FDA Grants Accelerated Approval to Telisotuzumab vedotin-tllv for NSCLC

Key Takeaways

- Telisotuzumab vedotin-tllv is approved for NSCLC patients with high c-Met overexpression after prior systemic therapy.
- Approval is based on overall response rate and duration of response, with further studies required for continued approval.
- It is the first antibody-drug conjugate targeting c-Met, addressing a critical unmet need in this patient population.
- This approval exemplifies the shift towards personalized, biomarker-driven cancer therapeutics, enhancing treatment outcomes.

Emrelis is a groundbreaking treatment for advanced non-small cell lung cancer, targeting high c-Met protein overexpression.

The FDA has granted accelerated approval to telisotuzumab vedotin-tllv (Emrelis; AbbVie) for the treatment of adult patients with locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC) with high c-Met protein overexpression (OE) who have received a prior systemic therapy.1

Telisotuzumab is a novel treatment approved based on positive overall response rate (ORR) and strong duration of response (DOR). However, its continued availability may depend on further studies confirming its clinical benefits. This indication marks telisotuzumab as the first and only approved antibody-drug conjugate (ADC) that targets the c-Met protein in this specific group of patients. ADCs are designed to precisely target biomarkers like c-Met, delivering an effective drug directly to the cancer cells expressing this protein, according to investigators in a news release.1

"We have observed a paradigm shift in oncology in recent decades toward personalized, biomarker-driven therapeutics, allowing for better selection and optimized treatment outcomes," Jonathan Goldman, MD, professor of medicine and director of thoracic oncology clinical trials at UCLA, said in a news release. "People with c-Met-overexpressing NSCLC have poor prognoses and limited treatment options, and EMRELIS is a first-in-class ADC that can address a critical unmet need for this patient population."1

NSCLC is the most common type of lung cancer that tends to grow slowly compared to small cell lung cancer. Despite its slow progression, NSCLC can still spread to other parts of the body before noticeable symptoms develop, according to Cleveland Clinic.2 Additionally, NSCLC accounts for about 85% of all lung cancers, and despite treatment improvements, it remains the top cause of cancer deaths globally.1

The c-Met protein, a type of enzyme found on cell surfaces, is also found in high levels in nearly 25% of advanced non-squamous NSCLC patients who do not have epidermal growth factor receptor (EGFR) mutations and is linked to a worse outcome. About half of these patients demonstrate very high levels of c-Met, defined as a strong staining in at least 50% of their tumor cells using a specific lab test.1

As a first-of-its-kind ADC, telisotuzumab targets c-Met, and it is made up of an antibody that binds to c-Met, a linker that can be broken down, and a drug called monomethyl auristatin E (MMAW), all designed to specifically attach to cells that show the c-Met protein.1

The accelerated approval is supported based on data from the ongoing phase 2 LUMINOSITY study (NCT03539536), which is assessing the efficacy and safety of telisotuzumab in c-Met OE advanced NSCLC populations. The findings have revealed a 35% (95% CI: 24, 46) ORR and DOR with a median of 7.2 months (95% CI: 4.2, 12) among individuals treated with telisotuzumab who had a high c-met OE. The most common adverse events include peripheral neuropathy, fatigue, decreased appetite, and peripheral edema.1

"Despite the progress we have seen in the treatment of lung cancer, we need more options for people whose treatments stop working," Upal Basu Roy, PhD, MPH, executive director of research, LUNGevity Foundation, a leading lung cancer nonprofit organization, said in a news release. "This approval is a welcomed targeted therapy for those with high c-Met

protein overexpressing late-stage, non-small cell lung cancer who have seen very limited treatment innovation in the last decade."1

Currently, telisotuzumab is being evaluated in a phase 3 confirmatory global study, TeliMET NSCLC-01, as a monotherapy for individuals previously treated with c-Met OE NSCLC.1

REFERENCES

1. U.S. FDA Approves EMRELIS™ (telisotuzumab vedotin-tllv) for Adults With Previously Treated Advanced Non-Small Cell Lung Cancer (NSCLC) With High c-Met Protein Overexpression. Abbvie. News release. May 14, 2025. Accessed May 14, 2025. https://news.abbvie.com/2025-05-14-U-S-FDA-Approves-EMRELIS-TM-telisotuzumab-vedotin-tllv-for-Adults-With-Previously-Treated-Advanced-Non-Small-Cell-Lung-Cancer-NSCLC-With-High-c-Met-Protein-Overexpression
2. Non-Small Cell Lung Cancer. Cleveland Clinic. News release. January 16, 2025. Accessed May 14, 2025. https://my.clevelandclinic.org/health/diseases/6203-non-small-cell-lung-cancer

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