Eisai and Henlius Enter into Exclusive Commercial License Agreement for Anti-PD-1 Antibody Serplulimab in Japan

TOKYO and SHANGHAI, Feb. 5, 2026 – Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") and Shanghai Henlius Biotech, Inc. (Headquarters: Shanghai, China, CEO: Jason Zhu, "Henlius") announced today the conclusion of an exclusive commercialization and co-exclusive development and manufacturing license agreement for the anti-PD-1 antibody serplulimab (generic name, marketed as HANSIZHUANG in China and Hetronifly® in the EU) in Japan.

Serplulimab, a novel anti-PD-1 monoclonal antibody developed by Henlius, is reported to possess a unique binding mode that differs from existing anti-PD-1 antibodies.[1] In China, it has been approved for indications such as squamous non-small cell lung cancer (sqNSCLC), extensive-stage small cell lung cancer (ES-SCLC), non-squamous non-small cell lung cancer (nsNSCLC), and esophageal squamous cell carcinoma (ESCC). In the EU, it has been approved for ES-SCLC. It is the world's first anti-PD-1 antibody to be used as a first-line treatment for ES-SCLC.

In Japan, Henlius is currently conducting a Phase II bridging clinical trial for ES-SCLC, and plans to submit an application for fiscal year 2026 based on the results of this trial as well as the Phase III clinical trial data that supported approvals for this indication in China and Europe. Furthermore, a Phase III multi-national clinical trial for non-high-frequency microsatellite instability (non-MSI-High) metastatic colorectal cancer is underway, with development for new indications also planned.

In Japan, it is estimated that there are approximately 13,000 patients diagnosed with ES-SCLC and about 28,000 patients diagnosed with non-MSI-High metastatic colorectal cancer, both of which are considered to have high unmet medical needs.[2,3,4,5]

Under the terms of this agreement, Eisai will obtain exclusive rights to commercialize serplulimab in Japan. In addition to ES-SCLC and non-MSI-High metastatic colorectal cancer, Henlius plans to also conduct a clinical trial for perioperative gastric cancer in Japan, and will assume the responsibilities of the Marketing Authorization Holder.

Eisai will pay Henlius a contractual upfront payment of USD 75 million (approximately JPY 11.6 billion*), in addition to regulatory milestone payments of up to USD 80.01 million (approximately JPY 12.4 billion), and sales milestone payments of up to USD 233.3 million (approximately JPY 36.2 billion). Furthermore, Eisai will pay double-digit royalties based on sales of the product. Eisai anticipates no changes to its consolidated financial forecast for the period ending March 31, 2026.

"We are pleased to collaborate with Eisai in Japan to advance the development of serplulimab in this important market," said Dr. Jason Zhu, CEO of Henlius. "Serplulimab has demonstrated its potential across multiple tumor types through global clinical development and regulatory approvals, and Japan represents a critical step in its international journey. By combining Henlius' innovation capabilities with Eisai's deep local expertise, we aim to support the efficient development of serplulimab and address unmet medical needs for patients in Japan."

“Serplulimab is an anti-PD-1 monoclonal antibody that has been developed with high priority for indications with significant unmet medical needs, including ES-SCLC, and has already obtained approval for multiple indications in China and the EU. We anticipate that it will also become a promising treatment option in Japan for ES-SCLC and non-MSI-high metastatic colorectal cancer, for which development is underway, as well as for other intractable cancers,” said Toshihiko Yusa, Executive Officer and Head of Japan Business at Eisai. “Eisai will make every effort, in cooperation with Henlius, to deliver serplulimab to patients as soon as possible.”

* Converted at an exchange rate of USD 1 = JPY 155

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Notes to Editors

1. **About Serplulimab**
   Serplulimab (generic name, marketed as HANSIZHUANG in China and Hetronifly® in the EU) is an anti-PD-1 monoclonal antibody first developed by Shanghai Henlius Biotech, Inc. (“Henlius”), and launched in China in 2022. It has been approved by the National Medical Products Administration of China for indications including squamous non-small cell lung cancer, extensive-stage small cell lung cancer (ES-SCLC), esophageal squamous cell carcinoma, and non-squamous non-small cell lung cancer, and is the world's first anti-PD-1 antibody to be used as a first-line treatment for ES-SCLC. It has been approved for the treatment of ES-SCLC in over 40 markets, including the EU, Southeast Asia (Indonesia, Cambodia, Thailand, Singapore, Malaysia), and South America (Peru). Henlius is actively promoting the broader use of serplulimab both as a standalone product and in combination with other innovative therapies, including those developed in-house and externally. Furthermore, the company is conducting numerous clinical trials worldwide on therapies for conditions where existing anti-PD-1 antibodies have not yet been used, focusing on indications such as lung cancer and gastrointestinal tumors.

2. **About Eisai Co., Ltd.**
   Eisai's Corporate Concept is "to give first thought to patients and people in the daily living domain, and to increase the benefits that health care provides." Under this Concept (also known as *human health care* (*hhc*) Concept), we aim to effectively achieve social good in the form of relieving anxiety over health and reducing health disparities. With a global network of R&D facilities, manufacturing sites and marketing subsidiaries, we strive to create and deliver innovative products to target diseases with high unmet medical needs, with a particular focus in our strategic areas of Neurology and Oncology.

In addition, we demonstrate our commitment to the elimination of neglected tropical diseases (NTDs), which is a target (3.3) of the United Nations Sustainable Development Goals (SDGs), by working on various activities together with global partners.

For more information about Eisai, please visit www.eisai.com (for global headquarters: Eisai Co., Ltd.), and connect with us on X, LinkedIn and Facebook. The website and social media channels are intended for audiences outside of the UK and Europe.

3. About Shanghai Henlius Biotech, Inc.

Shanghai Henlius Biotech, Inc. (2696.HK) is a global, innovation-driven biopharmaceutical company committed to delivering high-quality, affordable biologic therapies to patients worldwide. The Company focuses on major disease areas including oncology, autoimmune diseases, and ophthalmic diseases. Founded in 2010, Henlius has established an integrated, end-to-end biopharmaceutical platform encompassing global R&D, clinical operations, regulatory affairs, manufacturing, and commercialisation. The Company employs nearly 4,000 people globally and operates across multiple regions, including China, the United States, and Japan. Leveraging the stable cash flow generated from its biosimilar portfolio to support innovation, Henlius is steadily advancing into its "Globalisation 2.0" phase, building a scalable and sustainable global growth model. As of early 2026, Henlius has achieved regulatory approvals for 10 products across 60 countries and regions worldwide, including seven approvals in China. The Company has also reached multiple milestones in major biopharmaceutical markets, with four products approved by the U.S. Food and Drug Administration (FDA) and four products authorized by the European Medicines Agency (EMA), reflecting its globally aligned R&D capabilities, quality systems, and manufacturing standards.

Driven by innovation, Henlius has built a diversified, platform-based technology ecosystem through coordinated R&D efforts across Shanghai, the United States, and other regions. Its innovation platforms span immune checkpoint inhibitors, immune cell engager technologies (including multispecific T cell engagers), antibody-drug conjugates (ADCs), and AI-enabled early discovery platforms. The Company currently has more than 50 early-stage innovative assets, approximately 70% of which are expected to be best-in-class, with over 30 clinical trials ongoing globally. Henlius' core product, serplulimab (trade name: Hetronifly® in Europe), is the world's first anti–PD-1 mAb approved for first-line treatment of small cell lung cancer and has been approved in more than 40 markets worldwide with an accelerated globalisation process. In parallel, multiple high-potential innovative assets—including the PD-L1 ADC HLX43 and the novel epitope anti-HER2 mAb HLX22—are advancing through global pivotal clinical development. Supported by a biologics manufacturing network with a total capacity of 84,000L and GMP certifications from regulatory authorities in China, Europe, and the United States, Henlius has established a stable global supply system serving six continents. Guided by a patient-centred mission, Henlius remains focused on addressing unmet medical needs and translating scientific innovation into meaningful clinical value and patient access, contributing sustainably to the global biopharmaceutical ecosystem.

To learn more about Henlius, visit https://www.henlius.com/en/index.html and connect with us on LinkedIn at https://www.linkedin.com/company/henlius/.

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