Press release

For media and investors only

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Nelkarmi (neladalkib) approved in the US for previously-treated advanced ALK-positive non-small cell lung cancer

- Approval based on phase I/II ALKOVE-1 trial demonstrating clinically meaningful and durable responses in pretreated patients
- Next-generation ALK inhibitor designed to help address resistance, disease in the brain and tolerability challenges
- GSK's second approval in lung cancer this year[1]

GSK plc (LSE/NYSE: GSK) today announced the US Food and Drug Administration (FDA) has granted accelerated approval to *Nelkarmi* (neladalkib) for the treatment of adults with locally advanced or metastatic anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC) who have previously received the following therapy in the unresectable locally advanced or metastatic setting: one prior ALK tyrosine kinase inhibitor (TKI) consisting of alectinib, or two or more prior ALK TKIs and platinum-based chemotherapy.[2]

This approval comes ahead of the original FDA target action date of 27 November 2026 and follows the FDA's Breakthrough Therapy and Orphan Drug designations.[3]

Tony Wood, Chief Scientific Officer, GSK said: "*Nelkarmi* is our second new medicine approved in lung cancer this year. It was designed to help address key challenges of ALK-positive non-small cell lung cancer through its broad coverage of ALK resistance mutations, ability to cross the blood-brain barrier and high target selectivity. ALK-positive patients are often younger and can remain on treatment for years, making effective and tolerable new treatment options especially important, and we are pleased to bring this innovation to patients in the US."

The approval is based on results from the phase I/II ALKOVE-1 trial. For patients previously treated with alectinib as their only prior ALK TKI, the confirmed overall response rate (ORR) was 49% (33/67; 95% CI: 37%, 62%), with a duration of response (DOR) as assessed by blinded independent central review (BICR) of 6 or more months in 76% of responders and 12 or more months in 52% of responders. For patients with two or more prior ALK TKIs and chemotherapy, the ORR was 32% (50/155; 95% CI: 24%, 40%), with DOR of 6 or more months in 69% of responders and 12 or more months in 51% of responders.[2]

Among patients with measurable central nervous system (CNS) metastases at baseline, intracranial ORR was 55% (11/20; 95% CI: 32% 77%) (including 25% complete responses) in those previously treated with alectinib as their only prior ALK TKI, and 26% (14/53; 95% CI: 15%, 40%) (including 11% complete responses) in those who had received two or more prior ALK TKIs and chemotherapy.[2]

The most common (≥20%) adverse reactions were hepatotoxicity, musculoskeletal pain, constipation, dysgeusia, peripheral neuropathy, edema, and fatigue. Permanent discontinuation of *Nelkarmi* due to adverse reactions occurred in 5% of patients. The most frequent adverse reaction that led to permanent discontinuation was hepatotoxicity.[2]

Alice Shaw, MD, PhD, an ALKOVE-1 trial investigator, Chair of the Department of Medical Oncology and Chief of Strategic Partnerships at Dana-Farber Cancer Institute, said: "Patients with ALK-positive lung cancer are often treated with multiple targeted therapies over many years. Advances in treatment have brought us closer to the goal of managing ALK-positive lung cancer as a chronic condition, but balancing disease control and long-term tolerability remains a significant challenge. The approval of neladalkib provides an important new treatment option for patients."

Kirk Smith, President, ALK Positive, said: "For people living with ALK-positive lung cancer, one of the hardest moments is learning that a treatment that had been working is no longer controlling the disease. As patients move through multiple therapies over the course of their disease, they need options that balance durable disease control with the ability to tolerate and remain on treatment and maintain quality of life. Today's approval represents important progress for our community."

Nelkarmi, part of the portfolio from the recent acquisition of Nuvalent, Inc, is also being evaluated in ALKAZAR, an ongoing phase III trial in TKI-naïve ALK-positive NSCLC, and in other solid tumours.

About *Nelkarmi* (neladalkib)
Nelkarmi is an ALK-selective tyrosine kinase inhibitor (TKI) granted accelerated approval in the US for the treatment of adults with locally advanced or metastatic anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC) who have previously received the following therapy in the unresectable locally advanced or metastatic setting: one prior ALK tyrosine kinase inhibitor (TKI) consisting of alectinib, or two or more prior ALK TKIs and platinum-based chemotherapy.

It was designed to help address treatment resistance and disease that has spread to the brain, key challenges in ALK-positive NSCLC and other cancers.

The US Prescribing information will be available here.

About the ALKOVE-1 trial
ALKOVE-1 (NCT05384626) is a global single-arm phase I/II trial evaluating neladalkib in patients with advanced ALK-positive NSCLC and other ALK-positive solid tumours. The trial enrolled 700 patients with ALK-positive solid tumours across the phase I and phase II portions. The primary efficacy analysis supporting the FDA approval included 222 patients with previously treated ALK-positive NSCLC. The major efficacy outcome measures were confirmed overall response rate (ORR) and duration of response (DOR) as assessed by blinded independent central review.

About NSCLC
NSCLC is the most common form of lung cancer and is often characterised by specific genetic alterations, such as those in ALK, ROS1 or HER2. It can often metastasise (i.e. spread) to the central nervous system. It primarily affects working-age individuals. Current treatments may have efficacy and/or tolerability limitations that leave unmet need for patients.

About GSK in oncology
GSK is focused on developing differentiated medicines for cancers where patients continue to face poor outcomes, treatment resistance, limited options or significant treatment burden. We focus where advances in science and technology offer the greatest opportunity to improve outcomes across haematological, lung, gastrointestinal, genitourinary and gynaecological cancers. Across multiple modalities, including targeted small molecules, antibody-drug conjugates (ADCs) and immunotherapies, GSK applies deep expertise in cancer biology and immune system science to develop differentiated medicines designed to deliver durable responses, overcome resistance and reduce treatment burden.

About GSK
GSK is a global biopharma company with a purpose to unite science, technology, and talent to get ahead of disease together. Find out more at www.gsk.com.

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Cautionary statement regarding forward-looking statements
GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Such factors include, but are not limited to, those described in the "Risk Factors" section in GSK's Annual Report on Form 20-F for 2025, and GSK's Q3 Results for 2026.

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References

[1] GSK press release, Jideytro (zidesamtinib) approved in the US for previously treated ROS1-positive non-small cell lung cancer, July 2026
[2] Nelkarmi (neladalkib) US Prescribing Information. November 2026.
[3] Nuvalent Announces Submission of New Drug Application to FDA for Neladalkib in TKI Pre-treated Advanced ALK-positive NSCLC - Apr 7, 2026