Clarivate™

FDA grants accelerated approval to Hernexeos for NSCLC under National Priority Voucher pilot program

Market Event Summary

Charlotte Jago, Ph.D. | March 2026

Approval brings targeted treatment for *HER2*-mutant disease to the first-line population

Context

- *HER2* mutations occur in ~2-4% of nonsquamous NSCLC patients. Patients in the first-line metastatic population are typically treated with chemoimmunotherapy due to the absence of targeted therapies in that treatment setting.
- Patients who progress typically receive the intravenous HER2-targeted ADC Enhertu (trastuzumab deruxtecan; AstraZeneca / Daiichi Sankyo). However, the oral tyrosine kinase inhibitors Hernexeos (zongertinib; Boehringer Ingelheim) and Hyrnuo (sevabertinib; Bayer) became additional later-line options upon FDA approval for later-line use in 2025.

Hernexeos approval timeline

- August 8, 2025: Hernexeos becomes the first FDA-approved oral drug for later-line metastatic *HER2*-mutated nonsquamous NSCLC. Accelerated approval was based on later-line ORR (75%) and DOR (58% ≥ 6 months) data from the Phase 1b Beamion LUNG-1 trial.
- November 6, 2025: FDA awards Hernexeos a Commissioner's National Priority Voucher (CNPV). The program targets an expedited approval timeline of 1 to 2 months.
- January 13, 2026: Hernexeos was filed with the FDA for use in the first-line population.
- February 26, 2026: Hernexeos becomes the first HER2-targeted agent to gain FDA approval for use in the first-line setting. Accelerated approval was based on first-line ORR (76%) and DOR (64% ≥ 6 months) data from Beamion LUNG-1.
- The confirmatory Phase 3 Beamion LUNG-2 trial of first-line Hernexeos versus Keytruda plus chemotherapy is expected to reach primary completion in November 2026.

Clarivate's takeaways

Competition in the first-line setting

We expect Enhertu and Hyrnuo to also receive first-line approvals by the end of 2028, supported by the Phase 3 DESTINY-Lung04 and SOHO-02 trials, respectively.

HER2 treatment paradigm will shift

We forecast that targeted treatment will become the first-line standard-of-care for *HER2*-mutated nonsquamous metastatic NSCLC. Orally administered drugs will be preferred over intravenous ones.

CNPV hastens drug approval process

Hernexeos is the second drug, and first oncology drug, approved under the CNPV pilot program. Four other CNPVs have been granted to oncology drugs to date.

About the author

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Charlotte Jago is a pharmaceutical industry analyst with more than 20 years' experience, preceded by 5 years of laboratory research in academia and industry. She wrote the company's flagship Drugs to Watch reports in 2013, 2014, 2015, and 2019 and led the improvement in immuno-oncology coverage on the Cortellis Competitive Intelligence platform. She holds a Ph.D. in immunology, a first-class B.Sc. (Hons) degree in pharmacology, and a postgraduate certificate in journalism.

Clarivate coverage of NSCLC

- NSCLC | Disease Landscape & Forecast | G7 | last updated February 2026
  - Provides comprehensive market intelligence with world-class epidemiology, keen insight into current treatment paradigms, and drug forecasts supported by detailed primary and secondary research
- NSCLC | Current Treatment: Physician Insights | US | published February 2026
  - Provides physician insights on treatment dynamics, prescribing behavior, and drivers of brand use in NSCLC
- NSCLC | Treatment Sequencing | US | published February 2026
  - Provides sequential treatment patterns in market-relevant treatment scenarios and drug share mapped to treatment journey in NSCLC
- NSCLC | Unmet Need | US/EU | published May 2025
  - Provides insights into areas of unmet need in specific subpopulations

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