# 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]

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**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 November 27, 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 tumors.

**About *Nelkarmi* (neladalkib)**
*Nelkarmi* is an ALK-selective tyrosine kinase inhibitor (TKI) approved 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.

**Indication and Important Safety Information for NELKARMI (neladalkib)**

NELKARMI™ (neladalkib) is indicated for the treatment of adult patients with locally advanced or metastatic ALK-positive non-small cell lung cancer (NSCLC) who have previously received the following therapy in the unresectable locally advanced or metastatic setting:
•1 prior ALK TKI consisting of alectinib; or
•2 or more prior ALK TKIs and platinum-based chemotherapy

This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

**IMPORTANT SAFETY INFORMATION**

**WARNINGS AND PRECAUTIONS:**
Warnings and Precautions reflect the pooled safety population (N=700) of patients enrolled in ALKOVE-1, who received NELKARMI at a dose of 150 mg orally once daily until disease progression or unacceptable toxicity.

**Hepatotoxicity:**

- NELKARMI can cause severe and life-threatening hepatotoxicity, including drug induced liver injury (DILI) resulting in hepatic failure.
- Hepatotoxicity occurred in 56% of patients who received NELKARMI; of these, 18% were Grade 3 and 7% were Grade 4. Grade 3 or 4 DILI occurred in 0.3% of patients and Grade 3 or 4 hepatic failure occurred in 0.4% of patients.
- Increased alanine aminotransferase (ALT) occurred in 62% of patients, including Grade 3 in 13% and Grade 4 in 4.8%. Increased aspartate aminotransferase (AST) occurred in 63%, including Grade 3 in 11% and Grade 4 in 2.5% of patients.
- NELKARMI was interrupted due to hepatotoxicity in 25%, the dose was reduced in 11% and permanently discontinued in 3% of patients.
- Monitor liver function tests (ALT, AST, and total bilirubin) at baseline, every 2 weeks during the first 2 months of treatment, and then monthly and as clinically indicated, with more frequent testing in patients who develop transaminase elevations. Withhold, then resume at the same dose or reduced dose, or permanently discontinue NELKARMI based on severity.

**Renal Toxicity:**

- NELKARMI can cause severe and life-threatening renal toxicity including acute kidney injury.
- Acute kidney injury occurred in 1.1%, including Grade 3 in 0.3%, Grade 4 in 0.3%. Grade 2 chronic kidney disease occurred in 0.3% of patients.
- Increased serum creatinine occurred in 24%, including Grade 3 in 0.1% and Grade 4 in 0.3% of patients.
- NELKARMI was interrupted for renal toxicity in 0.6% and permanently discontinued in 0.4% of patients.
- Monitor serum creatinine at baseline and every 2 weeks for the first month and then periodically as clinically indicated during treatment. Withhold, then resume at the same or reduced dose or permanently discontinue NELKARMI based on severity.

**Ocular Toxicity:**

- NELKARMI can cause ocular toxicity including retinal detachment, corneal erosion, and keratopathy.
- Ocular toxicity occurred in 14%. Grade 2 ocular toxicity occurred in 2.9%, Grade 3 (diplopia, retinal detachment, corneal erosion, and keratopathy) was observed in one patient each and Grade 4 (retinal detachment) was observed in one patient.
- NELKARMI was interrupted in 0.7% of patients due to ocular toxicity.
- Monitor for vision changes at regular intervals during treatment with NELKARMI. Promptly refer patients with new or worsening visual symptoms to an eye care professional, such as an ophthalmologist or optometrist. Withhold, then reduce the dose or permanently discontinue NELKARMI based on severity.

**Creatinine Phosphokinase (CPK) Elevation:**

- NELKARMI can cause severe CPK elevation.
- Increased CPK occurred in 28%, including Grade 3 in 2.7% and Grade 4 in 1.2% of patients.
- NELKARMI was interrupted for CPK elevation in 1.9%, and the dose was reduced in 0.4% of patients.
- Monitor serum CPK levels at baseline and every 2 weeks for the first 2 months, then periodically as clinically indicated during treatment with NELKARMI. Withhold, then resume at the same or reduced dose, or permanently discontinue NELKARMI based on severity.

**Embryo-Fetal Toxicity:**

- Based on literature reports in humans with congenital mutations leading to changes in tropomyosin receptor kinase (TRK) signaling, findings from animal studies, and its mechanism of action, NELKARMI can cause fetal harm when administered to a pregnant woman.
- Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Advise females of reproductive potential to use effective nonhormonal contraception during treatment with NELKARMI and for 2 weeks after the last dose.
- Advise males with female partners of reproductive potential to use effective contraception during treatment with NELKARMI and for 2 weeks after the last dose.

**ADVERSE REACTIONS:**

The serious and fatal adverse reactions reflect exposure to NELKARMI in 656 patients with ALK-positive NSCLC enrolled in ALKOVE-1.

- Serious adverse reactions occurred in 30% of patients who received NELKARMI. Serious adverse reactions reported in ≥2% of patients included hepatotoxicity (7%), pneumonia (3.7%), pleural effusion (2.4%) and dyspnea (2.3%).
- Fatal adverse reactions occurred in 1.1% of patients who received NELKARMI, including cardiac arrest (0.3%), pulmonary embolism (0.2%), sudden death (0.2%), pneumonia (0.2%), aspiration pneumonia (0.2%), and shock hemorrhagic (0.2%).

The most common adverse reactions (≥20%) and most common Grade 3 or 4 laboratory abnormalities (≥2%) reflect exposure to NELKARMI in the pooled safety population (N=700) of patients enrolled in ALKOVE-1.

- The most common adverse reactions (≥20%) were hepatotoxicity (56%), musculoskeletal pain (33%), constipation (28%), dysgeusia (24%), peripheral neuropathy (23%), edema (21%), and fatigue (21%).
- The most common Grade 3 or 4 laboratory abnormalities (≥2%), were increased ALT (18%), increased AST (13%), increased CPK (3.9%), decreased lymphocytes (2.5%), decreased potassium (2.3%), and decreased hemoglobin (2.3%).

**DRUG INTERACTIONS:**

**Strong and Moderate CYP3A Inhibitors:**

- Avoid concomitant use of NELKARMI with strong or moderate CYP3A inhibitors, as this may increase neladalkib plasma concentrations, which may increase the risk of NELKARMI-associated adverse reactions.

**Strong and Moderate CYP3A Inducers:**

- Avoid concomitant use of NELKARMI with strong or moderate CYP3A inducers, as this may decrease neladalkib plasma concentrations and may decrease the effectiveness of NELKARMI.

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 tumors. The trial enrolled 700 patients with ALK-positive solid tumors 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 characterized by specific genetic alterations, such as those in ALK, ROS1 or HER2. It can often metastasize (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 hematological, lung, gastrointestinal, genitourinary and gynecological 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