FDA approves AbbVie's Emrelis, the first drug targeting MET overexpression in NSCLC

Market Event Summary

Charlotte Jago | May 2025

Emrelis provides later-line treatment option for MET-overexpressing metastatic NSCLC

Background

- **MET receptor tyrosine kinase** alterations and aberrations are linked to tumorigenesis.
- Although drug therapies are available for *MET* exon 14 skipping mutations in NSCLC, **MET protein overexpression lacked approved therapies**.
- MET overexpression occurs in approximately one-quarter of nonsquamous *EGFR*-wild-type NSCLC, with approximately **half of these cases showing high overexpression** (≥50% of tumor cells with strong [3+] staining by immunohistochemistry).
- Emrelis (telisotuzumab vedotin) is a **MET-directed antibody-drug conjugate**.

Event

- **The Phase 2 LUMINOSITY trial** assessed Emrelis in previously treated nonsquamous *EGFR*-wild-type advanced NSCLC with MET protein overexpression.
- **ORR of 34.5%, median PFS of 5.5 months, and median OS of 14.3 months** were reported in patients with high levels of MET protein overexpression in interim data from the ongoing trial.
- **The FDA's accelerated approval of Emrelis in May 2025** for previously treated advanced nonsquamous NSCLC with high MET protein overexpression makes it the first drug approved specifically for this patient population. ORR and duration of response data supported this accelerated approval.
- **The confirmatory, global Phase 3 TeliMET NSCLC-01 trial is ongoing** in previously treated advanced nonsquamous NSCLC with MET protein overexpression.

Clarivate's takeaways

Emrelis set to be relatively unchallenged

We expect the TKI savolitinib to enter the MET overexpression setting but in *EGFR*-positive patients. We do not expect the launch of any other MET-targeting agents during the forecast period.

Significant sales in the later-line settings

We forecast Emrelis will earn significant sales in the later-line metastatic nonsquamous NSCLC setting, where an unmet need exists for effective treatment options.

Success hinges on biomarker testing

The success of Emrelis in later-line metastatic NSCLC will depend on adoption of routine MET overexpression testing. The FDA has approved Roche's companion MET assay for Emrelis.

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 (Imperial College London) and industry (Celltech, now UCB). She wrote the flagship Cortellis 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 degree in pharmacology, and a postgraduate certificate in journalism.

Clarivate coverage of NSCLC

- NSCLC *Disease Landscape & Forecast* (G7)
  - 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
  - Provides physician insights on treatment dynamics, prescribing behavior, and drivers of brand use in NSCLC
- NSCLC *Treatment Sequencing*: US
  - Provides sequential treatment patterns in market-relevant treatment scenarios and drug share mapped to treatment journey in NSCLC
- NSCLC *Unmet Need:* US/EU
  - Provides insights into areas of unmet need in specific subpopulations

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