Henlius' HANDAYUAN (Adalimumab Biosimilar) Secures DRAP Approval in Pakistan, Marking Its First Overseas Approval

Henlius announces its partner Getz Pharma received DRAP registration for HANDAYUAN, its adalimumab biosimilar, sold as Adaliget in Pakistan.

SHANG HAI, SHANGHAI, CHINA, October 15, 2026 /EINPresswire.com/ -- Shanghai Henlius Biotech, Inc. (2696.HK) announces that its commercial partner Getz Pharma (Private) Limited has received the relevant registration certificates from the Drug Regulatory Authority of Pakistan (DRAP) for HANDAYUAN, Henlius' self-developed adalimumab biosimilar, marketed under the brand name Adaliget® in Pakistan. This clearance marks the first international approval of HANDAYUAN and expands Henlius' global footprint as its eighth self-developed product to secure marketing authorization outside China.

The Pakistani approval covers all indications of the reference adalimumab product approved within the country. HANDAYUAN joins Henlius' growing ex-China product portfolio, which already includes HANQUYOU (trastuzumab), HANSIZHUANG (serplulimab), Poherdy (pertuzumab), and HANBEITAI (bevacizumab).

Adalimumab is one of the world's top-selling biologic medicines, with approvals for more than 10 autoimmune conditions globally, such as rheumatoid arthritis (RA), ankylosing spondylitis, psoriasis and uveitis. It is endorsed by clinical practice guidelines for autoimmune disorders across North America and Europe. Data from the Global Burden of Disease 2023 study estimates more than 50 million patients living with rheumatoid arthritis and psoriasis in 2023, with patient numbers continuing to rise. Despite widespread clinical recognition, adalimumab access remains limited in many emerging markets.

The Pakistan approval builds on a 2022 licensing and supply agreement between Henlius and Getz Pharma. Under the deal, Getz Pharma will roll out Adaliget® across 11 emerging markets in Asia, Africa and Europe, with Pakistan representing the first regulatory approval under this collaboration.

HANDAYUAN is Henlius' first self-developed product approved for the treatment of autoimmune diseases. It received marketing approval from China's National Medical Products Administration (NMPA) in December 2020, and Fosun Wanbang is responsible for the domestic commercialisation of HANDAYUAN in China.. In July 2026, HANDAYUAN was included in China's

National Essential Medicines List (2026 Edition).

DRAP's review relied primarily on the data package originally submitted to the NMPA as part of HANDAYUAN's new drug application. Henlius completed a comprehensive programme of head-to-head comparative testing against reference adalimumab, comprising analytical characterisation, non-clinical studies and clinical trials. The dataset demonstrated that HANDAYUAN is highly similar to the reference product in quality, safety and efficacy. Notably, HANDAYUAN is the first adalimumab biosimilar to be evaluated in a Phase 3 clinical trial enrolling Chinese patients with psoriasis.

HANDAYUAN's production site and associated quality management system adhere to international standards. Henlius' manufacturing infrastructure and quality systems have passed roughly 100 regulatory inspections and audits by bodies including the NMPA, European Medicines Agency (EMA), U.S. Food and Drug Administration (FDA), PIC/S members Indonesia BPOM and Brazil ANVISA, EU Qualified Persons, and multiple global commercial partners. Henlius and Getz Pharma broadened their strategic partnership in December 2024, granting Getz Pharma exclusive commercial rights for HANQUYOU (trastuzumab) in Pakistan. Moving forward, Henlius will maintain international quality benchmarks and continue collaborating with Getz Pharma and other global partners to advance regulatory submissions and product launches for additional biologics worldwide, expanding treatment options for patients across diverse markets.

About Henlius
Shanghai Henlius Biotech, Inc. (2696.HK) is a globally focused, innovation-driven biotech firm dedicated to developing high-quality, accessible biologic therapies for patients worldwide. The company's pipeline targets high-unmet-need areas including oncology, autoimmune diseases and ophthalmology. Founded in 2010, Henlius operates a fully integrated biopharmaceutical platform spanning global research and development, clinical development, regulatory strategy, manufacturing and commercialisation. It employs over 4,000 staff across China, the United States, Japan and other regions.

Cash flow generated from its biosimilar portfolio supports Henlius' innovative pipeline, as the company progresses through its Globalisation 2.0 strategy to build a scalable, sustainable international growth model. To date, Henlius has secured regulatory approvals for 10 products in more than 60 countries and regions globally, with eight approvals within China. Four of its products have received FDA clearance and five have been approved by the European Commission, validating its globally aligned R&D, quality and manufacturing capabilities.

Henlius operates a decentralised innovation network with coordinated R&D in Shanghai, the U.S. and other locations, building a diversified technology platform covering immune checkpoint inhibitors, immune cell engagers including bispecific T-cell engagers, antibody-drug conjugates (ADCs), and AI-powered early discovery tools. The company holds over 50 pre-clinical innovative assets; approximately 70% are designed as potential best-in-class candidates, with more than 50

clinical trials active globally.

Its flagship asset, serplulimab, marketed as Hetronifly® in Europe, is the world's first anti-PD-1 monoclonal antibody approved for first-line extensive-stage small cell lung cancer and for perioperative treatment of gastric cancer. Serplulimab has gained authorisation in more than 50 global markets, with its global rollout accelerating. Multiple promising novel candidates, including the PD-L1 ADC HLX43 and novel epitope anti-HER2 antibody dulpatatug (HLX22), are advancing into global pivotal trials.

Supported by a biologic manufacturing network with a total capacity of 84,000 litres and GMP certification from Chinese, European and U.S. regulators, Henlius maintains a reliable global supply chain serving six continents. Centred on a patient-first mission, the company continues to address unmet medical needs, translate scientific research into tangible clinical value and improve patient access, contributing to the global biopharmaceutical ecosystem.

Yun Chen
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