



New data on Lilly's investigational treatment olomorasib at ESMO 2026 show durable first-line activity in KRAS G12C-mutant non-small cell lung cancer

October 25, 2026

Data presented at ESMO highlight the promising efficacy of olomorasib in combination with standard-of-care immunotherapy with or without chemotherapy in first-line advanced KRAS G12C-mutant non-small cell lung cancer (NSCLC) across PD-L1 expression levels

First-line treatment options remain an unmet need for patients with KRAS G12C-mutant NSCLC, as most patients do not receive second-line therapy due to the aggressive nature of the disease

Lilly expects first randomized Phase 3 data from SUNRAY-01 in first-line KRAS G12C-mutant NSCLC in the first half of 2027

INDIANAPOLIS, Oct. 25, 2026 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced new first-line data on olomorasib, its investigational, next-generation KRAS G12C inhibitor, at the 2026 [European Society for Medical Oncology \(ESMO\) Congress](#) in Madrid, Spain. Results shared in a poster presentation from the Phase 1/2 LOXO-RAS-20001 trial and the safety lead-in portion of the Phase 3 SUNRAY-01 trial of olomorasib plus Merck's anti-PD-1 therapy KEYTRUDA® (pembrolizumab), without chemotherapy, in first-line KRAS G12C-mutant non-small cell lung cancer (NSCLC) show that median progression-free survival (PFS) and duration of response (DOR) had not been reached after a median follow-up of nearly 21 months, with durable activity observed across PD-L1 levels. Separate results in a rapid oral presentation show olomorasib plus chemoimmunotherapy (pembrolizumab, pemetrexed and platinum chemotherapy) achieved an investigator-assessed overall response rate (ORR) of 62% and median DOR of 14.5 months in first-line advanced KRAS G12C NSCLC with a median of nearly 19 months follow up.

Dr. Marcelo V. Negrao, Associate Professor of Thoracic and Head and Neck Medical Oncology at The University of Texas MD Anderson Cancer Center and presenting author of the study: "Responses lasting a median of more than a year in patients across all PD-L1 tumor expression levels - including many with low expression - is the type of progress we want to see in the first-line setting. The data presented at ESMO support continued study of olomorasib with immunotherapy, with or without chemotherapy, to give patients the possibility of more options from the outset of their treatment journey, where we successfully utilize other genomically-targeted therapies in lung cancer."

KRAS G12C mutations occur in approximately 13% of people with NSCLC, the most common form of lung cancer.¹ These patients generally have high-risk clinical characteristics and more comorbidities.² There are no approved targeted therapies for the first-line treatment of KRAS G12C-mutant NSCLC; standard of care is immunotherapy with or without chemotherapy, and most patients do not go on to second-line therapy.³ KRAS G12C inhibitors have been limited in this setting because toxicity has been a persistent challenge for some combinations with immunotherapy.⁴

Olomorasib is a potent, selective next-generation oral KRAS G12C inhibitor specifically intended to target the mutation: it binds the mutated protein and locks it in its inactive state, with properties that allow for high predicted target occupancy and potency, potentially allowing for safer, flexible combination with standard-of-care immunotherapy, with or without chemotherapy.

Jacob Van Naarden, Executive Vice President and President of Lilly Oncology: "KRAS G12C-mutant lung cancer has been notoriously difficult to treat, and for most patients, the disease is so aggressive that the first line is their only line, underscoring just how critical that first treatment choice is. These results deepen our conviction in the role olomorasib could play in combination with standard PD1-based backbone therapy, while potentially offering a tolerability profile that doesn't require prophylactic medications. We recognize that the oncology community has been waiting for years for a targeted therapy regimen that can address first-line patients with G12C mutations, and we are hopeful that the pivotal Phase 3 data on olomorasib in combination with chemoimmunotherapy in the first half of next year will be a seminal moment for the field."

In a poster presentation, updated results for olomorasib plus pembrolizumab without chemotherapy in 85 patients receiving first-line treatment for KRAS G12C-mutant NSCLC showed durable efficacy across all PD-L1 expression levels. The majority of patients (64%) had PD-L1 expression of 50% or higher. The median DOR and median PFS was not yet reached after a median follow-up of 20.7 months, in either the overall population or in those patients (64%) with PD-L1 expression of 50% or higher. The safety profile was consistent with previous reports and the known profiles of each medicine. The most common Grade 3 or higher treatment-related adverse events (TRAEs) were increased ALT (15.3%), increased AST (12.9%) and diarrhea (8.2%). TRAEs led to olomorasib dose reduction in 31.8% of patients and discontinuation of the treatment regimen in 11.8% of patients. No Grade 5 TRAEs occurred. No prophylactic medications for olomorasib are required by the protocol.

In a separate rapid oral presentation, the updated, single arm analysis of olomorasib plus chemoimmunotherapy (pembrolizumab, pemetrexed and platinum chemotherapy), with an additional nine months of follow up, included 77 patients receiving first-line treatment for advanced KRAS G12C-mutant NSCLC, with a median follow-up of 18.7 months. Most (74%) had a PD-L1 expression below 50%. The investigator-assessed confirmed ORR was 62% (48/77), median DOR was 14.5 months (95% CI, 8.5-not estimable [NE]), and median PFS was 11.6 months (95% CI, 9.5-21.5). The safety profile was consistent with previous reports and the known profiles of each medicine. The most common Grade 3 or higher TRAEs were neutropenia (21%), anemia (17%), increased alanine aminotransferase (12%) and thrombocytopenia (12%). TRAEs led to olomorasib dose reduction in 19.5% of patients and discontinuation of the treatment regimen in 7.8%. No Grade 5 TRAEs occurred. No prophylactic medications for olomorasib are required by the protocol.

Together, these analyses support the rationale for the ongoing Phase 3 SUNRAY-01 study (NCT06119581) in first-line KRAS G12C-mutant NSCLC. SUNRAY-01 is a global master protocol containing two randomized Phase 3 trials. Part A is a randomized, double-blind, placebo-controlled evaluation of olomorasib plus pembrolizumab versus placebo plus pembrolizumab in patients with PD-L1 expression of 50% or higher. Part B, a randomized, double-blind, placebo-controlled evaluation of olomorasib plus chemoimmunotherapy versus placebo plus chemoimmunotherapy in patients regardless of PD-L1 expression, has completed enrollment. Part C of the study is designed to assess olomorasib plus pembrolizumab in patients with

PD-L1 expression below 50%. The olomorasib program, which includes the SUNRAY-02 Phase 3 trial in patients with resectable and unresectable non-metastatic disease, spans early and advanced NSCLC across all PD-L1 expression levels, evaluating olomorasib in combination with immunotherapy, with or without chemotherapy.

For more information on Lilly's oncology pipeline, click [here](#).

Frequently Asked Questions

1. What is olomorasib and how does it work?

Olomorasib (LY3537982) is an investigational, oral, potent, and highly selective next-generation *KRAS* G12C inhibitor from Lilly. It was specifically intended to target *KRAS* G12C, a mutated form of the *KRAS* protein: it binds the mutated protein and locks it in its inactive state, with properties that allow for high predicted target occupancy and potency as monotherapy or in combination. Olomorasib is being studied in *KRAS* G12C-mutant non-small cell lung cancer (NSCLC) and other solid tumors.

2. Is olomorasib approved?

No. Olomorasib is an investigational medicine and is not approved by the FDA or any other regulatory authority for any use. The FDA has granted two Breakthrough Therapy designations: olomorasib with pembrolizumab for first-line *KRAS* G12C-mutant NSCLC with PD-L1 expression of 50% or higher, and olomorasib alone for previously treated *KRAS* G12C-mutant advanced pancreatic cancer. Breakthrough Therapy designation is designed to expedite the development and review of medicines for serious conditions. It does not mean a medicine is approved.

3. What clinical trial data exist for olomorasib in first-line *KRAS* G12C-mutant NSCLC?

At ESMO 2026, Lilly presented updated analyses of investigational olomorasib in first-line *KRAS* G12C-mutant NSCLC from the Phase 1/2 LOXO-RAS-20001 trial and the safety lead-in portion of the Phase 3 SUNRAY-01 trial. In a poster presentation, updated results for olomorasib plus pembrolizumab without chemotherapy included 85 patients receiving first-line treatment for *KRAS* G12C-mutant NSCLC after a median follow-up of 20.7 months, demonstrated durable efficacy across all PD-L1 expression levels. The majority of patients (64%) had a PD-L1 expression of 50% or higher. The median DOR and median PFS was not yet reached after a median follow-up of 20.7 months, in either the overall population or in those patients with PD-L1 expression of 50% or higher. At 18 months, the PFS rate was 55% in the overall patient population and 65% in patients with PD-L1 expression of 50% or higher.

A separate rapid oral presentation of olomorasib plus chemoimmunotherapy included 77 patients receiving first-line treatment for advanced *KRAS* G12C-mutant NSCLC, with a median follow-up of 18.7 months. Most (74%) had a PD-L1 expression below 50%. The investigator-assessed confirmed ORR was 62% (48/77), median DOR was 14.5 months (95% CI, 8.5-not estimable [NE]), and median PFS was 11.6 months (95% CI, 9.5-21.5).

4. Are there clinical trials of olomorasib, and what is SUNRAY-01?

Yes. SUNRAY-01 ([NCT06119581](#)) is a global master protocol containing two Phase 3 studies of olomorasib in first-line *KRAS* G12C-mutant advanced or metastatic NSCLC. Part A is randomized, double-blind and placebo-controlled, comparing olomorasib plus pembrolizumab with placebo plus pembrolizumab in patients with PD-L1 expression of 50% or higher. Part B compares olomorasib plus chemoimmunotherapy with placebo plus chemoimmunotherapy regardless of PD-L1 expression and has completed enrollment. Part C of the study is designed to assess patients with PD-L1 expression below 50%. SUNRAY-02 ([NCT06890598](#)) is a global, Phase 3 study in an early-stage setting studying olomorasib in resected and unresectable NSCLC. Eligibility and locations are listed at [clinicaltrials.gov](#).

5. What is *KRAS* G12C-mutant NSCLC, and why has first-line treatment been challenging?

KRAS G12C is an oncogenic driver mutation in the *KRAS* gene that can promote cancer growth and occurs in approximately 13% of people with non-small cell lung cancer (NSCLC), the most common form of lung cancer.¹ Biomarker testing identifies the mutation. People with *KRAS* G12C-mutant NSCLC generally have higher-risk disease; first-line treatment is currently immunotherapy with or without chemotherapy, and most do not go on to second-line therapy.^{2,3} *KRAS* has long been difficult to target because of its protein structure, and toxicity has been a persistent challenge for some combinations of *KRAS* G12C inhibitors with immunotherapy.^{4,5}

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

About Olomorasib

Olomorasib (LY3537982) is an investigational, oral, potent, and highly selective next-generation inhibitor of the *KRAS* G12C protein. *KRAS* is the most common oncogene across all tumor types, and *KRAS* G12C mutations occur in 13% of patients with non-small cell lung cancer (NSCLC), and 1–3% of patients with other solid tumors.¹ Olomorasib is a highly potent covalent inhibitor with potential for greater than 90% target occupancy, which may allow for safer combinations with less toxicity.⁶

Olomorasib is currently being studied in *KRAS* G12C-mutant cancers in combination with pembrolizumab with or without chemotherapy for first-line

treatment of advanced NSCLC, in combination with immunotherapy for the treatment of resected and unresectable NSCLC, and as monotherapy and in combinations in other advanced solid tumors ([NCT06119581](#), [NCT06890598](#), and [NCT04956640](#)).

About Lilly

Lilly is a medicine company turning science into healing to make life better for people around the world. We've been pioneering life-changing discoveries for 150 years, and today our medicines help tens of millions of people across the globe. Harnessing the power of biotechnology, chemistry and genetic medicine, our scientists are urgently advancing new discoveries to solve some of the world's most significant health challenges: redefining diabetes care; treating obesity and curtailing its most devastating long-term effects; advancing the fight against Alzheimer's disease; providing solutions to some of the most debilitating immune system disorders; and transforming the most difficult-to-treat cancers into manageable diseases. With each step toward a healthier world, we're motivated by one thing: making life better for millions more people. That includes delivering innovative clinical trials that reflect the diversity of our world and working to ensure our medicines are accessible and affordable. To learn more, visit [Lilly.com](#) and [Lilly.com/news](#), or follow us on [Facebook](#), [Instagram](#), and [LinkedIn](#). P-LLY

Trademarks and Trade Names

All trademarks or trade names referred to in this press release are the property of the company, or, to the extent trademarks or trade names belonging to other companies are references in this press release, the property of their respective owners. Solely for convenience, the trademarks and trade names in this press release may be referred to without the ® and ™ symbols, but such references should not be construed as any indicator that the company or, to the extent applicable, their respective owners will not assert, to the fullest extent under applicable law, the company's or their rights thereto. We do not intend the use or display of other companies' trademarks and trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

Cautionary Statement Regarding Forward-Looking Statements

This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about olomorasib as a potential treatment for certain KRAS G12C-mutant advanced solid tumors and reflects Lilly's current beliefs and expectations. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of drug research, development, and commercialization. Among other things, there is no guarantee that planned or ongoing studies will be completed as planned, that future study results will be consistent with study results to date, that olomorasib will prove to be a safe and effective treatment or receive regulatory approval, or that Lilly will execute its strategy as expected. For further discussion of these and other risks and uncertainties that could cause actual results to differ from Lilly's expectations, see Lilly's Form 10-K and Form 10-Q filings with the United States Securities and Exchange Commission. Except as required by law, Lilly undertakes no duty to update forward-looking statements to reflect events after the date of this release.

Endnotes & References

1. Singhal A, Li BT, O'Reilly EM. Targeting KRAS in cancer. *Nat Med.* 2024;30(4):969-983. doi:10.1038/s41591-024-02903-0
2. Peters S, et al. SUNRAY-01 trial protocol: an innovative study design of olomorasib and pembrolizumab with or without chemotherapy in KRAS G12C NSCLC. *Future Oncol.* 2026 Apr;22(9):1073–1082.
3. Sheffield KM, Puri T, Thoele K, Karu H, Mansharamani A, Uprety D. Real-world treatment patterns and clinical outcomes after first-line therapy in patients with KRAS G12C-mutant advanced non-small-cell lung cancer in the United States. *Cancers (Basel).* 2026;18(17):2869. doi:10.3390/cancers18172869
4. Li BT, Falchook GS, Durm GA, Burns TF, Skoulidis F, Ramalingam SS, Ahluwalia MS, Grotelueschen DL, Jabbour SK, Raby S, et al. OA03.07 Safety and Efficacy of D-1553 in Patients with KRAS G12C Mutated Non-Small Cell Lung Cancer: A Phase 1 Trial. *Journal of Thoracic Oncology.* 2022;17(9 Suppl):S10–S11.
5. Huang L, Guo Z, Wang F, et al. KRAS Mutation: From Undruggable to Druggable in Cancer. *Signal Transduction and Targeted Therapy.* 2021.
6. Peng S-B, Si C, Zhang Y, et al. Abstract 1259: Preclinical characterization of Ly3537982, a novel, highly selective and potent KRAS-G12C inhibitor. *Cancer Research.* 2021;81(13_Supplement):1259-1259. doi:10.1158/1538-7445.am2021-1259

Refer to: Kyle Owens; owens_kyle@lilly.com (Media)

Michael Czapar; czapar_michael_c@lilly.com (Investors)



[at-esmo-2026-show-durable-first-line-activity-in-kras-g12c-mutant-non-small-cell-lung-cancer-302918479.html](https://www.esmo.org/abstracts/2020/abstract-302918479)

SOURCE Eli Lilly and Company