary current priorities include establishing collaborative partnerships with catheter manufacturers and finalizing device specifications. Although the Company has engaged in discussions and negotiations with multiple manufacturers to date, each manufacturer possesses unique catheter characteristics, and a definitive partner has not yet been selected. Moving forward, the Company plans to seek expert guidance on device specifications and related technical matters from its scientific advisor, Dr. Yasunori Arai (Chief, Department of Diagnostic Radiology, National Cancer Center Hospital East). The timing for executing partnership agreements and fabricating prototypes will be specified as development and commercialization activities progress.

Through Perfusio®, the Company remains dedicated to providing novel treatment options to patients who previously faced limited choices, while actively contributing to the reduction of physical burdens and side effects associated with medical treatments.

END

● Glossary for Reference

*1 Drug Delivery System (DDS): This system has been developed to administer the active pharmaceutical ingredients to the intended target organs. Typically, methods such as chemically attaching molecules that selectively reach the target organ to the drug or encapsulating the drug within a lipid bilayer membrane are used. However, our company considers physically delivering the drug—by approaching the target organ via an arterial catheter and additionally approaching it via a venous catheter—to be one form of drug delivery system.

*2 Pre-development Consultation for Medical Devices (Official PMDA consultation category): A regulatory consultation scheme in which developers consult with the Pharmaceuticals and Medical Devices Agency (PMDA) during the development stage of medical devices. Through this process, companies receive official guidance and advice regarding their development strategies, regulatory requirements for marketing approval applications, and the necessity of conducting clinical trials.

For Further Information, Contact:

● Veritas In Silico Website Inquiry Form : https://www.veritasinsilico.com/en/contact/