

NAGASE and HALIX to Begin Contract Development and Manufacturing Services for Biopharmaceuticals, Active Pharmaceutical Ingredients in Japan

End-to-End Services from Process Development to GMP Manufacturing and Final Formulation Exhibits at: 9th Interphex Week Osaka (March 8-10)

NAGASE & CO., LTD. (Chiyoda-ku, Tokyo; President: Kenji Asakura) has concluded a Memorandum of Understanding (MOU) with HALIX B.V. (The Netherlands; CEO: Alex Huybens; hereinafter "HALIX"), a company that develops and manufactures biopharmaceuticals and active pharmaceutical ingredients (API), including viral vectors and recombinant proteins, to provide development and manufacturing services in Japan. We will introduce this service at a seminar and a booth at the 9th Interphex Week Osaka, a research and manufacturing exhibition for pharmaceuticals and cosmetics, to be held from March 8 (Wed.) to 10 (Fri.), 2023.

In recent years, the drug discovery industry has seen rapid progress in the research, development, and commercialization of biopharmaceuticals, as typified by vaccines and antibody drugs, and an increase in drug development using new drug discovery modalities rather than small molecule, which has been the mainstream of conventional drug discovery. In line with this, there is a growing need for development and manufacturing technologies that are compatible with new drug discovery modalities.



HALIX provides integrated contract development and manufacturing services for biopharmaceuticals such as viruses and vaccines, from process development of APIs to manufacturing of investigational drugs, scale-up, and final formulation (aseptic filling, lyophilization (incl. development), etc.) with GMP manufacturing. NAGASE already has experience in providing mid-molecular pharmaceuticals (peptides and nucleic acids), and through this agreement will expand its business into the field of high-molecular pharmaceuticals using biomanufacturing methods, which is one of HALIX's strengths. With NAGASE's solid network in Japan and its industrial expertise, we will promote this contract development and manufacturing service for pharmaceutical companies in Japan. At the same time, we will continue to search for needs in the biopharmaceuticals market. By leveraging NAGASE Group's functions beyond the framework of a distributor, NAGASE will contribute to a safe, secure, and warm society in which people can live comfortably, while leveraging our functions as a NAGASE Group that transcends the framework of a "trading company." We will contribute to a sustainable world where people live with peace of mind.

■ HALIX's Strengths

- **HALIX has a proven track record of development and manufacturing in the biopharmaceutical field and meets diverse needs for drug discovery.**

Ex. COVID-19 replication-deficient adenovectors, viral vectors for gene therapy, tumor-soluble viruses, influenza vaccines, monoclonal antibodies (biosimilars), dual specificity antibodies, etc.

- **Based on the culture technology of mammalian cells, etc., HALIX has the capacity for small to commercial scale production.**

Ex. Adhesion or suspension culture using mammalian and insect cells such as HEK293, CHO, VERO, PERC6, SF9, etc.

- **HALIX achieves efficient process development and increased productivity through single-use technology.**

- **HALIX's expert staff provides support for regulatory compliance, etc.**

■ About HALIX B.V.

HALIX B.V. is a biopharmaceutical CDMO for biologics, enabling the treatment and prevention of life-threatening diseases. The company is focused on mammalian expression systems for the production of viral vectors and recombinant proteins. HALIX leverages scalable single-use, state-of-the-art bioprocessing technologies to provide its customers with services for the development and GMP manufacturing of drug substances and drug products. HALIX has entered into a number of contracts for the production of oncolytic immunotherapies and vaccines, utilizing innovative technologies, most notably the large-scale commercial drug substance manufacture of AstraZeneca's COVID-19 vaccine. The company opened its state-of-the-art 6,700 m² GMP manufacturing facility in 2019, offering 1,000 L SUB capacities, at the Leiden Bio Science Park, the Netherlands. HALIX is part of the family-owned Droege Group AG.



For more information, please visit: <https://www.halix.nl/>

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