Lilly's olomorasib receives U.S. FDA's Breakthrough Therapy designation for the treatment of previously treated KRAS G12C-mutant advanced pancreatic cancer

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INDIANAPOLIS, Aug. 3, 2026 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy designation to olomorasib as a monotherapy for the treatment of adult patients with advanced pancreatic cancer who have received at least one prior systemic therapy and have a *KRAS* G12C mutation, as determined by an FDA-approved test. Olomorasib is an investigational, potent and highly selective next-generation inhibitor of KRAS G12C. Olomorasib was previously granted Breakthrough Therapy designation, in combination with anti-PD-1 therapy KEYTRUDA (pembrolizumab), for the first-line treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with a *KRAS* G12C mutation and PD-L1 expression ≥ 50%, as determined by FDA approved tests.

Breakthrough Therapy designation aims to expedite the development and review of drugs that are intended to treat a serious condition when preliminary clinical evidence indicate that the drug may demonstrate substantial improvement on a clinically significant endpoint(s) over already available therapies that have received full FDA approval.

Pancreatic cancer is diagnosed in approximately 60,000 people in the United States each year, with an estimated 50,000 deaths projected annually.[1] Outcomes for patients with metastatic pancreatic cancer are typically poor, with a five-year survival rate under 5%.[2] Growing evidence suggests outcomes for patients with *KRAS* G12C-mutant pancreatic cancer are worse than those without the mutation, underscoring a persistent gap in treatment and an opportunity to address a significant unmet need.[3] There currently are no approved therapies that specifically target *KRAS* G12C-mutant pancreatic cancer.

"Pancreatic cancer has historically been one of the most difficult-to-treat cancers and people whose tumors harbor a *KRAS* G12C mutation face limited options once their disease progresses," said Jacob Van Naarden, executive vice president, and president of Lilly Oncology. "This Breakthrough Therapy designation reflects the early potential we're seeing with olomorasib in this setting and the critical need for new treatment options. With now two Breakthrough Therapy designations across pancreatic and lung cancers, olomorasib continues to demonstrate broad potential clinical evidence across *KRAS* G12C-driven tumors and reflects our commitment to bringing meaningful new treatment options to patients living with these cancers."

The FDA Breakthrough Therapy designation is based on encouraging preliminary results from the open-label, multicenter, Phase 1/2 LOXO-RAS-20001 study (NCT04956640) of olomorasib in patients with *KRAS* G12C-mutant, advanced solid tumors, including those with advanced pancreatic cancer who have received at least one prior systemic therapy.

Lilly is studying olomorasib in *KRAS* G12C-mutant cancers in multiple studies. Details on the trials can be found by visiting clinicaltrials.gov.

About LOXO-RAS-20001
LOXO-RAS-20001 is an open-label, multicenter, Phase 1/2 study evaluating the safety, tolerability and preliminary efficacy of olomorasib in patients with *KRAS* G12C-mutant advanced solid tumors (NCT04956640). The study includes a Phase 1a dose escalation phase of olomorasib monotherapy in *KRAS* G12C-mutant solid tumors and a Phase 1b dose expansion and optimization phase which are evaluating olomorasib as a monotherapy and in combination with other treatments.

About Olomorasib
Olomorasib (LY3537982) is an investigational, oral, potent, and highly selective next-generation inhibitor of the KRAS G12C protein. *KRAS* mutations account for approximately 85% of RAS-associated cancers in humans, including about 90% of pancreatic cancers, and *KRAS* G12C mutations occur in approximately 1% to 2% of patients with pancreatic cancer.[4,5] Olomorasib was specifically designed to target KRAS G12C and has pharmacokinetic properties which allow for high predicted target occupancy and high potency when used as monotherapy or in combination.[6]

Olomorasib is currently being studied in the LOXO-RAS-20001 Phase 1/2 trial (NCT04956640) in patients with *KRAS* G12C-mutant NSCLC and other advanced solid tumors and in the pivotal, registrational SUNRAY-01 global study (NCT06119581) investigating olomorasib in combination with pembrolizumab with or without chemotherapy for first-line treatment of *KRAS* G12C-mutant advanced NSCLC, and the SUNRAY-02 (NCT06890598) global study investigating olomorasib in combination with standard of care immunotherapy in patients with resected or unresectable *KRAS* G12C-mutant NSCLC. For additional information about olomorasib clinical trials, please refer to clinicaltrials.gov.

Frequently Asked Questions

What is Breakthrough Therapy designation and why does it matter?
Breakthrough Therapy designation is granted by the FDA to expedite the development and review of drugs intended to treat a serious condition when preliminary clinical evidence indicate the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint. It provides more intensive FDA guidance during development and may accelerate the path to approval.

What is olomorasib?
Olomorasib (LY3537982) is an investigational, oral, potent, and highly selective next-generation inhibitor of the KRAS G12C protein. Olomorasib was specifically designed to target KRAS G12C and has pharmacokinetic properties which allow for high predicted target occupancy and high potency when used as monotherapy or in combination.[6]

What is *KRAS* G12C-mutated advanced pancreatic cancer?
KRAS G12C-mutated advanced pancreatic cancer is a rare form of pancreatic cancer that is driven by a specific genetic change called the

KRAS G12C mutation and has spread beyond the pancreas.[7] *KRAS* mutations account for approximately 85% of RAS-associated cancers in humans, including about 90% of pancreatic cancers, and *KRAS* G12C mutations occur in approximately 1% to 2% of patients with pancreatic cancer.[8,9] Pancreatic cancer is a type of cancer that forms in the tissues of the pancreas.[10] Because early-stage pancreatic cancer is typically asymptomatic, the vast majority of patients are diagnosed at a locally advanced or metastatic stage where treatment options may be limited.[11]

What data supported this Breakthrough Therapy designation?
The Breakthrough Therapy designation is based on preliminary results from the Phase 1/2 LOXO-RAS-20001 study (NCT04956640) of olomorasib in patients with *KRAS* G12C-mutant, advanced solid tumors, including those with advanced pancreatic cancer who have received at least one prior systemic therapy.

Has olomorasib received Breakthrough Therapy designation before?
Yes. This is the second Breakthrough Therapy designation for olomorasib. The first was granted in September 2025 for olomorasib in combination with anti-PD-1 therapy pembrolizumab for the first-line treatment of patients with advanced or metastatic non-small cell lung cancer (NSCLC) with a *KRAS* G12C mutation and PD-L1 expression ≥ 50%, as determined by FDA approved tests.

What is the current standard of care for advanced pancreatic cancer?
The current standard of care for advanced pancreatic cancer consists of systemic chemotherapy, with treatment selection guided by a patient's overall health and performance status. Increasingly, comprehensive genomic profiling at diagnosis is recommended to identify actionable molecular alterations that may enable targeted therapies.

What is the LOXO-RAS-20001 trial?
LOXO-RAS-20001 (NCT04956640) is an open-label, multicenter, Phase 1/2 study evaluating the safety, tolerability and preliminary efficacy of olomorasib in patients with *KRAS* G12C-mutant advanced solid tumors. *KRAS* mutations account for approximately 85% of RAS-associated cancers in humans, including about 90% of pancreatic cancers, and *KRAS* G12C mutations occur in approximately 1% to 2% of patients with pancreatic cancer.[8,9] The study includes a Phase 1a dose escalation phase of olomorasib monotherapy in *KRAS* G12C-mutant solid tumors and Phase 1b dose expansion and optimization phases which are evaluating olomorasib as a monotherapy and in combination with other treatments. More information can be found at clinicaltrials.gov.

Where can patients find more information about the LOXO-RAS-20001 trial?
Patients and healthcare providers can find more information about the LOXO-RAS-20001 study at clinicaltrials.gov (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

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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 people with 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 for people with certain *KRAS* G12C-mutant advanced solid tumors, that olomorasib 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

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