

First Chinese PD-1 Inhibitor Hetronifly® (serplulimab) Recommended by NICE for NHS Lung Cancer Care

UK's NICE recommends China's serplulimab (trade name in Europe: Hetronifly) for routine use within the National Health Service (NHS) in England and Wales

SHANGHAI, CHINA, August 30, 2026 /EINPresswire.com/ -- A pioneering immune checkpoint inhibitor independently developed by Shanghai-based [Chinese biopharmaceutical company Henlius](#) — Hetronifly® (generic name: serplulimab, investigational code: HLX10) — is set to expand treatment options for patients

battling extensive-stage small cell lung cancer (ES-SCLC) across England and Wales, after the National Institute for Health and Care Excellence (NICE) issued a positive recommendation for routine use within the NHS. This milestone makes Hetronifly the first PD-1 monoclonal antibody independently developed by Henlius in China to be recommended by NICE for routine use within the National Health Service (NHS) in England and Wales.

Extensive-stage small cell lung cancer is an aggressive, fast-growing lung malignancy associated with limited treatment options and suboptimal long-term survival outcomes. Unlike conventional chemotherapy which damages both malignant tumours and healthy human cells, serplulimab is a type of immunotherapy that helps the body's own immune system recognise and attack cancer cells.

The favourable NICE recommendation supports the use of Hetronifly in combination with standard chemotherapy in adult patients diagnosed with ES-SCLC. The approval is firmly underpinned by robust global pivotal clinical trial data, which demonstrated a clear survival advantage: patients treated with serplulimab plus chemotherapy achieved a median overall survival of 15.8 months versus 11.1 months for placebo, with approximately 22% of patients still alive four years after starting treatment.



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Hetronifly® is a humanised PD-1 blocking immunotherapy. By inhibiting the PD-1 immune checkpoint pathway, the medicine releases the body's own T lymphocytes to identify and attack tumour cells, working alongside standard chemotherapy regimens to deliver improved clinical outcomes compared with chemotherapy alone. According to the European Medicines Agency (EMA) assessment, Hetronifly's safety profile is similar to that of other cancer medicines from the same class. While some of the side effects related to the activity of the immune system can be severe, these are considered manageable.

Building on its new NHS reimbursement pathway for England and Wales, Hetronifly® has built a broad footprint across Europe and worldwide. Within the European Union, the therapy holds EU marketing authorisations for four priority thoracic and gastrointestinal tumour settings: extensive-stage small cell lung cancer (ES-SCLC), oesophageal squamous cell carcinoma (ESCC/OSCC), driver gene-negative advanced non-squamous non-small cell lung cancer (nsqNSCLC) and driver-negative advanced squamous non-small-cell lung cancer (sqNSCLC). The four indications were approved in a staggered timeline:

- On 3 February 2025, the EC approved ES-SCLC for use in combination with carboplatin and etoposide as a first-line treatment.
- In 2026, the EC approved two additional indications simultaneously: nsqNSCLC — for first-line treatment of unresectable locally advanced or metastatic disease in adult patients with EGFR mutation-negative, ALK- or ROS1-negative status, in combination with carboplatin and pemetrexed; and ESCC/OSCC — for first-line treatment of unresectable locally advanced, recurrent or metastatic disease in PD-L1 positive (CPS≥5) adults, in combination with fluoropyrimidine and platinum-based chemotherapy.
- In 2026, the EC approved sqNSCLC for first-line treatment of unresectable locally advanced or metastatic disease in combination with carboplatin and nab-paclitaxel.

Each of these EU indications is supported by robust global Phase III datasets from multi-continental trials that enrolled diverse patient cohorts.

To date, Hetronifly® has been approved in 16 European nations and secured reimbursement in 12 major European markets including the United Kingdom, Germany, Italy, Spain, Sweden, Denmark, Austria and Ireland. Beyond Europe, serplulimab – marketed as HANSIZHUANG in Chinese mainland – has obtained marketing approvals across over 50 countries and regions globally, with more than 110 000 patients worldwide having received the treatment to date.

About Henlius

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 over 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. To date, Henlius has achieved regulatory approvals for 10 products across over 60 countries and regions worldwide, including eight 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 five products approved by the European Commission (EC), reflecting its globally aligned R&D capabilities, quality systems, and manufacturing standards.

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