

# NEWS RELEASE



**Veritas In Silico**



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## Determination of Target Disease for mRNA-Targeted Nucleic Acid Drug for In-house Pipeline

Veritas In Silico Inc. (Head Office: Shinagawa-ku, Tokyo Japan; Representative Director and CEO: Shingo NAKAMURA, Ph.D.) announced that the Company has launched its first In-house pipeline project for the treatment using nucleic acid drug as follows.

- Gene name: To be disclosed after patent application is filed
- Target disease: Ischemic acute kidney injury (AKI) induced after cardiovascular surgery
- Novelty: First-in-class (no existing approved drug)
- Modality: Nucleic acid drug
- Domestic target population: Cardiovascular surgery patients aged 65 or older
- Revenue forecast in Japan: 15 billion yen/year (\*)
- Estimated development period: 8-10 years (development schedule to be detailed)
- Development strategy: Approval is expected within short term by targeting patients aged 65 years or older because they would be at the high risk of developing AKI. After approval, line extension for all cardiovascular surgeries will be conducted, then expanded globally. Looking ahead, additional line extension for other ischemic organ injuries will be considered.

The Company has been conducting mRNA-targeted small molecule drug discovery using its proprietary drug discovery platform, ibVIS<sup>®</sup>, with partner pharmaceutical companies. Currently, the Company is conducting mRNA-targeted nucleic acid drug discovery using ibVIS<sup>®</sup> solely. The market of nucleic acid drug is expected to be a promising segment with the highest growth potential, while small molecule is the largest segment of the pharmaceutical market.

This action is based on the growth strategy of the Company to address unmet medical needs with nucleic acid drugs which are suitable for rare diseases. This action is also based on the business strategy of the Company to differentiate from competitors by its proprietary ibVIS<sup>®</sup> platform, which is applicable to not only small molecule drug discovery but also nucleic acid drug discovery.

Ischemic AKI is one of ischemic organ diseases caused by decrease of blood flow during cardiovascular surgery. About 50,000 cardiovascular surgeries are performed annually in Japan, and kidney damage occurs in 15–30% of these cases. The Company believes that prevention of the onset of this condition would be clinically meaningful. This disease has a clearly defined onset period, making it easier to design clinical trials. Additionally, it is possible to achieve statistically significant differences in clinical trials because of its considerable probability of onset.

The Company is planning its line extension for further revenue opportunities by extending indications and expanding into international markets.

Nucleic acid drugs are known to be its high manufacturing costs. The Company plans to establish cost-effective dosing regimens by both reducing the dosage by local administration and limiting single administration prior to surgery, which are expected to improve safety as well.

The Company will conduct drug discovery research, considering the unique manufacturing characteristics of nucleic acid drugs from the early stage.

The Company will leverage its accumulated knowledge and expertise to promote its pipeline business for nucleic acid drugs, in parallel with its platform business of collaborative drug discovery for small molecule drugs.

- Comments from Hirotaka James OKANO, M.D., Ph.D., Professor and Director of Research Center for Medical Sciences, The Jikei University School of Medicine, as a medical expert:

Administering ASO(\*\*) for AKI caused by cardiovascular surgery is an excellent idea. It would yield significant results while minimizing the number of administrations.

This new nucleic acid drug concept is expected to become a widely adopted treatment for cardiovascular surgery in the future. I look forward to the future progress of this project.

- **Comments from Ella Czarina MORISHITA, Ph.D., CSO of VIS, as a leader of drug discovery research and development:**

We are truly delighted to embark on our In-house drug discovery by leveraging our proprietary drug discovery platform, ibVIS<sup>®</sup>. We are confident that the expertise and experience we have cultivated through our platform business can be fully applied to ASO drug discovery as well. Since ASOs generally have shorter R&D timelines compared to small molecule drugs, we expect to deliver new treatment options to patients more quickly. Building upon this research, we will actively advance our In-house drug discovery research efforts, with the aim of contributing to the realization of a “warm society filled with hope.”

- **Impact on Future Business Performance**

This research project is the first one for KPI in the growth strategy “In-house Pipeline Creation” for FY2025.

Once the ASO compounds developed through the research project are approved and begin to be manufactured and sold, domestic sales (peak sales) are estimated to reach approximately 15 billion yen per year (\*).

The Company plans to spend R&D expenses in line with the progress of its In-house drug discovery research. Of this amount, the expenditure for FY2025 is already included in the performance forecast, which was announced on February 13, 2025, and no changes are expected to the performance forecast.

In case any matters requiring disclosure arise in the future, they will be promptly disclosed.

**Note (\*): Forecast of domestic sales**

The domestic sales forecast figures in this document are based on the assumption that approximately 50,000 cardiovascular surgeries will continue to be performed annually, that 35% of patients will be aged 65 or older (applying the percentage of the population aged 65 or older estimated for 2040), that the drug will be adopted for 85% (applying the percentage of people in Japan who have been vaccinated against COVID-19 at least once) of treatments as the first-in-class and only drug available, and that it will be administered as a single dose at an estimated drug price of 1 million yen. Additionally, we anticipate that peak sales will be reached three years after the launch, following an 8- to 10-year development period.

If the Company conducts research, development, manufacturing, and sales on its own, the entire amount of the estimated sales will be the Company's income. If the Company licenses out the drug to another company during the process, it will receive an upfront payment at the time of licensing, as well as milestone payments during the development phase prior to approval, and royalty income after the start of manufacturing and sales, as stipulated in the licensing agreement. The Company is going to decide whether to carry out the entire process from research through to sales on its own or to licensing out to another company during the process.

**Note (\*\*): ASO: Antisense Oligonucleotide**

A type of nucleic acid medicine, it is a substance that binds to target mRNA and inhibits protein production or promotes mRNA degradation.

For Further Information, Contact:

- Veritas In Silico Website Inquiry Form : <https://www.veritasinsilico.com/en/contact/>