

NSCLC: KOL Insight

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Abstracts

CheckMate-026 results are in. Will Opdivo's failure open up the field for rival immunotherapies?

News that the CheckMate-026 trial failed to meet its primary endpoint has left stakeholders scrambling to sort out what the results mean for Opdivo, and whether Keytruda will become the first-line PD-1/L1 inhibitor.

Based on interviews with 12 key opinion leaders (KOLs), the report covers 13 marketed drugs and 9 in the pipeline. It explores the changing first-line treatment landscape, the likely impact of immunotherapy combinations, the evolving role of standard-of-care treatments like Tagrisso and Alecensa, and the potential for PD-1/L1 inhibitors in earlier settings.

Plus: A special addendum, produced just days after the CheckMate-026 announcement, provides early KOL insight into the trial's near-term market impact.

Special Feature: KOLs weigh in on CheckMate-026 results

In the run up to publication, Bristol-Myers Squibb announced that the CheckMate-026 trial had failed to meet its primary endpoint. Over the next seven days, we spoke to three of the US KOLs originally interviewed for this report. A special addendum includes their insights, and answers key questions like:

Can we turn the hype down, please? Is an overly positive view of Opdivo driving overly dire reactions to the CheckMate-026 announcement? What does Opdivo's failure really mean for BMS, and for the use of PD-1/L1 inhibitors?

Did BMS make a strategic blunder? The strategy that helped Opdivo capture the

second-line treatment market fell short in the first-line setting. What do KOLs think BMS should have done differently?

What's next for Opdivo? Opdivo is down, but not out, KOLs say. What opportunities still exist for BMS in first-line NSCLC treatment, and what will it take to seize them?

TOP TAKEAWAYS

PD-1/L1 inhibitors shaking up first-line treatment: Rivals Keytruda and Opdivo are battling for top spot. Will the CheckMate-026 results hand Merck & Co. a decisive win? If so, what can BMS do to stay in the game? Can other PD-1/L1 inhibitors gain a foothold?

Combination therapies on the way: Several companies are investing in immunotherapy combinations. What will determine their use? Which ones are most likely to succeed? Will they unseat the reigning monotherapies?

Downstream consequences: Some KOLs say that a shakeup in first-line treatment will have an impact on the second-line landscape as well. What knock-on effects do they anticipate and how will those affect Opdivo's dominant position?

Branching out: Some PD-1/L1 inhibitors are being evaluated for use in adjuvant and stage III settings, but their prospects hinge on the answers to a few key questions. Which clinical trials will provide them?

Climbing the treatment algorithm: Beyond the PD-1/L1 landscape, KOLs are keeping a close eye on treatments for EGFR mutation-positive, and ALK positive NSCLC that have the potential to move up to first-line use. What will determine their prospects?

Brands covered

Marketed Drugs

Immunotherapies

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Opdivo (nivolumab; BMS)

Keytruda (pembrolizumab; Merck & Co.)

EGFR mutation-positive NSCLC

Gilotrif/Giotrif (afatinib; Boehringer Ingelheim)

Iressa (gefitinib; AstraZeneca)

Tarceva (erlotinib; Astellas)

Tagrisso (osimertinib; AstraZeneca)

ALK-positive NSCLC

Xalkori (crizotinib; Pfizer)

Zykadia (ceritinib; Novartis)

Alecensa (alectinib; Roche)

ALK and EGFR mutation-negative NSCLC

Avastin (bevacizumab; Roche)

Vargatef (nintedanib; Boehringer Ingelheim)

Cyramza (ramucirumab; Eli Lilly)

Portrazza (necitumumab; Eli Lilly)

Pipeline Drugs

Immunotherapies

Atezolizumab (RG7446; Genentech/Roche)

Durvalumab (MEDI4736; AstraZeneca)

Yervoy (ipilimumab; BMS)

Avelumab (MSB0010718C/PF-06834635; Merck Group/Pfizer)

Plinabulin (NPI-2358; BeyondSpring)

EGFR mutation-positive NSCLC

Rociletinib (CO-1686; Celgene Corporation/Clovis Oncology)

ALK-positive NSCLC

Brigatinib (AP26113; ARIAD)

ALK and EGFR mutation-negative NSCLC

Abemaciclib (LY2835219; Eli Lilly)

Selumetinib (AZD6244; Array BioPharma/AstraZeneca)

Key Opinion Leaders Interviewed for This Report

KOLs from North America

Catherine Azar, Clinical Associate Professor of Medicine, Hematology/
Oncology Department, University of Arizona, Tucson, AZ.

Paul Bunn, Distinguished Professor, Division of Medical Oncology, University of
Colorado, Boulder, CO.

Renata Ferrarotto, Assistant Professor, Department of Thoracic/Head and Neck

Medical Oncology, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center, Houston, TX.

Edward Garon, Associate Clinical Professor, Thoracic Oncology Program, Department of Hematology and Oncology, David Geffen School of Medicine, University of California, Los Angeles, CA.

Jared Weiss, Assistant Professor, School of Medicine, University of North Carolina at Chapel Hill, Clinical Research, Thoracic Oncology Program, Chapel Hill, NC.

Howard West, Medical Director, Thoracic Oncology Program, Swedish Cancer Institute; President & CEO, Global Resource for Advancing Cancer Education (GRACE), Seattle, WA.

Anonymous KOL, Associate Professor at a major US Medical School.

KOLs from Europe

Qamar Ghafoor, Consultant Clinical Oncologist at University Hospital Birmingham, UK.

Jose I. Mayordomo, Medical Oncologist, Medical Oncology at the University Hospital of Zaragoza, Spain/Professor, Division of Medical Oncology, University of Colorado School of Medicine, Denver, CO, USA.

Marie Wislez, Consultant, Tenon Hospital, Paris, France.

2 Anonymous German KOLs

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