



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

Descrizione

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TOKYO and SHANGHAI, Feb. 5, 2026 /PRNewswire/ ?? Eisai Co., Ltd. (??Eisai??) and Shanghai Henlius Biotech, Inc. (??Henlius??) today announced 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 Hetronifly?? in the EU) in Japan.

Serplulimab is a novel anti-PD-1 monoclonal antibody developed by Henlius and reported to have a unique binding mode distinct from existing anti-PD-1 antibodies. In China, it has been approved for multiple indications, including squamous non-small cell lung cancer, extensive-stage small cell lung cancer (ES-SCLC), non-squamous non-small cell lung cancer, and esophageal squamous cell carcinoma. In the EU, serplulimab has been approved for ES-SCLC and is the world??s first anti-PD-1 antibody approved as a first-line treatment for this indication.

In Japan, Henlius is currently conducting a Phase II bridging study for ES-SCLC and plans to submit a regulatory application in fiscal year 2026 based on the bridging study results and Phase III data supporting approvals in China and Europe. In addition, a Phase III multinational clinical trial for non-MSI-High metastatic colorectal cancer is ongoing, with further development in additional indications planned.

Under the agreement, Eisai will obtain exclusive rights to commercialize serplulimab in Japan. Henlius plans to conduct a clinical trial for perioperative gastric cancer in Japan and will assume the responsibilities of the Marketing Authorization Holder.

Eisai will pay Henlius an upfront payment of USD 75 million, regulatory milestone payments of up to USD 80.01 million, and sales milestone payments of up to USD 233.3 million. In addition, Henlius will receive double-digit royalties based on product sales. Eisai expects no impact on its consolidated financial forecast for the fiscal year ending March 31, 2026.

â??We are pleased to collaborate with Eisai in Japan to advance the development of serplulimab in this important market,â?• said Dr. Jason Zhu, CEO of Henlius. â??By combining Henliusâ?? innovation capabilities with Eisaiâ??s strong local expertise, we aim to support efficient development and address unmet medical needs for patients in Japan.â?•

â??Serplulimab has already demonstrated its potential in indications with significant unmet medical needs and has obtained approvals in China and the EU,â?• said Toshihiko Yusa, Executive Officer and Head of Japan Business at Eisai. â??Eisai will work closely with Henlius to deliver serplulimab to patients in Japan as quickly as possible.â?•

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