Final ASTRUM-002 Analysis Shows Survival Benefit with Hetronifly in Advanced nsqNSCLC After Four Years of Follow-Up

SHANGHAI, CHINA, August 10, 2026 /EINPresswire.com/ -- Shanghai Henlius Biotech, Inc. (2696.HK), headquartered in Shanghai and listed on the Hong Kong Stock Exchange, recently announced definitive final survival findings from its proprietary anti-PD-1 monoclonal antibody Hetronifly (serplulimab, investigational code: HLX10) in the first-line treatment of driver gene-negative advanced non-squamous non-small cell lung cancer (nsqNSCLC). The analysis has been formally published in Cancer Communications, a leading international oncology journal with an impact factor of 28.4. The final analysis with nearly four years of follow-up demonstrates sustained long-term survival benefits with Hetronifly for patients with nsqNSCLC.

Henlius —— A Chinese biopharmaceutical company with a global, innovation-driven mandate, dedicated to expanding access to biologic therapies for patients around the world

Phase 3 ASTRUM-002 Trial Confirms Consistent Survival Benefit Over Nearly Four Years of Follow-Up

The pivotal Phase 3 ASTRUM-002 study is a three-arm, randomized, double-blind, multicenter global trial enrolling 636 treatment-naïve adults diagnosed with locally advanced or metastatic nsqNSCLC without EGFR, ALK or ROS1 genomic alterations. Participants were randomized equally (c) into three treatment cohorts:

Group A: Hetronifly + HLX04 (bevacizumab biosimilar) + platinum chemotherapy

Group B: Hetronifly + chemotherapy + bevacizumab placebo

Group C: Dual placebo + chemotherapy alone

With a data cutoff date of August 7, 2025, median follow-up across all study arms approached four years: 48.4 months for Group A, 45.4 months for Group B and 45.7 months for Group C. Key primary survival endpoints demonstrate meaningful clinical benefits for Hetronifly combined with chemotherapy (Group B):

1) Median overall survival (mOS) reached 26.8 months for Hetronifly plus chemotherapy,

compared with 20.3 months for chemotherapy alone (Group C).
2) The immunotherapy combination reduced the risk of death by 34% versus chemotherapy monotherapy (HR=0.66, 95% CI: 0.52–0.83, P<0.001).
3) A total of 37.6% of patients in the control arm crossed over to receive Hetronifly-containing regimens, which may dilute observed survival differences. After statistical adjustment using two validated models to account for crossover, adjusted hazard ratios of 0.53 and 0.62 confirmed a reduced mortality risk among patients receiving Hetronifly.
Long-term survival rates further demonstrate the durability of the survival benefit: 34.0% of patients treated with Hetronifly plus chemotherapy were alive at 48 months, compared to 16.2% of patients receiving chemotherapy alone.
Progression-free survival (PFS) and tumour response endpoints further support the efficacy of Hetronifly combination therapy:
Median PFS was 11.0 months in Group B versus 5.7 months in the chemotherapy-only arm, corresponding to a 46% reduction in risk of disease progression.
The confirmed objective response rate (ORR) was 52.8% and median duration of response (DoR) reached 15.4 months for Hetronifly combination treatment. By comparison, chemotherapy alone yielded an ORR of 27.6% and a median DoR of 8.3 months.
Subgroup analyses showed a generally consistent trend toward improved survival outcomes, including in patients with PD-L1 TPS ≥50% and those with brain metastases.

Distinct Mechanism of Action Driving Hetronifly's Clinical Activity
Hetronifly (serplulimab) is a fully humanized anti-PD-1 monoclonal antibody engineered with a unique molecular profile. Preclinical studies suggest that serplulimab may support rapid and sustained immune activation through differentiated effects on PD-1 internalization and CD28 signalling:
- Hetronifly promotes PD-1 internalization on T cells, removing inhibitory PD-1 receptors to facilitate anti-tumour immune activity.
- The treatment limits PD-1-mediated sequestration of CD28, helping preserve CD28 co-stimulatory signalling, maintaining downstream AKT pathway activity and supporting sustained T-cell anti-tumour function.
This mechanism underpins Hetronifly's clinical performance across multiple common solid tumour types, supporting the continued clinical development of serplulimab across multiple tumour types and treatment settings.

Global Approvals and Ongoing Clinical Expansion of Hetronifly
Regulatory Approvals
In China, Hetronifly (marketed as Hansizhuang) has been approved by the National Medical Products Administration (NMPA) for five indications since its first market approval in March 2022:

- Squamous non-small cell lung cancer (sqNSCLC)
- Extensive-stage small cell lung cancer (ES-SCLC)
- Oesophageal squamous cell carcinoma (ESCC)
- Non-squamous non-small cell lung cancer (nsqNSCLC)

- Perioperative gastric cancer

In the European Union, Hetronifly has been approved for ES‑SCLC, ESCC and driver gene‑negative advanced non‑squamous NSCLC, with the nsqNSCLC approval granted in May 2026 as its third EU indication. The fourth EU indication, for driver‑negative advanced squamous NSCLC (sqNSCLC), was secured in June 2026.

Beyond China and Europe, Hetronifly has also received regulatory approvals in Switzerland, India, and multiple Southeast Asian markets including Indonesia, Singapore, Malaysia, Cambodia and Thailand. In December 2023, Indonesia became the first ex-China market to approve the product (under the trade name Zerpidio®) for ES-SCLC. Serplulimab has also received approval in South Korea for first-line treatment of ES-SCLC.

Commercial Access

Building on these regulatory approvals, Henlius has established commercial access for Hetronifly across multiple markets.

n the EU, Henlius works with Accord Healthcare as its commercial partner. To date, Hetronifly has been launched in 16 European nations and secured reimbursement in more than ten major European markets including the United Kingdom, Germany, Italy, Spain, Sweden, Denmark, Austria and Ireland.

Ongoing Clinical Development

Henlius continues expanding Hetronifly’s clinical programme via an extensive global Phase 3 trial portfolio:

- An international multicenter Phase 3 trial evaluating Hetronifly alongside concurrent chemoradiotherapy for limited-stage SCLC has completed full patient enrolment.
- Bridging studies for ES-SCLC in the United States and Japan have finished recruitment.
- Global Phase 3 ASTRUM-015, assessing Hetronifly combined with bevacizumab and chemotherapy for metastatic colorectal cancer (mCRC), has completed international enrolment, targeting unmet needs for patients with MSS mCRC.
- Multiple investigator-initiated trials (IITs) are exploring Hetronifly in perioperative and early-stage NSCLC settings to advance treatment strategies aimed at sustained disease control.

About Henlius

Shanghai Henlius Biotech is a Chinese biopharmaceutical company with a global, innovation-driven mandate, dedicated to expanding access to biologic therapies for patients around the world.

The Company focuses on major disease areas including oncology, autoimmune diseases, and ophthalmic diseases. Up 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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