August 5, 2025

Surv Biopharma Inc.
Nippon Zoki Pharmaceutical Co., Ltd.

Surv Biopharma and Nippon Zoki Pharmaceutical Sign Licensing Agreement for the Oncolytic Virus “Surv.m-CRA-1” Targeting Bone and Soft Tissue Tumors

— Targeting Japan’s First Full Regulatory Approval for Gene Therapy in Oncology by 2027
(Planned Indication: Rare Cancer “Primary Malignant Bone Tumor”) —

Surv Biopharma Inc. (Head Office: Kagoshima, Japan, President and CEO: Masaki Yamada; “Surv Biopharma”) and Nippon Zoki Pharmaceutical Co., Ltd. (Head Office: Osaka, Japan, President and CEO: Takafumi Konishi; “Nippon Zoki Pharmaceutical”) announce that they have entered into an exclusive licensing agreement (“the Agreement”) for the oncolytic virus “Surv.m-CRA-1,” originally developed by Dr. Ken-ichiro Kosai, the Chairman and Chief Scientific Officer of Surv Biopharma and the Chairman and Professor at Kagoshima University. The license covers the use of Surv.m-CRA-1 for the treatment of bone and soft tissue tumors within Japan.

(From left: Ken-ichiro Kosai; Masaki Yamada; Takafumi Konishi; Yuichi Takeoka, Head of R&D Headquarters, Nippon Zoki Pharmaceutical)

Under the Agreement, Nippon Zoki Pharmaceutical will hold the exclusive rights in Japan to develop, manufacture, and commercialize Surv.m-CRA-1 for the treatment of bone and soft tissue tumors,

including primary malignant bone tumors, malignant soft tissue tumors, and metastatic bone tumors. Surv Biopharma is eligible to receive up to ¥10.5 billion (approx. $70 million) in total payments, including an upfront payment, based on the achievement of future development milestones and post-marketing sales targets. In addition, Surv Biopharma will receive royalties based on annual domestic net sales.

Surv.m-CRA-1 is a Surv Biopharma's proprietary oncolytic virus that incorporates "survivin promoter," which is specifically activated in cancer cells. It replicates only in cancer cells and selectively destroys them without damaging normal cells, offering both high therapeutic efficacy and safety. Furthermore, it is expected to be a groundbreaking cancer therapy classified as a "regenerative medicine product", with the innovative ability to target cancer stem cells that are resistant to conventional therapies, as well as potent therapeutic effects and high safety.

To date, Surv Biopharma has focused its development efforts on malignant bone and soft tissue tumors, which present a high unmet medical need due to the lack of effective treatment options. As a first step, the company has been advancing clinical development targeting the rare cancer known as primary malignant bone tumor. Based on the extremely favorable results obtained in a Phase II clinical trial conducted in Japan, preparations are currently underway to initiate a Phase III trial in October 2025, with the aim of obtaining full regulatory approval in Japan.

Through the conclusion of the Agreement, Surv Biopharma will collaborate with Nippon Zoki Pharmaceutical, a company with a long-standing track record in the orthopedic field, to accelerate the clinical development, manufacturing, and quality control of Surv.m-CRA-1. Our shared goal is to deliver this therapy as quickly as possible to patients fighting primary malignant bone tumors and the healthcare professionals who support them, with the aim of obtaining full manufacturing and marketing approval in 2027. Following approval, Nippon Zoki Pharmaceutical plans to leverage its expertise, accumulated know-how, and extensive network in the orthopedic field to ensure the prompt and reliable delivery of Surv.m-CRA-1 to a broad population of patients.

Furthermore, with domestic approval as a starting point, both companies are considering expanding the development of Surv.m-CRA-1 for primary malignant bone tumors to international markets, including Asia, Europe, and North America. In addition, both companies plan to initiate domestic clinical development for additional indications of Surv.m-CRA-1, including rare cancers such as malignant soft tissue tumors and metastatic bone tumors.

Building on the strong partnership established through the Agreement, both companies will continue to collaborate toward the early social implementation of Surv.m-CRA-1 and to address the significant unmet medical needs in the treatment of bone and soft tissue tumors.

Executive Comment

Masaki Yamada, President and CEO, Surv Biopharma Inc.

"Our company was established as a certified venture originating from Kagoshima University, with the mission of bringing our founder Professor Ken-ichiro Kosai's groundbreaking viral modification

technology into practical application. We are truly pleased to have formed a partnership with Nippon Zoki Pharmaceutical, a leading company in the orthopedic field, for the development of Surv.m-CRA-1, our first pipeline product. This collaboration is proof of the high regard for our technology and the potential of this therapeutic agent. We are confident that we have secured the best possible partner, and we remain fully committed to delivering this innovative treatment to patients as swiftly as possible."

Ken-ichiro Kosai, Executive Chairman and Chief Scientific Officer (CSO) of Surv Biopharma Inc., said, "I developed the original platform technology for efficiently generating "conditionally replicating adenoviruses that can target and treat cancer cells with multiple factors (m-CRA)". Using this technology, I successfully generated the "survivin-responsive m-CRA (Surv.m-CRA)", an innovative oncolytic adenovirus. Surv.m-CRA has potent therapeutic effects and high safety, and can effectively treat cancer stem cells that are resistant to conventional therapies. Since survivin is highly expressed in all types of cancer, Surv.m-CRA is expected to be effective against a wide range of cancers. This research was conducted in Kosai's laboratory at Kagoshima University and was funded by grants from the Japan Agency for Medical Research and Development (AMED). I am very pleased that the potential of Surv.m-CRA-1, the first product resulting from this research, has been recognized by Nippon Zoki Pharmaceutical, leading to the signing of this licensing agreement."

Takafumi Konishi, President and CEO, Nippon Zoki Pharmaceutical Co., Ltd.
"Our company has built a strong track record, particularly in the fields of orthopedics and pain management, contributing significantly to both healthcare professionals and patients. We are truly honored to take on the challenge of delivering Surv.m-CRA-1, an innovative therapeutic option in the oncology field, specifically for primary malignant bone tumors, which are rare and associated with extremely high unmet medical needs. Through this agreement, we feel a strong sense of purpose and responsibility in expanding our mission. We aim not only to make a continued impact in the orthopedic field, but also to contribute to a broader group of patients. As we work toward obtaining regulatory approval by 2027, we will collaborate closely with Surv Biopharma. Following approval, we will make full use of the expertise we have developed in research and quality control, as well as our established network, to deliver meaningful value to patients and healthcare providers as swiftly as possible."

[Supplementary Information]
About Oncolytic Viruses
Oncolytic viruses are genetically engineered to selectively replicate in and destroy cancer cells. In addition to its direct cancer cell-killing effect, this novel cancer therapy is also expected to activate the patient's own immune system by promoting an immune response against cancer through the release of tumor antigens during the oncolysis process. The oncolytic virus "Surv.m-CRA-1" incorporates the "survivin promoter", which is specifically activated in cancer cells, and therefore demonstrates exceptionally high cancer specificity.

About bone and soft tissue tumors

Malignant bone and soft tissue tumors are sarcomas (primary tumors) and carcinomas (metastatic tumors) that exist in tissues, such as bone, muscle, fat, and blood vessels, and are classified as rare cancers.

Primary malignant bone tumors originate in the bone itself and include types, such as osteosarcoma, which frequently affects younger individuals. As effective treatment options remain limited, new therapeutic approaches are urgently needed. Malignant soft tissue tumors, which arise in tissues throughout the body including muscle and fat, are highly diverse, with more than 50 recognized histological subtypes. For cases that are advanced or have recurred, available treatment options remain limited. In addition, metastatic bone tumors, which can cause severe pain and pathological fractures, are also of great concern and represent an area of high unmet medical need.

Among these, metastatic bone tumors are particularly prevalent, with more than 100,000 people estimated to be affected in Japan. As the number of “cancer survivors” continues to increase each year, there is a growing need for therapies that can fundamentally reduce the pain and risk of fractures associated with bone metastases. Such treatments have the potential to greatly improve patients’ quality of life (QOL).

About Surv Biopharma Inc.

Surv Biopharma is a certified bio-venture company originating from Kagoshima University, established in August 2022 with the aim of bringing Professor Ken-ichiro Kosai’s proprietary technologies into practical application. Professor Kosai developed an innovative agent, “Survivin-responsive, conditionally replicating adenoviruses that can target and treat cancer cells with multiple factors (Surv.m-CRA),” which demonstrates exceptionally high safety and therapeutic efficacy and is also capable of effectively treating cancer stem cells that are resistant to conventional therapies. He achieved this by using his original platform technology to efficiently generate " conditionally replicating adenoviruses that can target and treat cancer cells with multiple factors (m-CRA)." In addition to “Surv.m-CRA-1,” the lead pipeline covered by the current licensing agreement, the company has also developed Surv.m-CRA-2-IC. This next-generation candidate incorporates three immunogenes and is designed to induce systemic anti-tumor immunity, making it capable of effectively treating metastases in distant organs. Surv.m-CRA-2-IC is currently in non-clinical development, with the goal of initiating first-in-human clinical trials in the near future. Beyond these current pipelines, Surv Biopharma remains committed to the continuous and effective development and commercialization of groundbreaking oncolytic virus and immunotherapy. Surv Biopharma aspires to become a global leader in gene therapy.

About Nippon Zoki Pharmaceutical Co., Ltd.

Since its founding in 1939, Nippon Zoki Pharmaceutical has consistently engaged in all aspects of pharmaceutical operations, including drug discovery, research, development, manufacturing, and sales. The company has earned the trust of medical professionals, particularly in the field of

orthopedics, by meeting their expectations over the decades. Drawing on its accumulated knowledge and experience, the company strives to deliver innovative solutions in collaboration with leading experts across various fields. It is committed to making an “unparalleled contribution to the field of orthopedic surgery” and expanding its efforts in the field of neuroscience, with a focus on pain management. To continue meeting the needs of healthcare professionals and patients, the company pursues a development policy that emphasizes the creation of both new pharmaceuticals and novel medical devices. Guided by a deep commitment to life sciences, Nippon Zoki Pharmaceutical will continue to embrace new challenges to realize better healthcare and a more advanced society, with science as its foundation.

Contact
Administration Department, Surv Biopharma Inc.
Email: info@survbiopharma.co.jp

Corporate Communications, Nippon Zoki Pharmaceutical Co., Ltd.
Email: corp-branch@nippon-zoki.co.jp